

# Pharmacovigilance: the inside track

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**North West Medicines Information Centre**



# Scope



The MHRA

Pharmacovigilance

The Yellow Card  
Scheme

International Work

Vaccines and PV

MedSafetyWeek  
2021

Pipeline projects

## Our vision



We protect and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research

SoS is the UK Licensing Authority for human medicines  
Executive function performed day to day by the  
Medicines and Healthcare products Regulatory Agency



# What is an Adverse Drug Reaction (ADR)?

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- An adverse reaction is a response to a medicine that is noxious (harmful or very unpleasant) and unintended. This includes adverse reactions which arise from:
  - the use of a medicine within the terms of the license
  - the use of a medicine outside the terms of the license, including
    - overdose
    - off-label use
    - misuse or abuse
    - medication errors
  - occupational exposure.



# Medication safety in the NHS

At the heart of future NHS challenges



of people over 70 years old take five or more medicines. With an ageing population and multiple chronic medical conditions these numbers will just keep increasing

600,000



non-elective hospital admissions are due to medicines



of these are preventable

5 classes of medicine account for most admissions

- NSAIDs
- Antiplatelets
- Anticoagulants
- Diuretics
- Antihypertensives



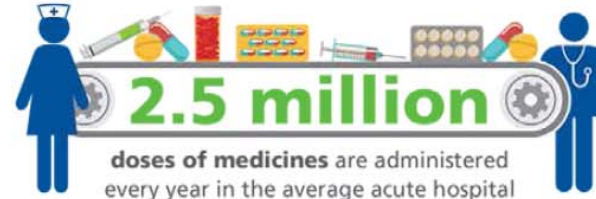
prescriptions are issued every year in primary care



prescribing errors



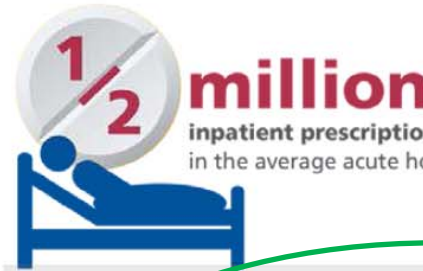
dispensing errors



doses of medicines are administered every year in the average acute hospital



errors



inpatient prescriptions every year in the average acute hospital



prescribing errors with 550 potentially fatal



dispensing errors



preventable deaths across all acute hospitals are due to medicines



patients admitted to all acute hospitals suffer from harm due to medicines

97% of medication errors reported to the NHS result in no or low patient harm



@yellowcardnw

# Pharmacovigilance

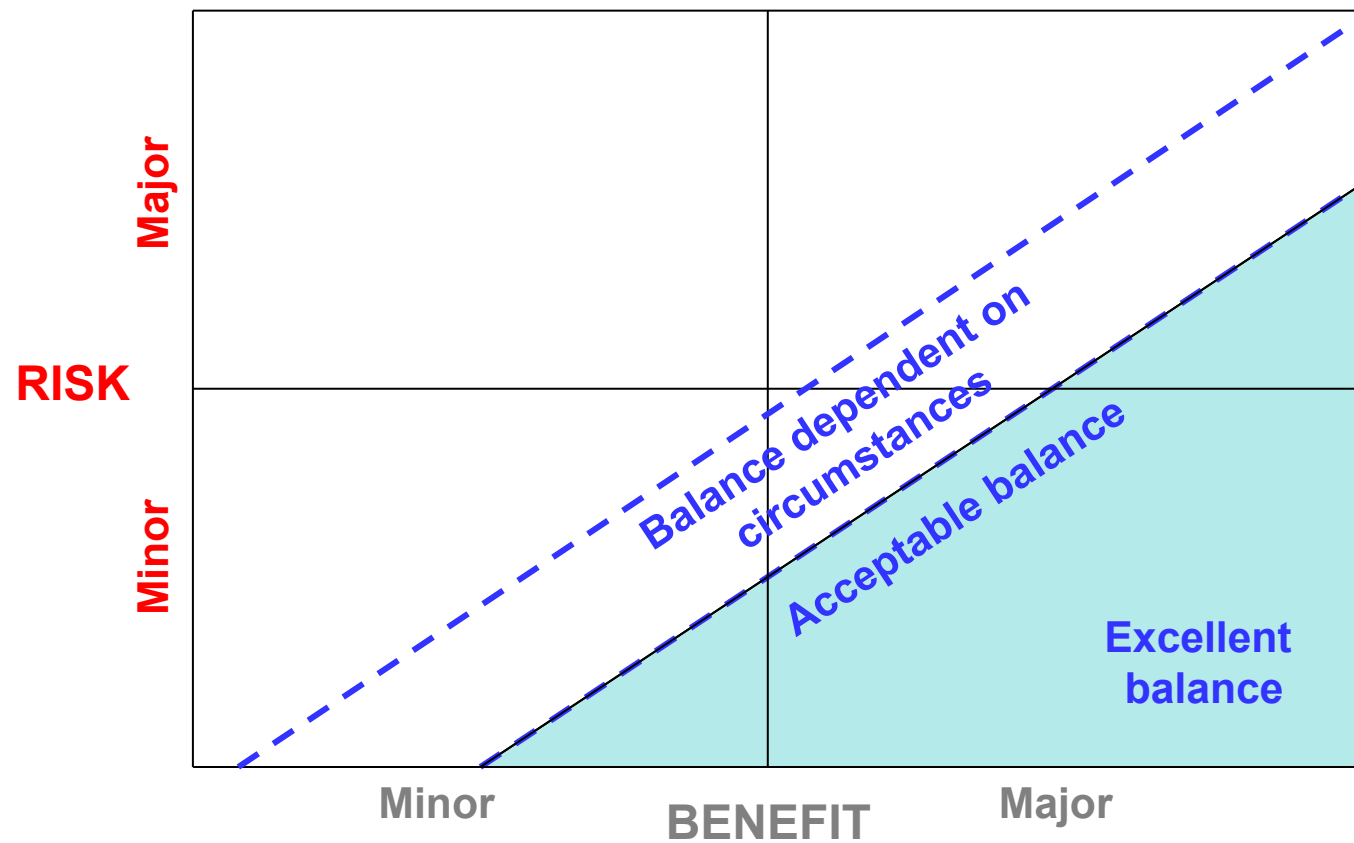
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*‘No medicinal product is entirely or absolutely safe for all people, in all places, at all times’*

- The study of the safety of marketed drugs and response to safety issues
- Carried out in large communities and in practical, clinical use
- Objectives of pharmacovigilance
  - Identify previously unrecognised hazards
  - Evaluate changes in risks and benefits
  - Take action to promote safer drug use
  - Provide optimal information to users
  - Monitor the impact of action taken
  - Audit effectiveness



# Risk-benefit balance



# The Yellow Card Scheme - Informing risk/benefit assessment

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**Benefit of  
treatment**



**Risk to  
patient**

**Bottom line – #patientsafety**

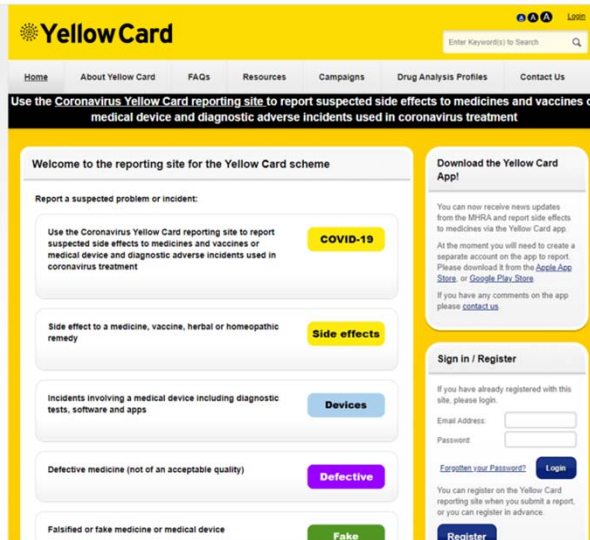


@yellowcardnw



# Reporting ADRs - the Yellow Card

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)



Due to pandemic only accepting electronic reporting

Online

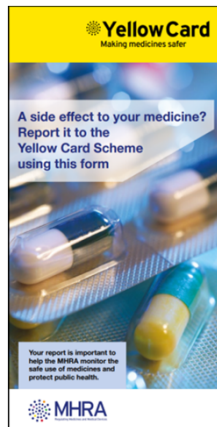


YC App

Download from  
App store  
Google Play



Paper



Patient reporting

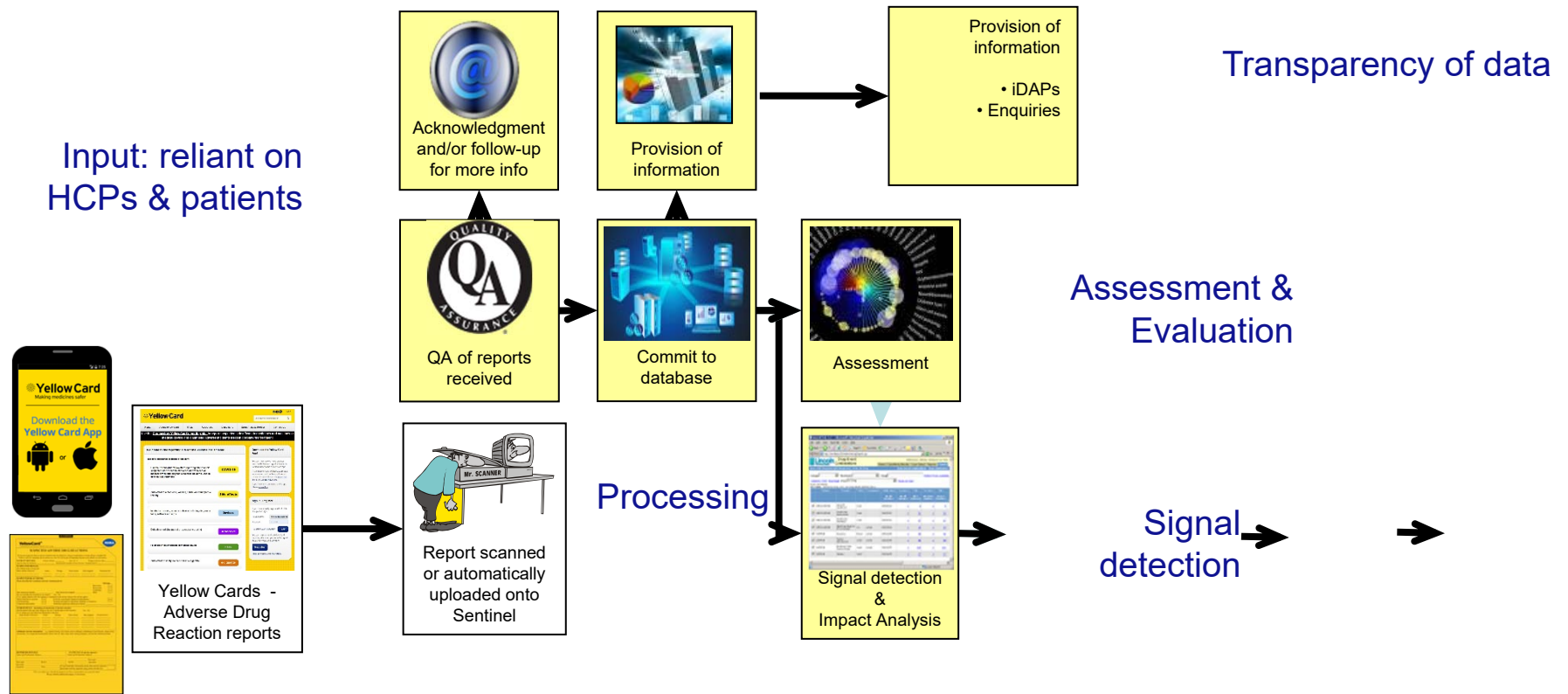
**Integrated** in ePMR systems

Primary care – EMIS, Vision, SystmOne  
Secondary care – MiDatabank  
Use of APIs?



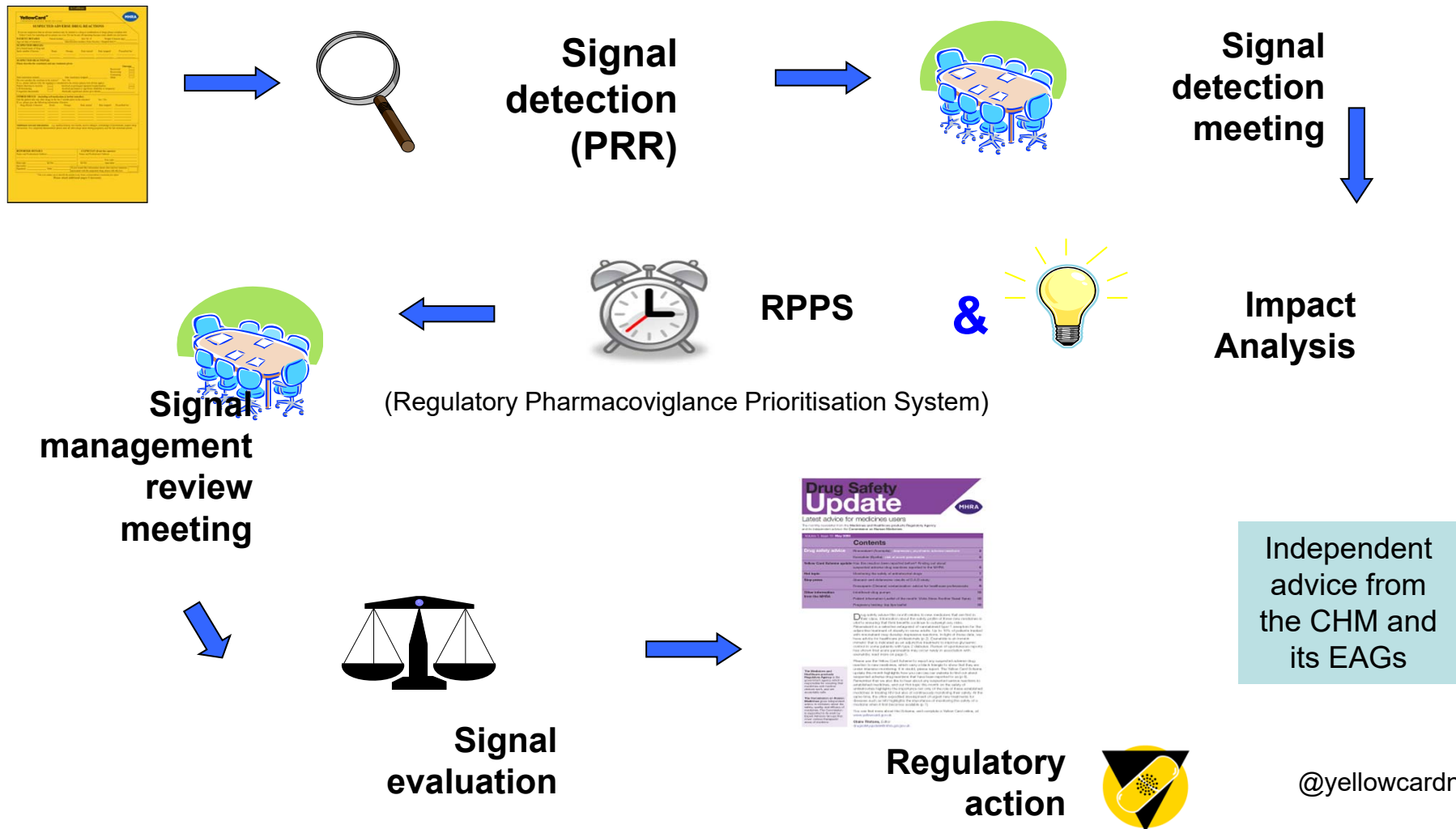
@yellowcardnw

# The Lifecycle of a Yellow Card report



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# Signal detection & prioritisation process



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# Commission on Human Medicines (CHM) & Scientific Advisory Committees

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- CHM role as defined in regulation 10 of the Human Medicines Regulations 2012
  - advise on safety, quality and efficacy of medicines
  - to promote collection and investigation of adverse drug reactions
  - consider applications that lead to Licensing Authority action
  - consider representations made by an applicant or marketing authorisation holder
- Supported by 11 Expert Advisory Groups (EAGs)



# Expert Advisory Groups

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- Cardiovascular, Diabetes, Renal, Respiratory & Allergy (CDRRAEAG)
- Chemistry, Pharmacy and Standards (CPS)
- Clinical Trials, Biologicals and Vaccines
- Gastroenterology, Rheumatology, Immunology & Dermatology (GRIDEAG)
- Infections (IEAG)
- Medicines for Women's Health (MWHEAG)
- Neurology, Pain and Psychiatry (NPPEAG)
- Oncology and Haematology (OHEAG)
- Paediatric Medicines (PMEAG)
- Patient and Public Engagement (PPEEAG)
- **Pharmacovigilance (PEAG)**
- & ad hoc Expert Working Groups (e.g. sodium valproate)



# Pharmacovigilance Expert Advisory Group (PEAG)

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- Advises CHM on the following in relation to human medicines, including herbal products:
  - the public health importance of potential new safety signals
  - the confirmation and quantification of risks identified
  - appropriate risk minimisation measures including communications
  - design and progress of pharmacovigilance plans
  - methodologies for pharmacovigilance.
- To advise the CHM and MHRA on the strategic direction of the Yellow Card Scheme



# Options for regulatory action

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- No action, investigate, expert advice, or wait for further evidence, continue to monitor periodically
- Strengthen or add changes to product information - variation of the marketing authorisation (usually voluntarily)
  - Limit indications, populations, restriction in use e.g. metformin and renal impairment.
  - Reduction in dose e.g. Tramadol dose.
  - Contraindications, concomitant diseases, interactions, pregnancy e.g. sodium valproate & PPP.
  - Special warnings and precautions e.g. alendronate and other bisphosphonates taken with 200ml water and remaining upright
  - Undesirable effects e.g. new ADRs and further info on listed effects.
- Change in legal status (P to POM)
  - oral diclofenac was reclassified from P to POM due to the risk of CV side effects.
  - Lidocaine-containing teething gels reclassified from GSL to pharmacy (P)



# Options for regulatory action

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- Label/box warnings
  - Not enough to warn in SmPC; all amphotericin B (severe fungal infections) products to display a clear warning to check the product name and dose (alert prescriber, pharmacist, nurse); fatal overdose if conventional form used at the strength of liposomal form.
- Packsize restrictions
  - To minimise the risk of paracetamol overdose, in 1998, UK legislation restricted the pack size available in pharmacies to 32 tablets (16 tablets outside pharmacy setting)
- Suspension of marketing authorisation
- Revocation of marketing authorisation
  - e.g. lumiracoxib (Prexige) withdrawal due to hepatotoxicity
- Risk Management Plans; safety reviews; renewals; studies (PASS/PAES);





# Communicating regulatory action

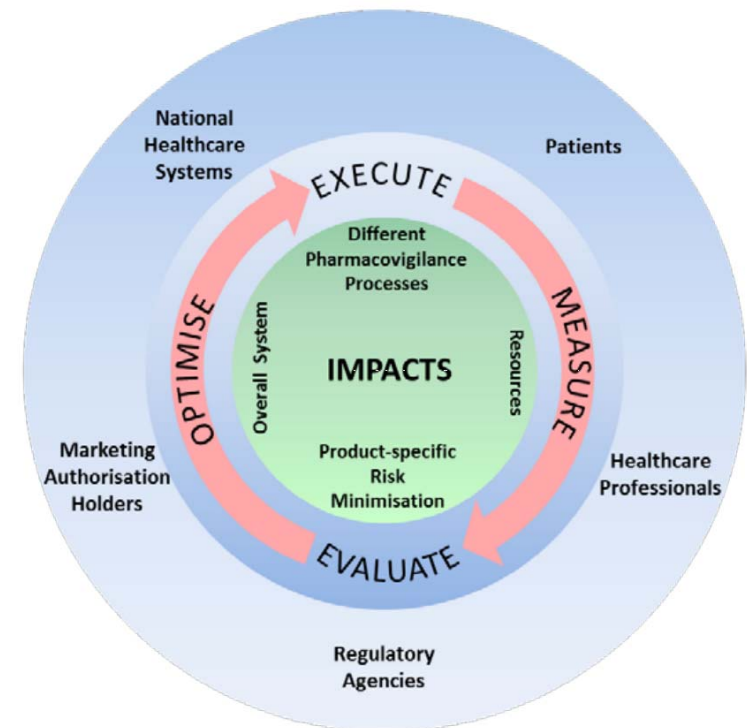
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- Central Alerting System (CAS)
- Updated product information (SmPC, PIL)
- Drug Safety Update (monthly)
- Dear Healthcare Professional letters (Ad hoc)
- Social Media
- Targeted information for patients and working with stakeholders
- Press releases campaigns
- MHRA website and info provision
- iDAPs [www.mhra.gov.uk/daps](http://www.mhra.gov.uk/daps)



# Outcomes of reporting

- About **20-70% of ADRs can be prevented** by ensuring the medicine is taken correctly. All reports from HCPs or patients play a critical role in understanding the benefit-risk for medicines on the market, allowing action to be taken to remove or change prescribing to patients.
- A **third of the reports received in 2015 led to changed advice** to prescribers and patients. Minimising the risks of taking these medicines and leading to improved public health .
- Although annual ADR reporting is increasing, studies estimate the level of **under-reporting is around 90%**. This could be higher for unlicensed medicines.
- Important to **communicate with ALL stakeholders to raise awareness**. The system only works if people are aware
- Important to **measure impact, health outcomes and continually improve PV systems**



# Can ONE report make a difference?

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- YES!
- Orciprenaline (Alupent®)
  - 2008 - Single report of serious cardiac ADRs, question on the report
    - ‘Why is this drug still available?’**
  - Safety review triggered
  - 2009 - safety review published
    - Risk/benefit no longer positive
    - Planned withdrawal
  - 2010 - withdrawn



# Yellow Card reporting more examples ...

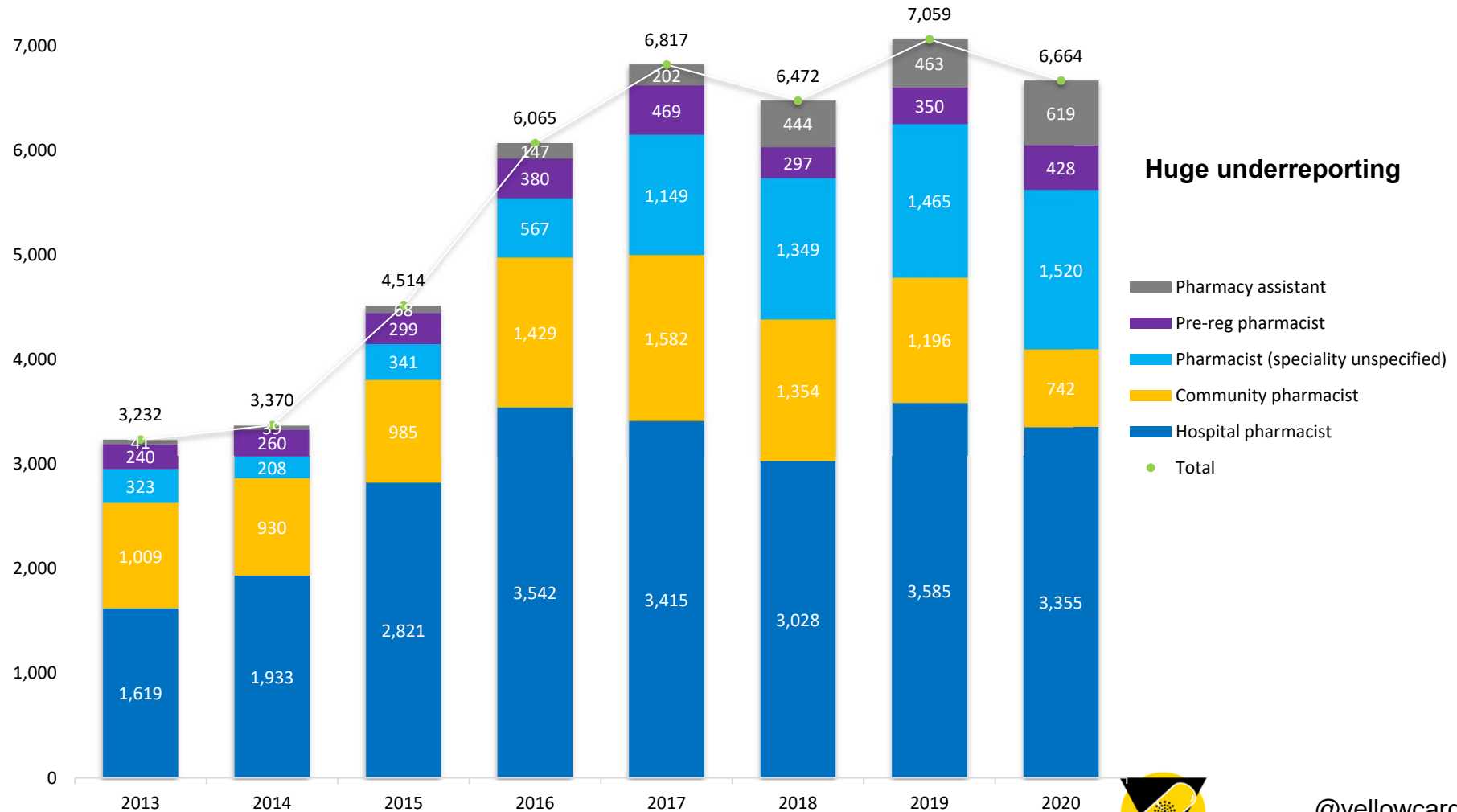
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- A pharmacist report - a 47 year old man on **simvastatin** who was hospitalised for **tendon rupture**. A further 6 reports in the database described tendinopathy. Outcome – ‘tendinopathy, sometimes complicated by rupture’ added to the product information.
- A pharmacist report - **purple glove syndrome** in a 66 year old female patient on **phenytoin**, reported to the manufacturer , forwarded to Yellow Card Scheme by the company (who have a legal obligation to send reports to the MHRA). The report triggered a review and subsequent addition of PGS to the phenytoin product information.
- A patient report - a 24 year old female reported hair loss on **Yasmin**, this triggered a review of 16 Yellow Card reports, 7 of which were made by patients. **Alopecia** added as an uncommon side effect. Without evidence supplied by patients reporting to the Yellow Card Scheme, this safety signal would have taken longer to be a recognised side effect.



# Yellow Cards from pharmacy

8,000



@yellowcardnw

# Does it matter if ...



- You make a duplicate report
  - No – system picks up, duplicates are good
  - [but never assume someone else will report!]
- You report a reaction that is not an ADR
  - No – all reports are suspicions
- You do not report your suspicions
  - Yes – an important safety signal may be delayed or lost



# What's in it for me?



- **You have contributed to patient safety**
  - Maybe your report will be used to inform a new signal investigation
- You have contributed to your Trust's commitment to using medicines safely
- You have fulfilled your professional responsibility
- You have new CPD!



# Reporting suspected side effects

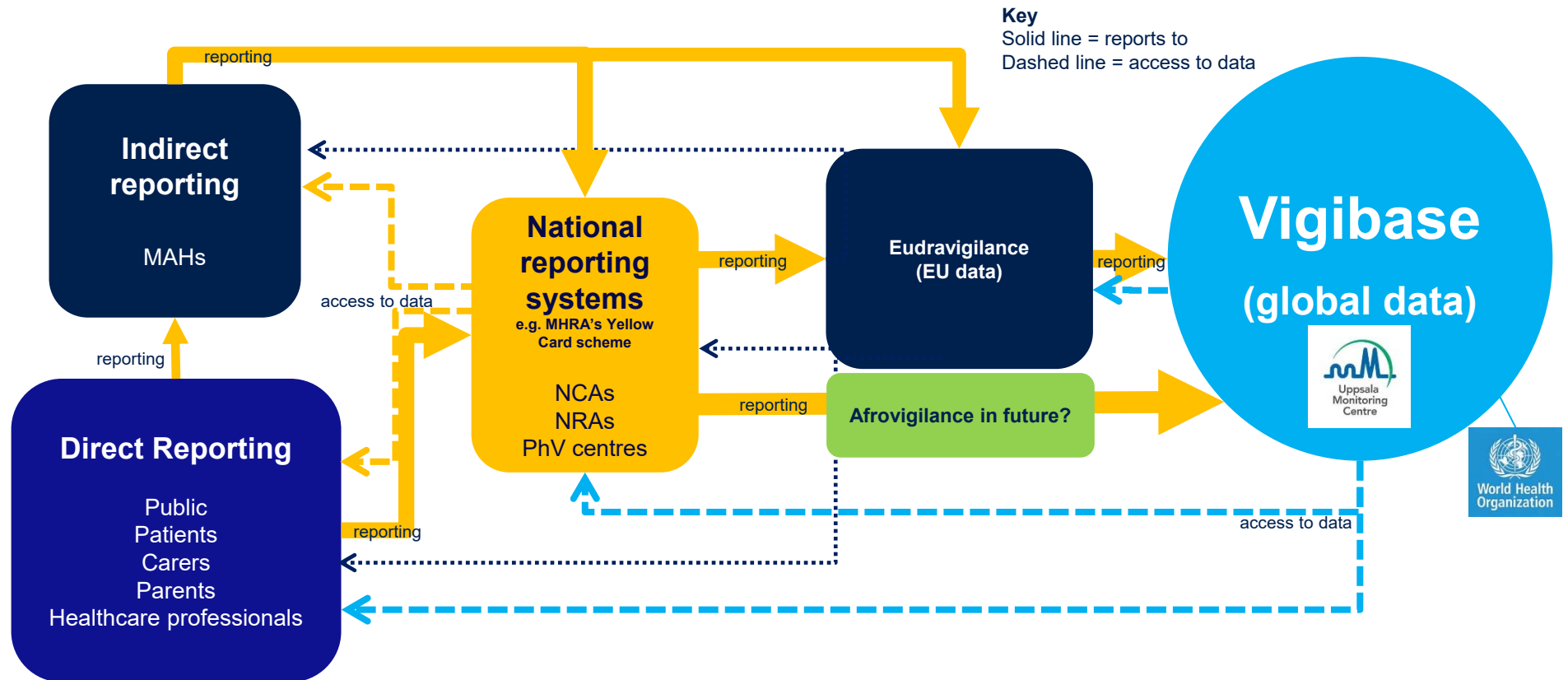


@yellowcardnw





# The global PhV machine & reporting of ICSRs (ADRs)



# Nature of evidence



Open Access

Research

## BMJ Open An investigation into drug products withdrawn from the EU market between 2002 and 2011 for safety reasons and the evidence used to support the decision-making

Rhian McNaughton,<sup>1,2</sup> Gwenaël Huet,<sup>1</sup> Saad Shakir<sup>1,2</sup>

- There is a call for a shift to explore real time data and technology for ADR reporting in PhV and for systems to evolve. However, 18 out of 19 drug withdrawals from EU 2002-11 were based on spontaneous ADR reports
- **‘Spontaneous case reporting remains central to pharmacovigilance as it allows for the detection of suspected adverse drug reactions and significant safety signals’**

Table 1 List of drugs withdrawn for safety reasons in all EU member states between 2002 and 2011 grouped by adverse drug reaction or safety concern

Drug name	Drug class or use	Year first marketed	Year of withdrawal	Length of time on market (years)	Adverse reaction or safety concern
Rofecoxib	NSAID (COX-2 inhibitor)	1999	2004	5	Thrombotic events

Table 2 List of evidence used to support medicinal product withdrawals in all EU member states between 2002 and 2011 derived from EMA reports, PubMed literature search and websites of competent authorities

Drug name	Case reports	Animal studies	Case-control	Cohort	RCTs	Meta-analysis	*Others
Rofecoxib	X		x	x	x	X	
Thioridazine	X	X	x	x	x	X	
Valdecoxib	X				x	X	
Rosiglitazone	X		x	x	x	X	
Sibutramine	X				x		x
Orciprenaline	X				x		
Benfluorex	X		x	x	x		
Clobutinol	X	X			x		
Buflomedil	X	X					
Veralipride	X						
Rimonabant	X				x	X	
Carisoprodol	X	X		x	x		x
Aceprometazine+Acepromazine	X						x
+Clorazepate							
Dextropropoxyphene	X						x
Nefazodone	X						x
Ximelagatran/melagatran					x		
Lumiracoxib	X				x		
Sitaxentan	X	X					
Bufexamac	X	X					x

\*Other studies include non-randomised and/or not controlled clinical trials and incidence studies. EMA, European Medicines Agency; EU, European Union.

Clorazepate							fatal side effect
Dextropropoxyphene	Opioid painkiller	~1960	2009	49			Fatal overdose
Nefazodone	Antidepressant	1994	2003	9			Hepatotoxicity
Ximelagatran/melagatran	Anticoagulant (thrombin inhibitor)	2003	2006	3			Hepatotoxicity
Lumiracoxib	NSAID (COX-2 inhibitor)	2003	2007	4			Hepatotoxicity
Sitaxentan	Antihypertensive (endothelin receptor antagonist)	2006	2010	4			Hepatotoxicity
Bufexamac	NSAID	~1970	2010	40			Contact allergic reactions

EU, European Union; NSAID, non-steroidal anti-inflammatory drug.

# Adoption of 'MedSafety app'



- Backend capability enables rapid adoption by new partners
- Customisation and management is easy.
- Countries initially supported by the WHO through their capacity building activities
- Opportunity for rapid deployment in health crisis situations
  - Branded for national context
  - Drug lists embedded i.e. WHO-Drug
  - MedDRA embedded
  - Can use free text
  - News feeds from national context
  - ADR data from national context
  - Connected to Vigibase & data access
  - Can also include other products/incidents

Yellow Card (UK)	15/07/2015
LAREB (Netherlands)	29/01/2016
HALMED (Croatia)	18/05/2016
Burkina Faso	15/06/2017
Zambia	29/06/2017
UAE RADR (UAE)	30/01/2019
Armenia	07/05/2019
Ghana	25/06/2019
Ethiopia	23/08/2019
Botswana	14/11/2019
Cote d'Ivoire	17/12/2019
Uganda	26/02/2020
DRC	14/04/2020
Pakistan	02/11/2020
Nigeria	04/11/2020
Kyrgyzstan	23/11/2020

App has potential for pharmaceutical industry adaptation too



# What is #MedSafetyWeek?



- Began with **adverse drug reaction (ADR) awareness week** social media campaign across EU led by MHRA
- Now an international and annual social media campaign to raise awareness of adverse drug reactions and national reporting systems; like the Yellow Card Scheme that operates across the UK
- **#MedSafetyWeek 2021 is the sixth annual campaign on social media**
- Medicines regulators across **64 countries** are participating, 6 supporting organisations, 41 languages!
- **Dates: 1-7 November 2021**
- **Theme: Vaccines**
- **Always use the #medsafetyweek hashtag – it helps us measure.**
- **Others to also use are: #MHRAYellowcard #patientsafety #vaccinesafety**
- UMC plus project team with regulators from: UK, Ghana, Ireland, ISoP Egypt Chapter
- Get in touch with your local MSOs or YCC to joint them in raising Yellow Card awareness



# MSW 2020 in numbers – a global campaign



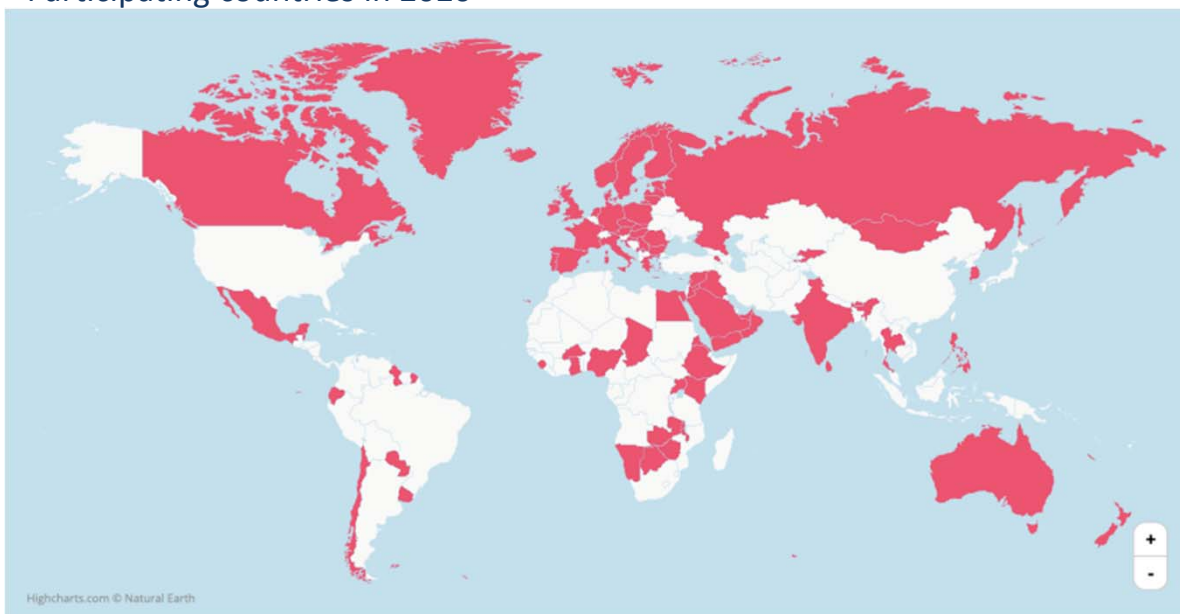
- **Over 75 countries** took part last year.
- Our messages reached **over 140 million people**
- included tweets by the WHO and the UN

76 medicines regulators

10 supporting organisations

45 languages

Participating countries in 2020



Participating countries in 2021

## Participants

### Medicines agencies

Albania	Denmark	Ireland	Niger
Algeria	Egypt	Italy	Oman
Armenia	El Salvador	Jamaica	Pakistan
Australia	Eritrea	Kenya	Panama
Barbados	Estonia	Latvia	Paraguay
Belgium	Ethiopia	Lithuania	Philippines
Bhutan	Finland	Luxembourg	Poland
Botswana	Georgia	Malaysia	Romania
Brunei	Germany	Malta	Russia
Bulgaria	Ghana	Mexico	Serbia
Cape Verde	Greece	Moldova	Slovakia
Chile	Honduras	Montenegro	Slovenia
Croatia	Iceland	Namibia	South Africa
Cyprus	India	Netherlands	Sri Lanka
Czech Republic	Iraq	New Zealand	Syria

Thailand  
United Kingdom  
United States  
Zambia

### Other organisations

- Asociación Colombiana de Farmacovigilancia
- Caribbean Public Health Agency
- European Medicines Agency
- International Society of Pharmacovigilance
- ISO Egypt Chapter
- Pan American Health Organisation





# What do we want to say?



- **General message**

- Vaccines are the most effective way to prevent infectious diseases and they save millions of lives worldwide.
- Like all medicines, vaccines can cause side effects.
- Report suspected side effects – it helps make vaccines better for everyone.

- **Secondary messages**

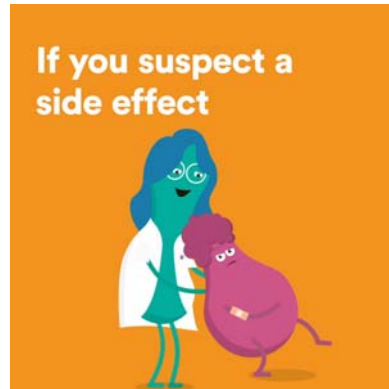
- Every report counts and your report matters.
- Importance of reporting brand and batch numbers
- You can report suspected side effects to the Yellow Card scheme to medicines also.
- With patients, discuss side effects and what to do including how to report themselves using the Yellow Card scheme.
- If you're concerned your health, speak to your healthcare professional.



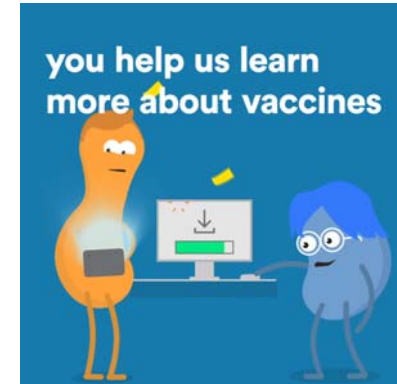
# New social media assets



Patient reporting



HCP reporting



Value of reporting




Social media cards



E-mail signature

# What can you and your organisation do?



1. Do you **follow MHRA on their social media channels**? Get connected to the MHRA social media channels and look out for the ADR awareness campaign in November
2. Help raise awareness by showing your support through **retweeting, commenting, liking, and sharing campaign material** with your social media contacts.
3. Get involved with the awareness week - **encourage greater dialogue between your colleagues, patients and organisations you deal with** about the importance of reporting suspected ARs. Engage locally with your one of our 5 regional Yellow Card Centres or MSO. **Work with local immunisation teams and stakeholders**
4. **Link to materials on organisational pages:** [resources page](#) and campaign tabs, [Drug Safety Update](#), e-learning modules and Yellow Card guidance for HCPs: <https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals>
5. **Email signature banner**  Right click to save the image and use locally  
The email signature banner is a rectangular graphic divided into two horizontal sections. The top section is yellow and contains the Yellow Card logo and the text "Yellow Card". The bottom section is black and contains the text "#MedSafetyWeek" and "1-7 November 2021" in white.
6. **Don't wait to report any safety issues, especially suspected adverse drug reactions to the Yellow Card Scheme.**

MHRA website will contain a **library of downloadable assets** from previous and current campaigns. 3 new animations will be added that MSW:

<https://yellowcard.mhra.gov.uk/campaigns/>

Mitul Jadeja, MHRA

<https://yellowcard.mhra.gov.uk/campaigns/>



Consider using infographics: Campaigns tab of the Yellow Card website

Asset #1 Animation

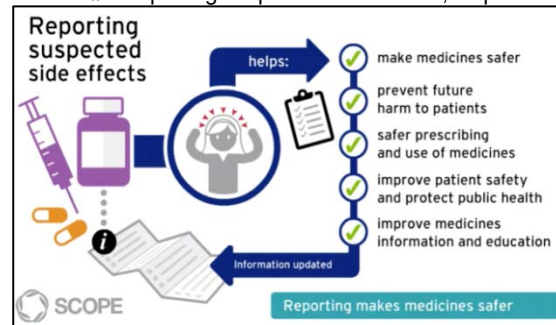
[www.youtube.com/watch?v=3et5LdYLc8M&feature=youtu.be](http://www.youtube.com/watch?v=3et5LdYLc8M&feature=youtu.be)



Patient waiting area video downloadable here for those using Jayex

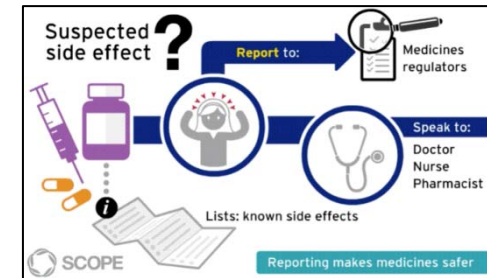
<http://www.medextranet.com/categories/awareness-campaigns.html>

Asset #2 Reporting suspected side effects, helps



Click image above for example animation (need to be connected to internet)

Asset #3 Suspected side effect? Report



Asset #4 (2017)



Asset #5 (2017)



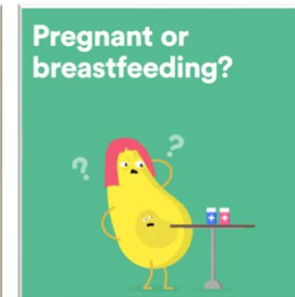
Asset #6 (2017)



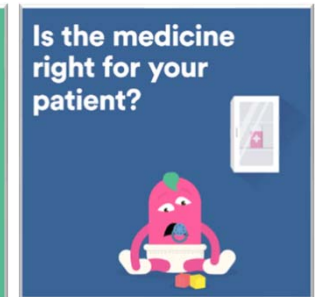
Asset #7 (2018)



Asset #8 (2018)



Asset #9 (2018)



Click image above for example animation (need to be connected to internet)

Click image above for example animation (need to be connected to internet)

Asset #10 (2019)



Asset #11 (2019)



Asset #12 (2019)

A short video is available for patients on how to report a suspected side effect from a medicine. Please note that there is no audio in this video



Asset #13-17 (2020)

View sample videos at [bit.ly/MSWvid](http://bit.ly/MSWvid)



# #MedSafetyWeek use videos on YouTube Channel



- Every Report Counts to showing the impact of reporting

<https://youtu.be/9SzUNbmEtIU>





# Professional Education

<https://vaccine-safety-training.org/vaccine-pharmacovigilance.html>

- Online e-learning materials on ADR modules
- All CPD accredited
- Be good to promote these during MedSafetyWeek
- Good practice to incorporate within induction training for new staff

<https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals#further-guidance-and-online-learning>



**SCOPE**

Adverse Drug Reactions:  
Reporting makes medicines  
safer

The Strengthening Collaboration  
for Operating Pharmacovigilance  
in Europe (SCOPE)

Select the **forward arrow** for more.



**CPPE** Adverse drug reactions and medicines safety

Outline My Notes

Adverse drug reactions and medicines safety

Welcome to this e-learning programme

- Introduction
- Technical details
- Target audience
- About this programme 1/2
- About this programme 2/2
- Learning objectives
- Reflective questions
- Continuing professional development (CPD)

Section 1 - Introduction to adverse drug reactions

Section 2 - Classification of adverse drug reactions

Section 3 - Assessing the safety of medicines

Summary

**Adverse drug reactions and medicines safety**

An e-learning programme for the pharmacy team

February 2012

CPPE CENTRE FOR PHARMACY POSTGRADUATE EDUCATION

Wales Centre for Pharmacy Professional Education Canolfan Addysg Fferyllyaeth Broffesiynol Cymru

MHRA

**Nursing Times.net**

'Make culture change the priority for 2014'

Jenni Middleton, Editor



SPEAK OUT SAFELY CAMPAIGN

HOME NURSING PRACTICE NURSING TIMES LEARNING OPINION STUDENT NURSING

## Adverse drug reactions: the Yellow Card Scheme

Welcome to the Nursing Times Learning online training unit on **Adverse drug reactions: the Yellow Card Scheme**.

The unit is one of many online training units for nurses available from Nursing Times, the UK's leading independent, peer-reviewed journal for nurses.



Created in association with the Medicines and Healthcare Products Regulatory Agency, the unit will:

MY LEARNING LOG



Please note: you need to sign in to nursingtimes.net to access your Learning Log

HOW DO I START LEARNING?

Already a subscriber? You have FREE access to all

# WHO module

- <https://vaccine-safety-training.org/vaccine-pharmacovigilance.html>



World Health Organization **VACCINE SAFETY BASICS** e-learning course

Search

Case study A  
Case study B  
Case study C  
Glossary

Module 1 Module 2 Module 3 **Module 4** Module 5 Module 6 General Assessment

### VACCINE PHARMACOVIGILANCE

**Definition**  
According to the CIOMS/WHO Working Group on Vaccine Pharmacovigilance, Vaccine pharmacovigilance is defined as  
*"the science and activities relating to the*  

- Detection,
- Assessment,
- Understanding and
- Communication

*of adverse events following immunization and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization".<sup>78</sup>*

Like drug pharmacovigilance, vaccine pharmacovigilance aims to detect adverse events early to trigger accurate risk assessment and appropriate response (risk-management) to the problem. This ensures the minimization of negative effects to individuals. Another goal of vaccine pharmacovigilance is to lessen the potential negative impact on immunization programmes.<sup>49</sup>

Vaccine pharmacovigilance relies on three steps:<sup>39</sup>

```
graph LR; A[SIGNAL DETECTION] --> B[DEVELOPMENT OF CAUSALITY HYPOTHESIS]; B --> C[TESTING OF CAUSALITY HYPOTHESIS]
```

**Question**  
In Module 1 you were introduced to the rotavirus vaccine case. Take a look at the additional information in the Rotavirus vaccine example given in this question.

What hypothesis was developed as a result of the post-licensure surveillance of RotaShield<sup>®</sup> vaccine to explain why the original clinical trial (on 10 000 vaccinees) did not detect the incidence of intussusception?

« back

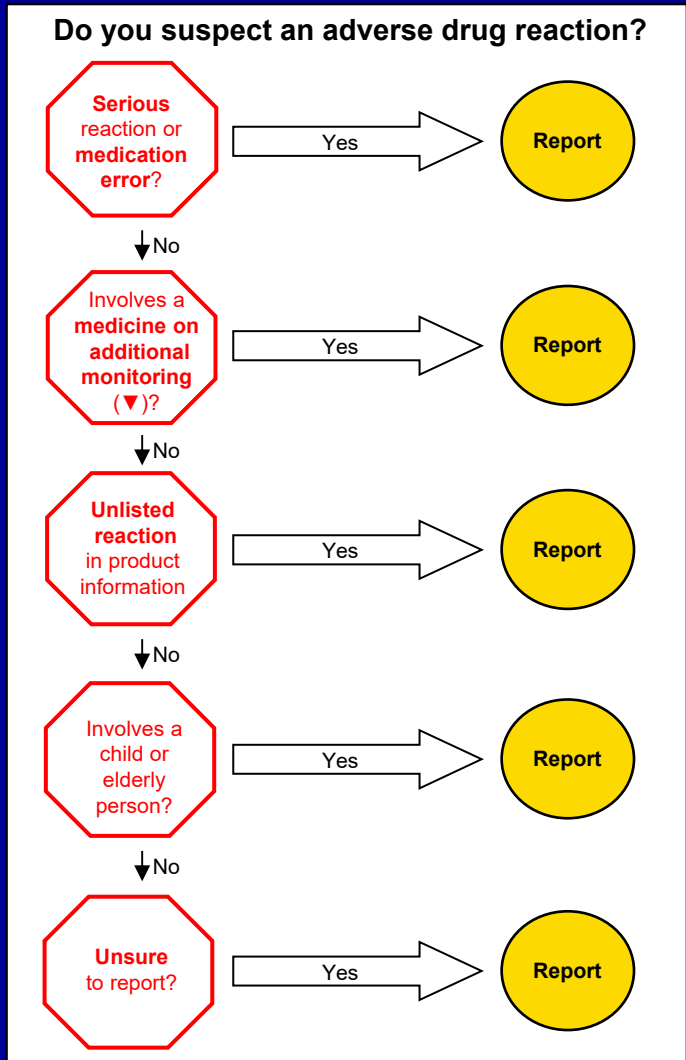
Use this crib sheet to help complete a Yellow Card if you suspect an adverse drug reaction (ADR)



**Adverse Drug Reaction suspected?**

Report it via a Yellow Card

[mhra.gov.uk/yellowcard](http://mhra.gov.uk/yellowcard) or via the App



The minimum information needed for completing a Yellow Card:	Additional information to supply (this information helps assess the Yellow Card):
<p><b>Names of the medicine(s)</b> suspected to have caused the reaction</p>	<p>Details of the suspect medicine(s) if available. For example;</p> <ul style="list-style-type: none"> <li>✓ dose</li> <li>✓ start and stop dates</li> <li>✓ route of administration</li> <li>✓ <b>Batch numbers especially for vaccines, biosimilars and biological medicines</b></li> <li>✓ action taken with the drug - stopped, dose change, restarted, none etc.</li> </ul>
<p><b>Suspected reaction(s)</b></p>	<p>Details of the reactions if available:</p> <ul style="list-style-type: none"> <li>✓ a brief description of reaction</li> <li>✓ diagnosis if relevant</li> <li>✓ start and stop dates of reaction</li> <li>✓ seriousness (use tick boxes on Yellow Card)</li> <li>✓ treatment given</li> <li>✓ reaction outcome</li> </ul>
<p><b>At least one patient identifier:</b></p> <ul style="list-style-type: none"> <li>✓ Sex</li> <li>✓ Age</li> <li>✓ Weight</li> <li>✓ initials</li> <li>✓ local identifier</li> </ul> <p>All should be completed if available</p>	<p>Any additional information you have:</p> <ul style="list-style-type: none"> <li>✓ relevant medical history</li> <li>✓ test results</li> <li>✓ other drugs taken in the last 3 months</li> <li>✓ if any rechallenge was performed</li> <li>✓ If it is a congenital abnormality, state all other drugs taken during pregnancy and date of last menstrual period</li> </ul> <p><b>If no further information is available, please indicate this on the Yellow Card</b></p>
<p><b>Reporter details:</b></p> <p>Include your name, qualification and full address</p>	

# **Yellow Card** Making medicines safer



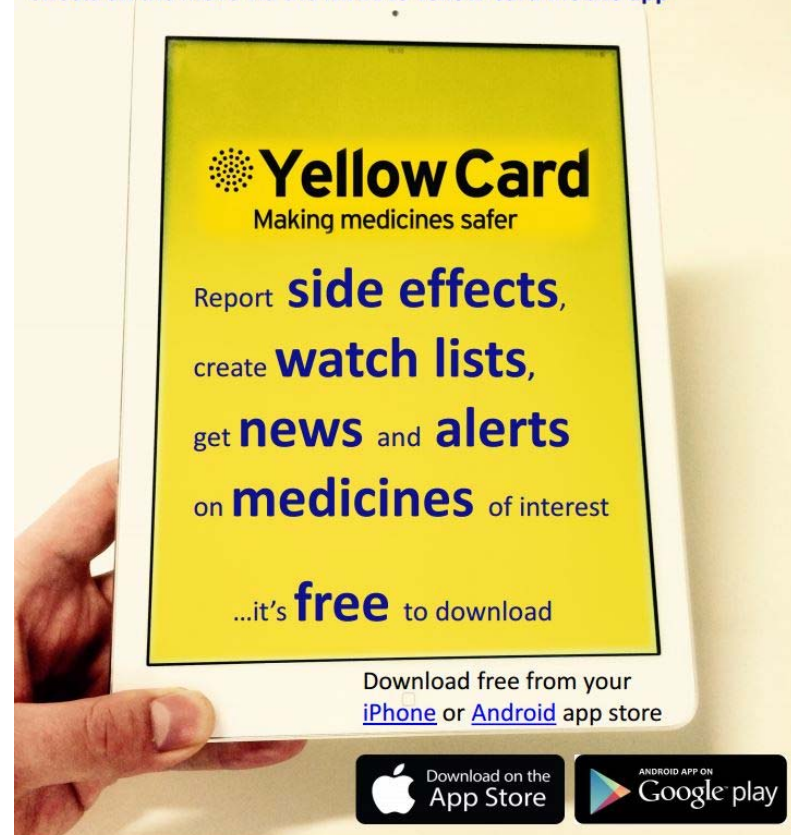
## A side effect to a medicine?

Anyone can report suspected side effects using the Yellow Card Scheme.

Visit:  
[mhra.gov.uk/yellowcard](https://mhra.gov.uk/yellowcard)  
or use the free app. For paper forms call: 0808 100 3352.

If you are worried about your health speak to a healthcare professional.

**Did you know?** You can now tell us about suspected side effects on the move via the **MHRA's Yellow Card mobile app**





**Yellow Card**  
Making medicines safer

Report **side effects**,  
create **watch lists**,  
get **news** and **alerts**  
on **medicines** of interest

...it's **free** to download

Download free from your  
[iPhone](#) or [Android](#) app store

 Download on the  
App Store

 ANDROID APP ON  
Google play



# Engage people beyond social media



Local engagement beyond social media but using it as a medium to inspire others

**MEDICINES SAFETY**

Here are some of our colleagues at Royal Event Pharmacy promoting a MedSafetyWeek #YellowCard

Our fantastic colleagues over at Yellow Card West Midlands have all the details for next weeks Medicines Safety Webinar mini-series

Join our YCC colleagues at 1pm every day next week

[yccwm.org.uk/index.php/2020...](https://yccwm.org.uk/index.php/2020...)

#MedSafetyWeek #PatientSafety #CPD #EveryReportCounts

**Tara-Louise Molloy** @TaraLouiseMolloy2 · Nov 3

Report an unexpected allergy to a medicine during surgery 🙌 Yes! This is how we collect data on high risk medicines, the app makes it so quick and easy 📱 #MedSafetyWeek #YellowCard #MHRA @EmmaKirkMSO @WUTHSurgery @leebennett77 @pipparoberts12 @WUTHpharmacy

1,000,000 likes 200 comments 100 shares

**Yellow Card Medicines Safety Webinar Mini-Series**

Join us for some or all of our daily 20 minute webinars to celebrate ADR awareness week 2020

2nd November - 6th November  
13:00 - 13:20

#MedSafetyWeek2020

**Nov 6th at 10:39 AM**

It's #MedSafetyWeek and the Pharmacy Team at Nuffield Health Newcastle Hospital have produced a wonderful display to support the campaign and raise awareness to increase reporting of suspected adverse drug reactions to the Yellow Card scheme.

Pictured: Our wonderful Pharmacy team supported by Housekeeping, Theatre and Hospital Matron.

<https://yellowcard.mhra.gov.uk/> #NuffieldHealthNewcastleHospital

**Emma Kirk** @EmmaKirkMSO · Nov 4

We can all report #yellowcards Here is Ais, one of our integrated pharmacists, showing local GP, Dr Nelson, how to report on the app.

#everyreportcounts @toriyou49109245 @pipparoberts12 @WUTHpharmacy

3 retweets 9 likes

#MedSafetyWeek #EveryReportCounts

**Kathryn** @KatCleminson · Nov 3

Aisya, one of our medicine management technicians, is showing our ward DT how to report an ADR via #yellowcard online. Her patient reported abdominal pain and general malaise side effects with their medication

#MedSafetyWeek @wuthnhs @WUTHpharmacy @EmmaKirkMSO

**Kathryn** @KatCleminson

WUTHpharmacy celebrating #MedSafetyWeek with amazing cakes from Kim! Today we are giving out these fab treats to anyone reporting a yellow card and letting our medication safety team know!

@EmmaKirkMSO #everyreportcounts

Here are a selection of our friendly pharmacy team showing the different ways you can report ADRs. They can answer life's big questions....what, how, who, where and why? #howdoyoureportyours #MedSafetyWeek #yellowcard @EastCheshireNHS @ECTStaff @KashHaque

**Southeast NHS Library** @SMC\_Library · Nov 2

Raising awareness about the importance of reporting suspected adverse drug reactions #MedSafetyWeek #EveryReportCounts #PatientSafety #YellowCard @MSD Hospitals

**Kathryn** @KatCleminson · Nov 6

Katie is one of our senior clinical pharmacists. Here she is reporting a #yellowcard for one of her patients who had a reaction to an antibiotic! Thanks Katie! #EveryReportCounts #MedSafetyWeek @WUTHpharmacy @wuthnhs

3 retweets 10 likes

**Emma Jane Williams**

1:10 PM · Nov 5, 2020 · Twitter for iPhone

4 retweets 15 likes

**Ask us about side effects.**






Our pharmacy team know what, how, who, where and why.

Yellow Card

# Biobank Overview



## What is it?

-  Yellow Card is the MHRA's scheme for public and healthcare professionals to **report side effects** to drugs and vaccines
-  The Biobank would collect and sequence **DNA samples** for a 'watchlist' of research topics to establish if specific **genetic variants** can **predispose** individuals to a certain side effect to a drug
-  Participants' **Electronic Health Records** and other **relevant data** would be collected to support the research
-  Ultimate aim is to support development of **genetic tests** to be used prior to prescription
-  **External researchers** (academia, industry etc) could apply to **access anonymised data** or **add their own topic** to the watchlist

## Why is it important?

-  **1 in 15 hospital admissions** are due to side effects and they account for **197,000 deaths** across Europe annually
-  Expands the utility of the existing Yellow Card database to generate **more insight on the safety profiles** of medicines and vaccines
-  Research will supporting tailoring of prescriptions to patients to enable **'personalised healthcare'**
-  Involvement from other researchers to contribute to and benefit from the Biobank will **strengthen the reach and impact** of the research
-  Output **data will be shared** with international pharmacogenomic groups, consortia and databases

## What are we doing?


-  **12 month scoping** project funded by UK Office for Life Sciences to work out:
  - Target operating model for YC Biobank
  - Potential for collaborations
  - Projected cost and plan for pilot
  - Funding sources
  - Plan for research and industry access
-  Ongoing **engagement** with patients, public, healthcare professionals, academia, healthcare organisations, biobanks and industry to shape our proposals
-  Final proposals to be delivered in **January 2022** with interim report in July 2021
-  Will start **funding applications** through second half of 2021 - ongoing

# Healthcare professional virtual workshop



We are keen to hear your views on the initiative to discuss potential healthcare professional involvement as our plans continue to develop

**Thursday 21<sup>st</sup> October 2021 at 13.00 via Zoom**

Event agenda	 The logo for Yellow Card Biobank, featuring a yellow background with a black banner at the bottom containing the word 'Biobank' in white. The background also includes a faint DNA double helix structure.
<ol style="list-style-type: none"><li>1. Pharmacogenomics in healthcare today</li><li>2. Introduction to the Yellow Card Biobank plans</li><li>3. Discussion topics:<ul style="list-style-type: none"><li>• participant contact and recruitment</li><li>• sample and data collection</li><li>• how you could support the biobank and how the biobank could support you</li></ul></li></ol>	

If you'd like to hear more about the initiative or the event, please get in touch at [YellowCardBiobank@mhra.gov.uk](mailto:YellowCardBiobank@mhra.gov.uk)

**[Click here to register](https://www.eventbrite.co.uk/e/yellow-card-biobank-a-virtual-workshop-for-healthcare-professionals-tickets-169323688711)**

<https://www.eventbrite.co.uk/e/yellow-card-biobank-a-virtual-workshop-for-healthcare-professionals-tickets-169323688711>



# Vaccines: special considerations MHRA

Situation	Vaccines	Medicines
Who?	Usually healthy people Often most of the population	Those with diseases or medical conditions
How?	Public health programmes	By doctor or pharmacist
Why?	To prevent disease	To treat, manage or prevent disease
When?	In childhood, disease outbreaks, seasonal, or travel	At time of illness
How many?	Around 8-15 in childhood	Thousands of medicines
Adverse events	Low acceptance of risk – may lead to vaccine hesitancy	Adverse events may be more acceptable depending on severity of disease or availability of treatments

GVSII Blueprint objective 3: “develop vaccine safety communication plans at country level, to promote awareness of vaccine risks and benefits, understand the perception of the risk and prepare for managing any adverse events and concerns about vaccine safety promptly

# Vaccine PhV needs special consideration



- Pharmacovigilance and Risk Management Planning for vaccine requires an understanding of the **biological nature of vaccines and how it is given need specific considerations for risk/benefit evaluation**. Real time surveillance often uses multiple sources of data including epidemiological data.
- An understanding of mass national immunisation programmes and the differential impact on the safety profile is essential.
- Risk Management should be planned well in advance, be proactive and tailored, with anticipation of future issues.
- **Communications** should be balanced, taking account of the variety of stakeholders in vaccine safety. Rumours and vaccine hesitancy can derail and have a damaging role.



9 December 2013  
EMA/488220/2012 Corr\*



[Guideline on good pharmacovigilance practices \(GVP\)](#)  
Product- or Population-Specific Considerations I: Vaccines for prophylaxis against infectious diseases

## Incidents

- Tuberculosis following oral BCG
- Polio following IPV
- H1N1 immunization and GBS, Narcolepsy

## Safety issues

- Programme errors
- Anaphylaxis
- Vaccine associated paralytic polio (VAPP)
- Disseminated BCG disease

## Rumours, bad science and mass hysteria

- Pertussis vaccine coverage in the UK
- MS and hepatitis B vaccine in France
- OPV and chronic diseases in Nigeria
- Thiomersal and neuro-developmental disorders

# Vaccines

## Who are the stakeholders in communications?

Decision-makers	Vaccine users	Other collaborators	Other parties
<p>Regulatory authorities</p> <p>Public health authorities</p> <p>National immunisation committees</p> <p>National advisory committees on AEFI</p> <p>Health technology assessment bodies</p> <p>Ministries of health</p> <p>Politicians</p>	<p>Representatives of vaccine target populations, vaccinees, parents, carers and the community, including anti-vaccine groups, citizen watchdogs</p> <p>Representatives from HCPs, HCP associations, learned societies</p>	<p>Vaccine manufacturers</p> <p>Media representatives and journalists</p> <p>Non-governmental organisations</p> <p>Technical development agencies</p> <p>Multilateral agencies, e.g. WHO and GACVS, UNICEF</p>	<p>Religious and community/public opinion leaders, including e.g. teachers</p> <p>Donors and procurement agencies</p>

# Special considerations for vaccines: rumour, misinformation and disinformation

## Debunking COVID-19 Vaccine Myths



1. The mRNA vaccines will modify my DNA.

2. Getting COVID-19 is better immunity than receiving the vaccine.

3. If I'm pregnant, I can't get the vaccine.

4. I don't need to wear a mask after getting the vaccine.

1. mRNA vaccines **do not affect or interact with** our DNA in any way.

2. We don't know how long protection lasts for those who get infected or those who are vaccinated. **Since COVID-19 can cause serious illness, get vaccinated.**

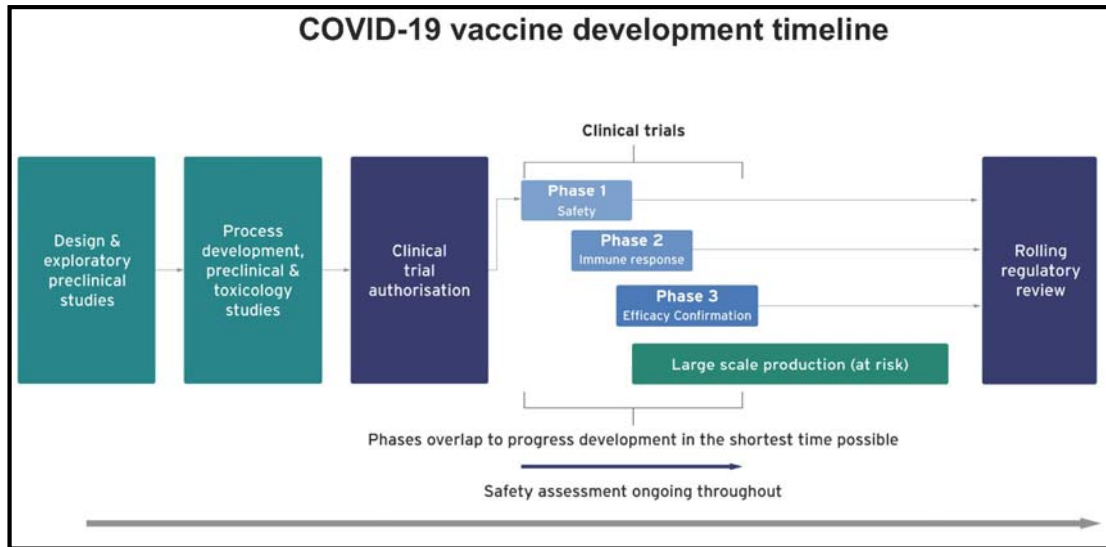
3. **If you are pregnant, you may choose to be vaccinated** when it's available to you.

4. **You should still wear a mask and avoid large crowds after vaccination** until otherwise guided.

# High level overview of the drug development process



Safety, Effectiveness and Quality to robust international standards



Monitoring →

Phase IV →

- Pharmacovigilance
- Spontaneous ADR reporting;
- Benefit Risk Management;
- Safety variations;
- Renewals of marketing authorisations;
- Reclassification;
- Regulation of product information and advertising.

Inspection, Enforcement & Standards

VRMM E-Cigarettes

MHRA regulates medicines and medical devices, ensures they work and are acceptably safe; focuses on core activities of product licensing, inspection and enforcement, and pharmacovigilance

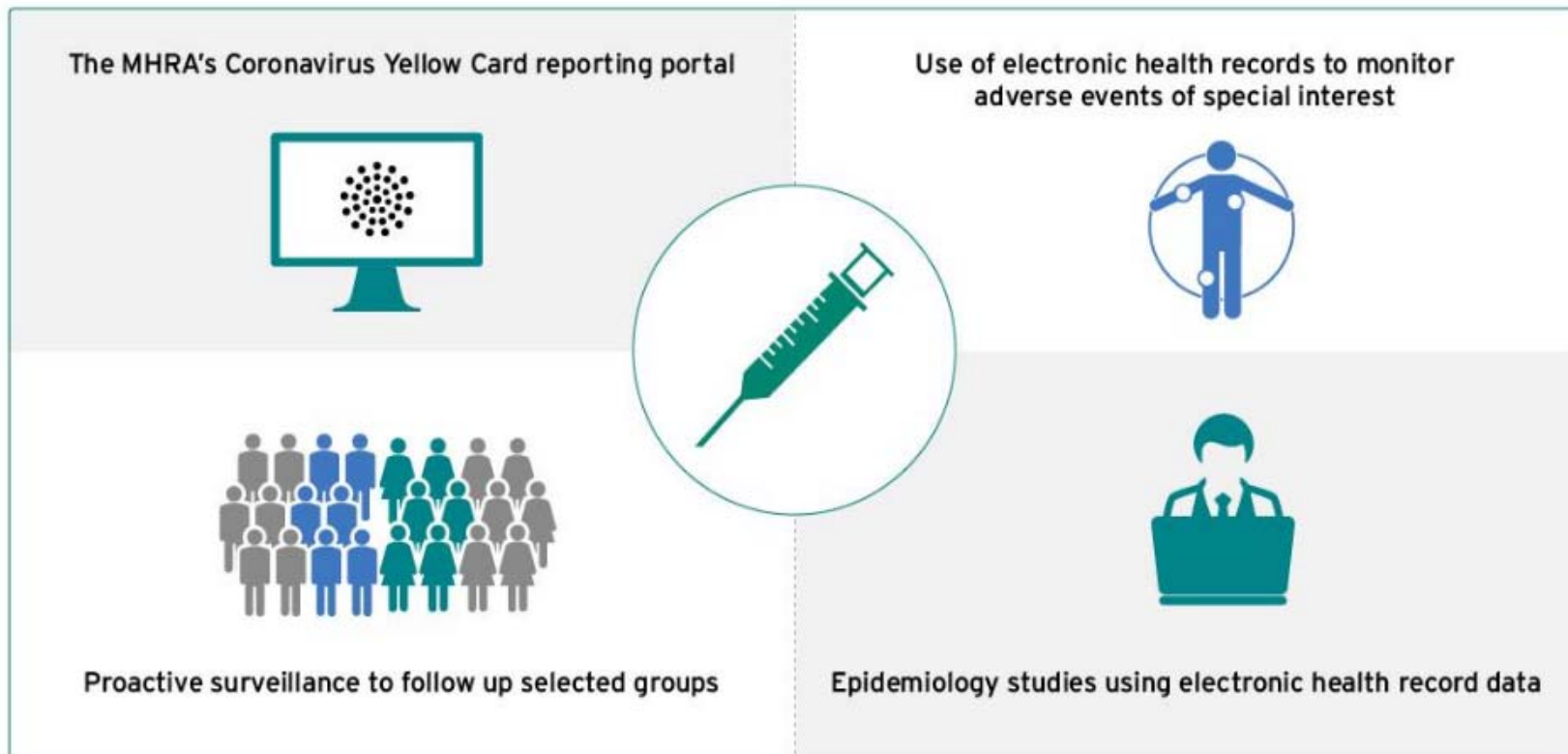


# COVID-19 Vaccine pharmacovigilance



- Two main aims
  - to rapidly detect, confirm, characterise and quantify any new risks that were not detected in clinical trials, to weigh these against the expected benefits and take any necessary action to minimise risks to individuals.
  - to be able to very quickly established if any serious events which are temporally-related to vaccination are merely a coincidental association, and to do this in a robust, evidence-based way so that public confidence in a vaccine is not eroded unnecessarily.

## Surveillance strategy



<https://www.gov.uk/government/publications/covid-19-vaccine-surveillance-strategy>

- <https://coronavirus-yellowcard.mhra.gov.uk/>  
or use the app



Yellow Card | Coronavirus (COVID-19) Existing Yellow Card App user? Sign in or register

About this site  
Latest News  
Contact us  
Vaccine Product Information

## Coronavirus Yellow Card reporting site

Report suspected side effects to medicines, vaccines or medical device and diagnostic adverse incidents used in coronavirus treatment to the Medicines and Healthcare products Regulatory Agency to ensure safe and effective use

Find the medicine / vaccine / device you wish to report.

Enter medicine, vaccine or device name Start report

Can't find what you are looking for? You can report on any other medicines, vaccines, devices, defective or falsified products (including fake coronavirus testing kits) via the [Yellow Card](#) website.

**Where to go for medical advice**

We are unable to provide you with medical advice. However, we encourage you to speak to your doctor, pharmacist or to call [NHS 111](#) if you are worried about your health.

Please do not stop taking your medicine without first seeking advice from your doctor or pharmacist.

Visit [Coronavirus \(COVID-19\): what you need to do](#) to find out the government response to coronavirus.

**Latest news** [See all news](#)

[COVID-19 vaccines \(Pfizer/BioNTech and COVID-19 Vaccine AstraZeneca\): current advice](#) [↗](#)  
Updated: 8 January, 2021

[Access Consortium statement on COVID-19 vaccines evidence](#) [↗](#)  
Updated: 8 January, 2021

[Exemptions from Devices regulations during the coronavirus \(COVID-19\) outbreak](#) [↗](#)  
Updated: 8 January, 2021

**Ventilator incident reporting**

A dedicated phone line is available to report specifically for ventilators and respiratory support.

Call [0800 731 6789](tel:08007316789) for free between 9am and 5pm, Monday to Friday. Outside of these hours please leave a message with your name and

**Fake medicines and devices**

For counterfeit or fake medicines or medical devices, including coronavirus testing kits, report as usual on the [Yellow Card](#) site.

For any queries involving counterfeit or fake medical devices contact [devices.compliance@mhra.gov.uk](mailto:devices.compliance@mhra.gov.uk)

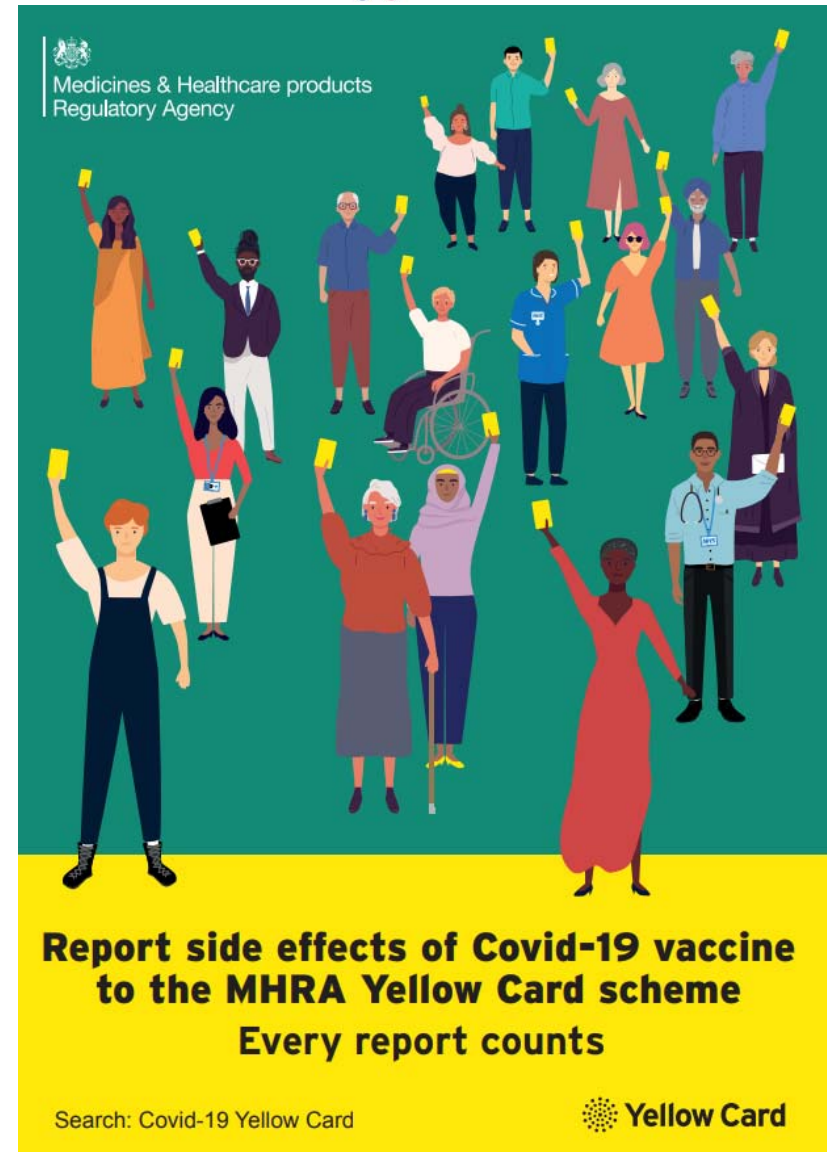
- [Weekly publication on ADR data on MHRA website](#)
- Comms [campaign e-toolkit](#) available on Coronavirus Yellow Card website
- Developed at pace
- Additional questions on reporting form added as well as follow up q's for TE+TP events when reported
- Detailed review and full safety review of each case
- Working with haematology community, PHE, CHM, other regulators globally, etc
- Advice from independent CHM & EWGs for regulatory position

**It is crucial healthcare professionals keep reporting non Covid-19 related suspected adverse drug reactions to the Yellow Card scheme or via the app**

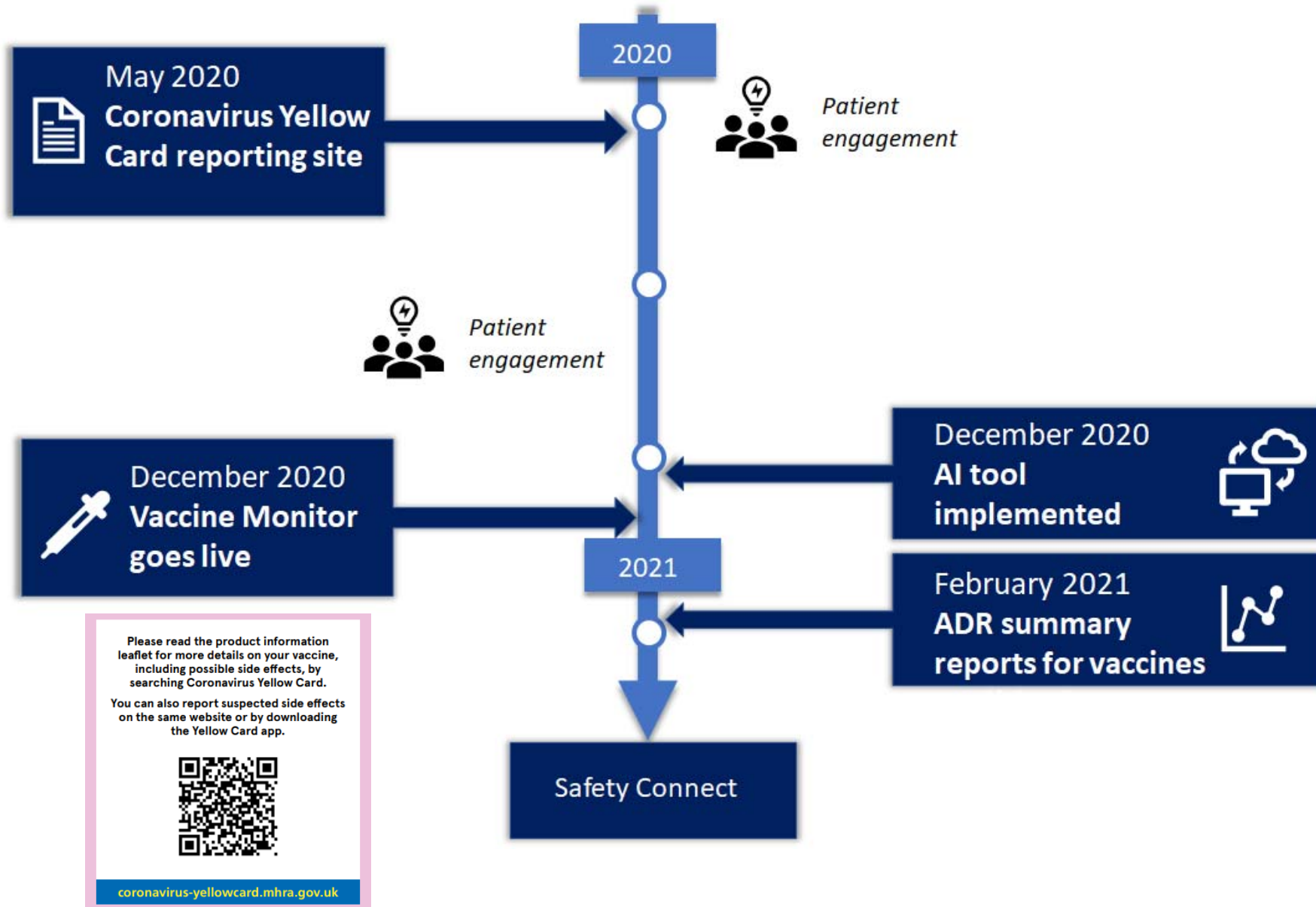
# Reminder about the COVID-19 campaign toolkit



- [Campaign toolkit briefing sheet](#)
- **PDF formats for in-house colour printing**
- **Posters**
- [A4 Poster - PDF](#)
- [A3 Poster - PDF](#)
- **Postcard/ leaflet**
- [Postcard – A6 \(single\) - PDF](#)
- [Postcard – 4x A6 postcards on one A4 page - PDF](#)
- [Digital screen 16 x 9 – JPEG \(horizontal\)](#)
- [Digital screen 9 x 16 – JPEG \(vertical\)](#)
- Graphic and animation assets and posts wording for use across social media. [File type – Zip file](#)
- **Email signature**
- Signature banner or text hyperlinked to the reporting site - <https://coronavirus-yellowcard.mhra.gov.uk>
- [Email signature banner- version 1 – PNG](#)
- [Email signature banner – version 2 – PNG](#)
- Text version (if you can't use the banner, please use the following text hyperlinks)
- [Report side effects of Covid-19 vaccine to the MHRA Yellow Card scheme. Every report counts.](#)



<https://coronavirus-yellowcard.mhra.gov.uk/campaignpage>



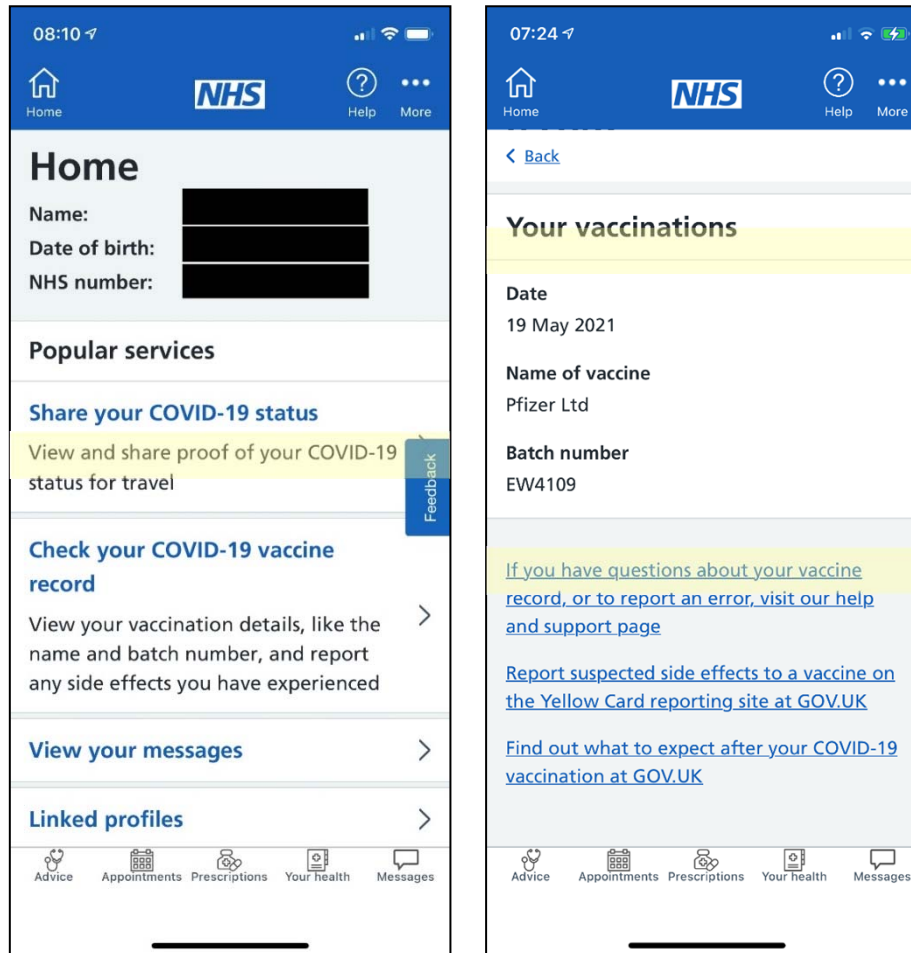
# Enhanced passive surveillance: Challenges



- Assessment of large datasets meant need for greater triage and an agile process
- Systems processes had to be closely monitored as they weren't used to the high volumes
- AI introduction
- Enhancements to the websites e.g. mandating MedDRA



# NHS App Integration



- Stage one of integration of Yellow Card into the NHS App is complete
- Full vaccination record and prominent linking to side effect reporting
- This will be rolled out to all other products after the new Yellow Card launch
- Further integration stages will enable NHS login to be used for Yellow Card delivering a fully integrated experience

# Active monitoring of COVID-19 vaccine



Invitation letter



Patient requested to register before they have first dose of vaccine



Patient provides background on medical history



At time of vaccination, the patient enters vaccine details, including brand and batch



Patient is contacted at points thereafter to check for any side effects

A screenshot of the 'Yellow Card Vaccine Monitor' website. The page has a yellow header with the text 'Yellow Card | Vaccine Monitor' and a 'My Account' button. The main content area is white and contains several sections: 'About Yellow Card Vaccine Monitor', 'Signing up', 'Background to the MHRA', 'Latest News', and 'Contact us'. The central heading is 'Yellow Card Vaccine Monitor'. Below this, it states: 'The Medicines and Healthcare products Regulatory Agency (MHRA) is monitoring suspected side effects to COVID-19 vaccines.' There is a 'My Account' button with a yellow bar to its left. Below the button, it says: 'If you are registering you will be asked to read, and agree to, the signing up details and privacy statement before progressing. If you are logged in, select 'My account'.' The next section is 'The purpose of this programme', which states: 'The Vaccine Monitor is a data collection programme which actively follows up with individuals after they have received a COVID-19 vaccination.' This is followed by 'The MHRA also run the Coronavirus Yellow Card reporting site, for reporting suspected side effects to medicines or device incidents used in this pandemic, which anyone can report to.' The final section is 'How this site differs from other COVID-19 websites and apps', which states: 'There are a number of COVID-19 Apps available; including NHS Covid-19 and the COVID Symptom Study app. The Yellow Card Vaccine Monitor is a standalone data collection platform which does not directly link to other COVID-19 websites or apps.'

<https://vaccinemonitor-yellowcard.mhra.gov.uk/>

## Follow-ups are sent

- One week after first and second dose
- Two weeks after first and second dose
- Twelve weeks after first dose
- Then every three months thereafter for approximately one year from the date of the first dose



# Vaccines: communications following launch



- Provision of information about vaccines, their assessment, side-effects reported... and any uncertainties about these (transparency)
- Information about vaccine rollout programme (and any changes to this based on new safety information)
- Continuous encouragement to report AEFI (for HCPs and patients)
- Safety messages to communicate will **evolve** with vaccine rollout; developed in collaboration with stakeholders

Research and analysis

## Coronavirus (COVID-19) vaccine adverse reactions

A weekly report covering adverse reactions to approved COVID-19 vaccines

From: Medicines & Healthcare products Regulatory Agency  
 Published:  
 Last updated:

Documents



Decision  
**Summary of the Public Assessment Report for Pfizer/BioNTech COVID-19 vaccine**  
 Updated 31 March 2021

Press release  
**JCVI issues new advice on COVID-19 vaccination for pregnant women**

Summ: JCVI issues new advice on COVID-19 vaccination for pregnant women

Contents: Summary of the Public Assessment Report, Lay summary, COVID-19 mRNA Vaccine BN116202, Authorisation (RNA) concen

The JCVI has advised that pregnant women should be offered the COVID-19 vaccine at the same time as the rest of the population, based on their age and clinical risk group.

The screenshot shows a news article from The Guardian. The headline is "Jonathan Van-Tam heads the fab four to steer news on AstraZeneca 'course correction'". Below the headline is a composite image of four people: Jonathan Van-Tam, June Raine, Wei Shen Lim, and Munir Pirmohamed. The article text below the image reads: "From left: Jonathan Van-Tam, June Raine, Wei Shen Lim and Munir Pirmohamed were given the challenging task of explaining the link between the Oxford/AstraZeneca vaccine and CVST blood clots. Composite: PA, Reuters, EPA, Rex. Scientists 'JVT', Raine, Lim and Pirmohamed give the government a lesson in clear communication". There are also links for "Coronavirus - latest updates" and "See all our coronavirus coverage". A "Most viewed" section shows an article about Italian absentees.

Government response

## MHRA response to JCVI advice on COVID-19 Vaccine AstraZeneca for people aged under 40

Statement from Dr June Raine, MHRA Chief Executive, following the Joint Committee on Vaccination and Immunisation's new advice

News story

## The MHRA concludes positive safety profile for Pfizer/BioNTech vaccine in 12- to 15-year-olds

This follows a rigorous review of the safety, quality and effectiveness of the vaccine in this age group.

# Yellow Card - Booster additions



Please enter which dose this was; first, second or booster dose. If you think multiple doses contributed to the suspected reaction please add these separately using the 'Add' button' (Optional)

If you had a top-up dose, please select booster dose.

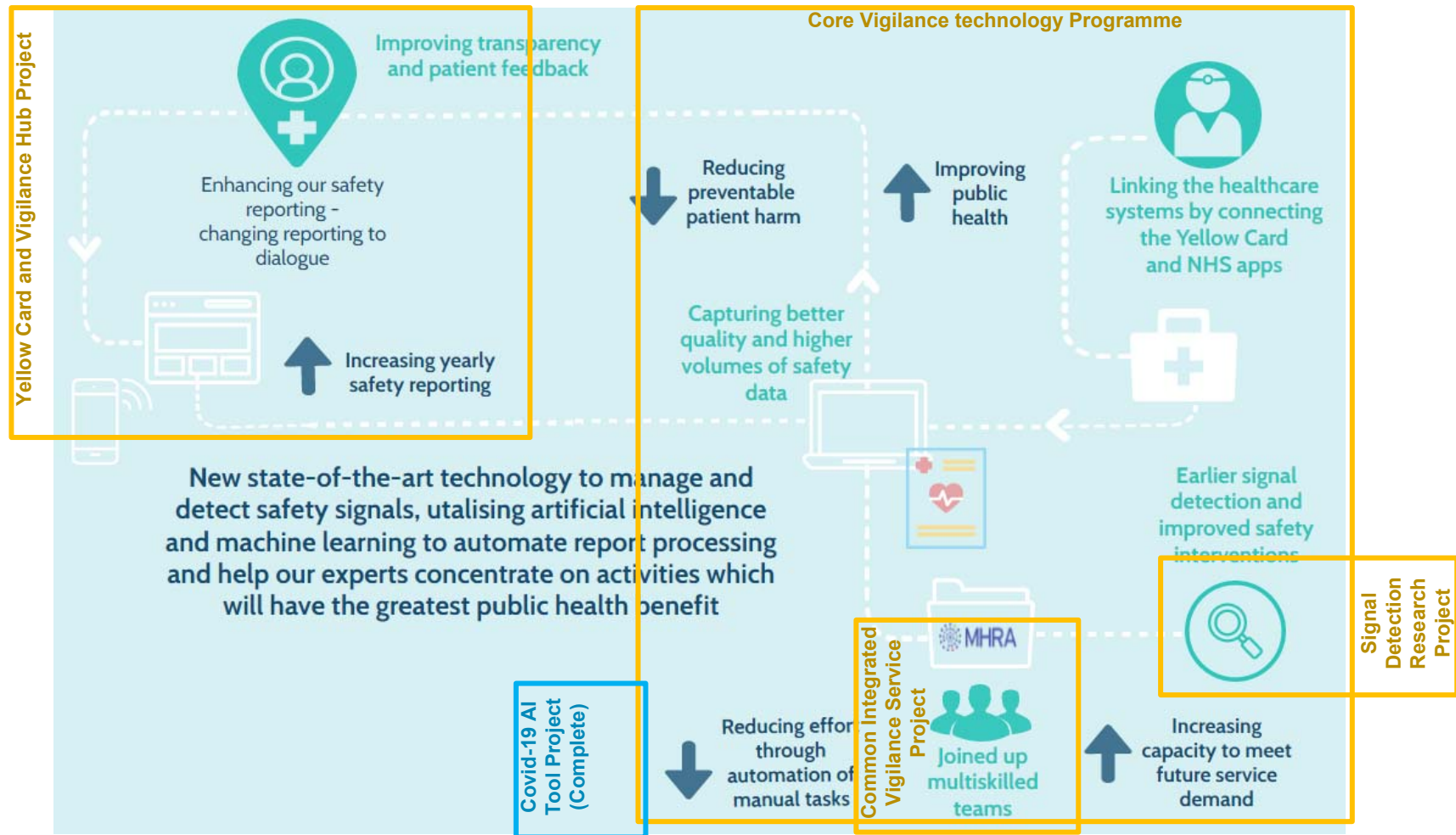
Please select

- Please select
- First Dose
- Second Dose**
- Booster - same brand as primary vaccines
- Booster - different brand to primary vaccines
- Booster - other/unknown brand

Add

- Reporters are advised to add previous COVID-19 vaccines as concomitant medications
- Be mindful of some reporters selecting the wrong dose

# How will we improve the patient journey?



**A final thought....**



**And I want to end by expressing our sincere gratitude**