Royal College of Physicians

MHRA
Regulating Medicines and Medical Devices

The Changing World of Pharmacovigilance

June M Raine Director of Vigilance and Risk Management Division

Changing World of Pharmacovigilance

Where have we come from?

- Learning from landmark safety issues
- From reactive to proactive risk management

What is current state of play?

- Strengthened signal detection
- Using real world evidence to contextualise

How are we moving forward?

- Key challenges and opportunities
- Focus on physician's role

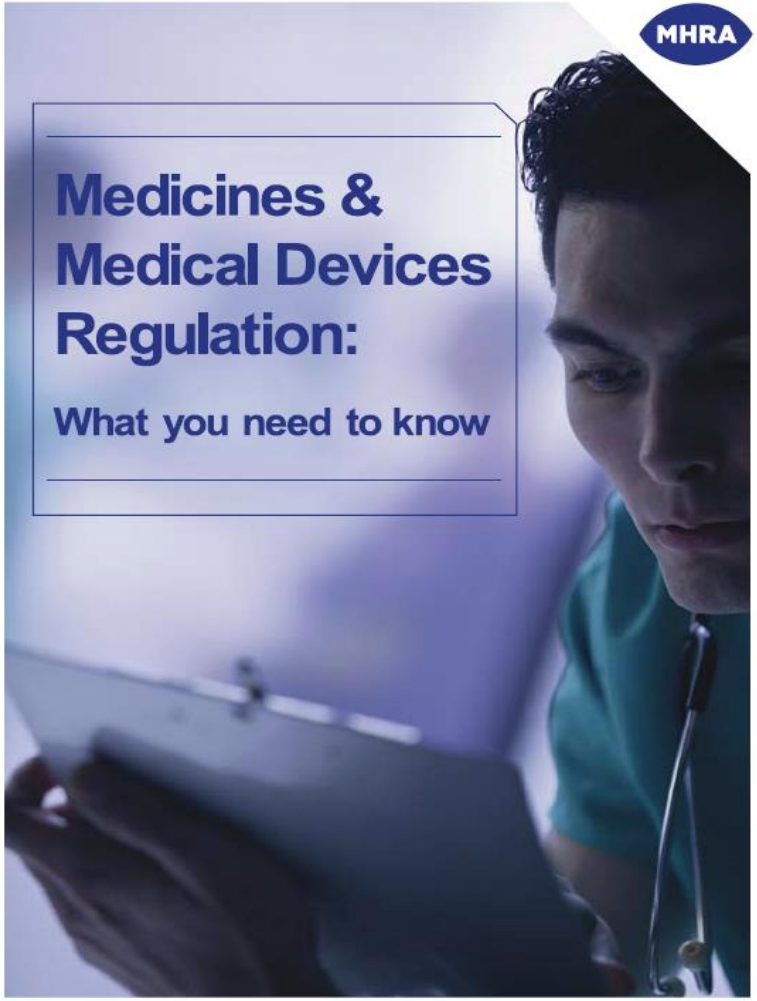
Royal College of Physicians

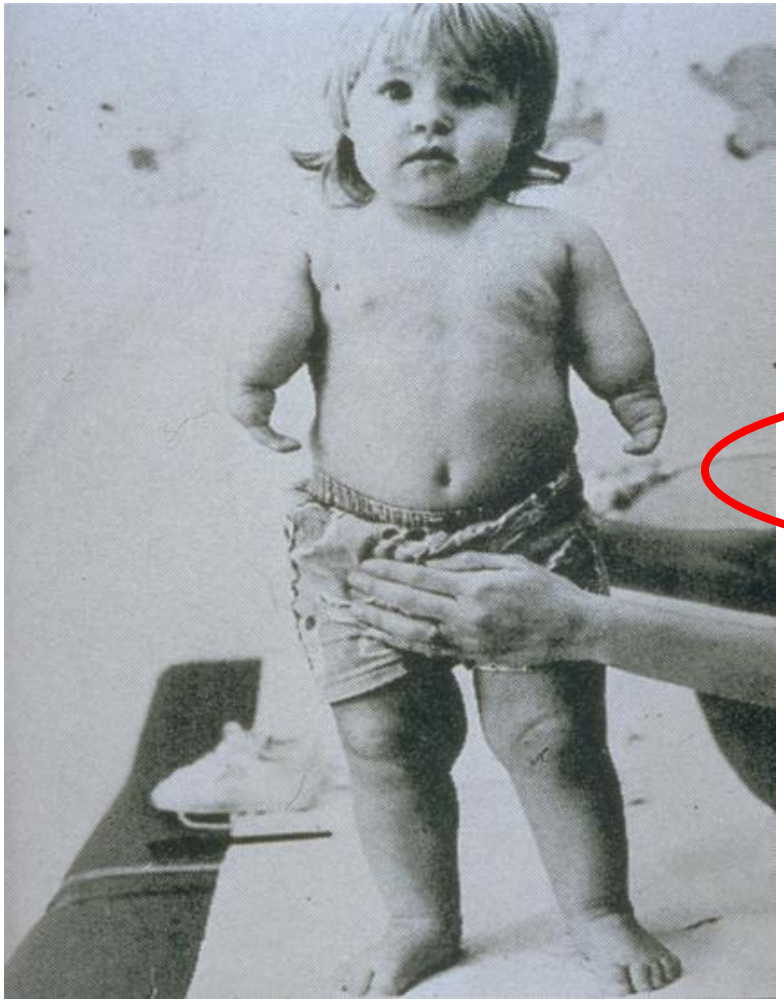
What is the MHRA's role?

Availability of new treatments & technologies without delay

Proactive vigilance based on best evidence and prompt risk management

As much information to patients and healthcare professionals as possible on the benefits and risks





Lancet 16 December 1961

THALIDOMIDE AND CONGENITAL ABNORMALITIES

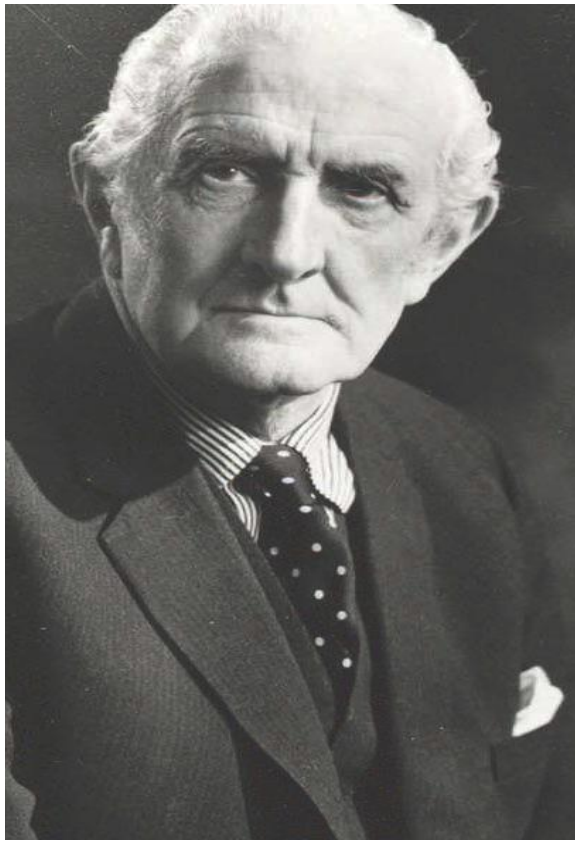
SIR,—Congenital abnormalities are present in approximately 1·5% of babies. In recent months I have observed that the incidence of multiple severe abnormalities in babies delivered of women who were given the drug thalidomide (' Distaval ') during pregnancy, as an antiemetic or as a sedative, to be almost 20%.

These abnormalities are present in structures developed from mesenchyme—i.e., the bones and musculature of the gut. Bony development seems to be affected in a very striking manner, resulting in polydactyly, syndactyly, and failure of development of long bones (abnormally short femora and radii).

Have any of your readers seen similar abnormalities in babies delivered of women who have taken this drug during pregnancy?

Hurstville, New South Wales. W. G. McBRIDE.

Sir Derrick Dunlop 1964



Letter to all UK doctors

We ask you to report promptly to us details of any untoward condition in a patient which might be the result of drug treatment

Yours sincerely,

Derrick Dunlop Jr.

Yellow Card Scheme


BNF

In Confidence

YellowCard It's easiest to report online at www.yellowcard.gov.uk

COMMISSION ON HUMAN MEDICINES (CHM)

MHRA

SUSPECTED ADVERSE DRUG REACTIONS

If you suspect an adverse reaction may be related to one or more drugs/vaccines/complementary remedies, please complete this Yellow Card. See 'Adverse reactions to drugs' section in BNF or www.yellowcard.gov.uk for guidance. Do not be put off reporting because some details are not known.

PATIENT DETAILS Patient Initials:_____ Sex: M / F Ethnicity:_____ Weight if known (kg):_____

Age (at time of reaction):_____ Identification number (e.g. Your Practice or Hospital Ref):_____

SUSPECTED DRUG(S)/VACCINE(S)

Drug/Vaccine (Brand if known) Batch Route Dosage Date started Date stopped Prescribed for

SUSPECTED REACTION(S) Please describe the reaction

Date reaction(s) started:_____ Date reaction(s) st

Do you consider the reactions to be serious? Yes / No

If yes, please indicate why the reaction is considered to be serious (p

Patient died due to reaction

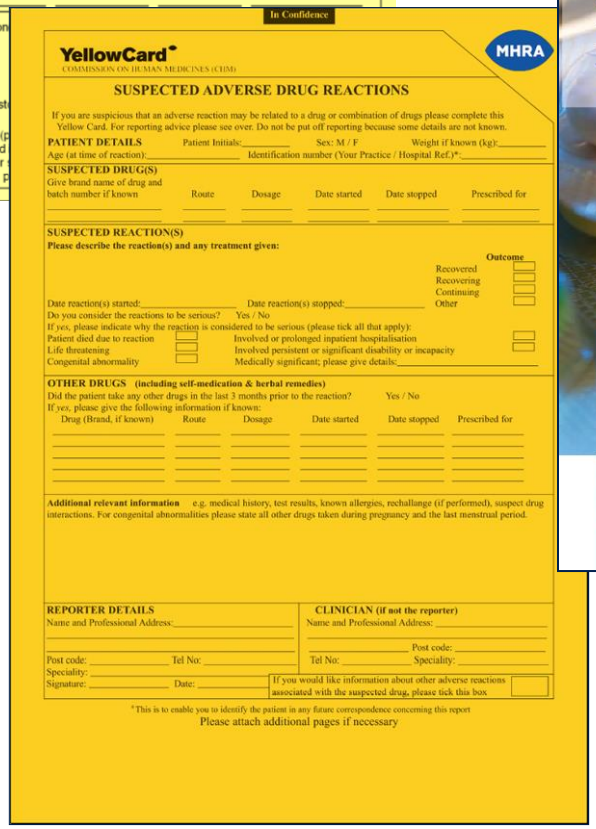
Life threatening

Congenital abnormality

Involved or prolonged

Involved persistent or

Medically significant; p


In Confidence

YellowCard

COMMISSION ON HUMAN MEDICINES (CHM)

MHRA

SUSPECTED ADVERSE DRUG REACTIONS

If you are suspicious that an adverse reaction may be related to a drug or combination of drugs please complete this Yellow Card. For reporting advice please see over. Do not be put off reporting because some details are not known.

PATIENT DETAILS Patient Initials:_____ Sex: M / F Weight if known (kg):_____

Age (at time of reaction):_____ Identification number (Your Practice / Hospital Ref.)*:_____

SUSPECTED DRUG(S)

Give brand name of drug and batch number if known | Route | Dosage | Date started | Date stopped | Prescribed for

SUSPECTED REACTION(S)

Please describe the reaction(s) and any treatment given:

Outcome

Recovered

Recovering

Continuing

Other

Date reaction(s) started:_____ Date reaction(s) stopped:_____

Do you consider the reactions to be serious? Yes / No

If yes, please indicate why the reaction is considered to be serious (please tick all that apply):

Patient died due to reaction

Life threatening

Congenital abnormality

Involved or prolonged inpatient hospitalisation

Involved persistent or significant disability or incapacity

Medically significant; please give details:_____

OTHER DRUGS (including self-medication & herbal remedies)

Did the patient take any other drugs in the last 3 months prior to the reaction? Yes / No

If yes, please give the following information if known:

Drug (Brand, if known) | Route | Dosage | Date started | Date stopped | Prescribed for

Additional relevant information e.g. medical history, test results, known allergies, rechallange (if performed), suspect drug interactions. For congenital abnormalities please state all other drugs taken during pregnancy and the last menstrual period.

REPORTER DETAILS

Name and Professional Address:_____

Post code:_____ Tel No:_____

Speciality:_____

Signature:_____ Date:_____

CLINICIAN (if not the reporter)

Name and Professional Address:_____

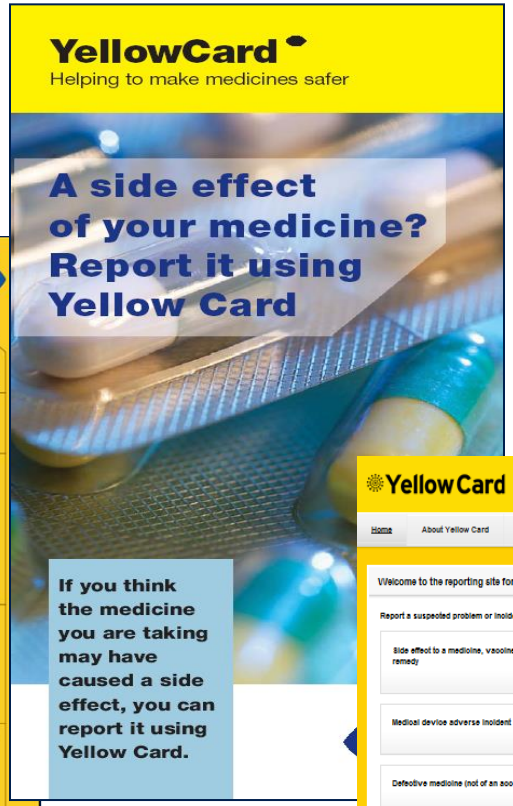
Post code:_____

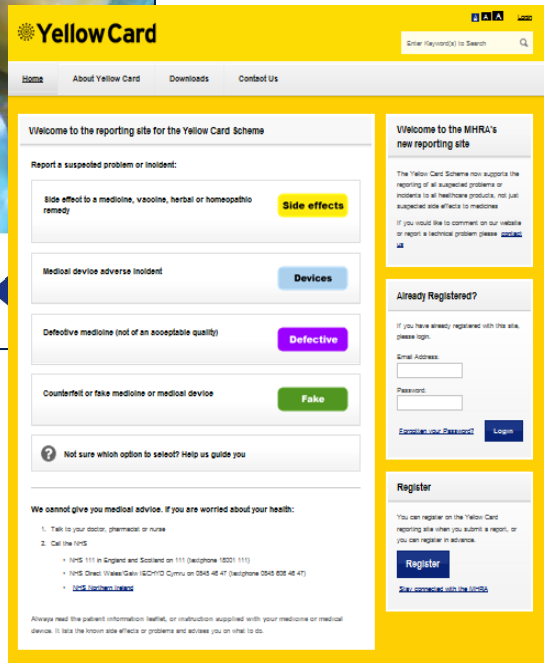
Tel No:_____ Speciality:_____

If you would like information about other adverse reactions associated with the suspected drug, please tick this box

*This is to enable you to identify the patient in any future correspondence concerning this report

Please attach additional pages if necessary



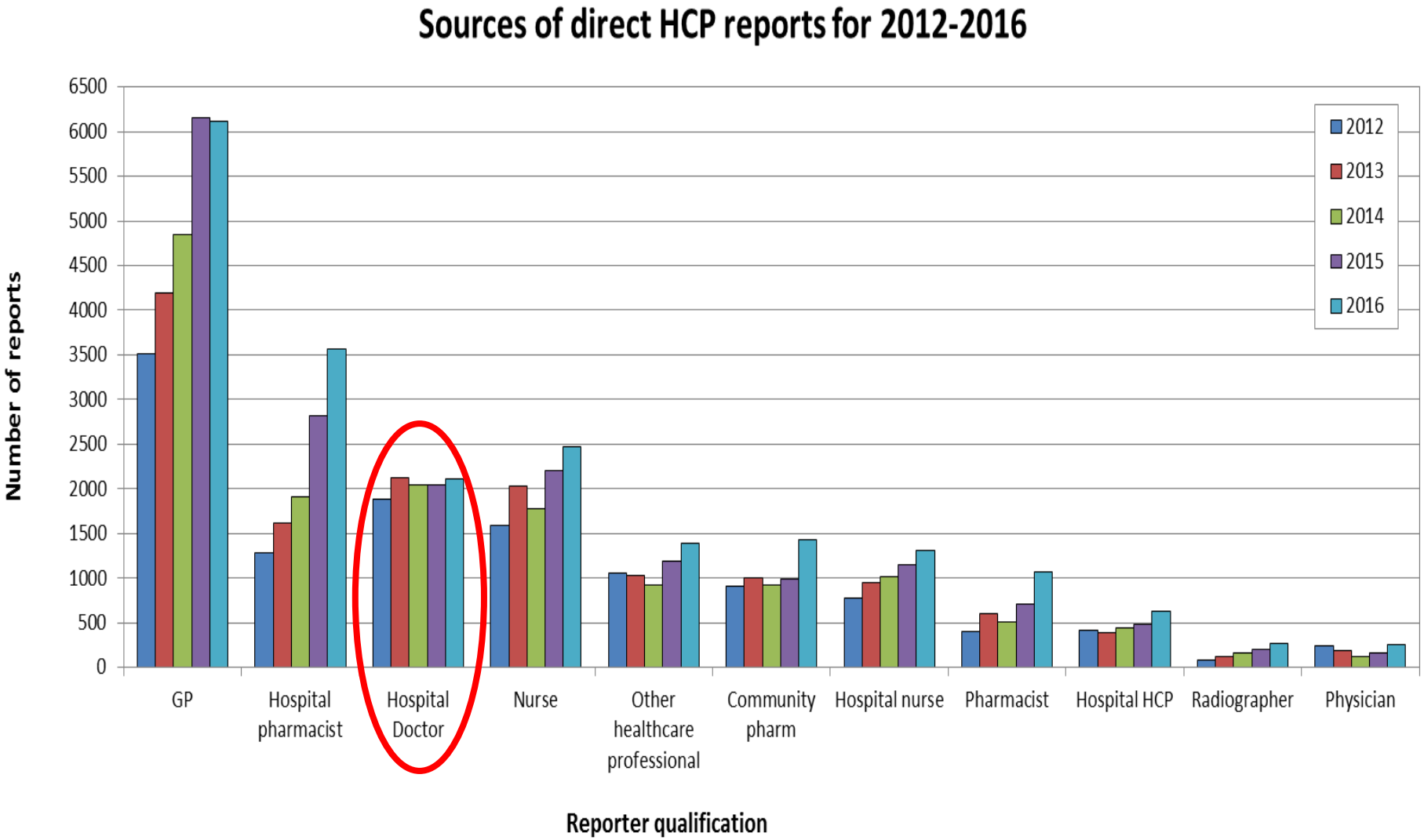


Commission on Human Medicines

Promoting collection and investigation of information relating to adverse reactions

Chairman Professor Stuart Ralston

Healthcare professional ADR reports

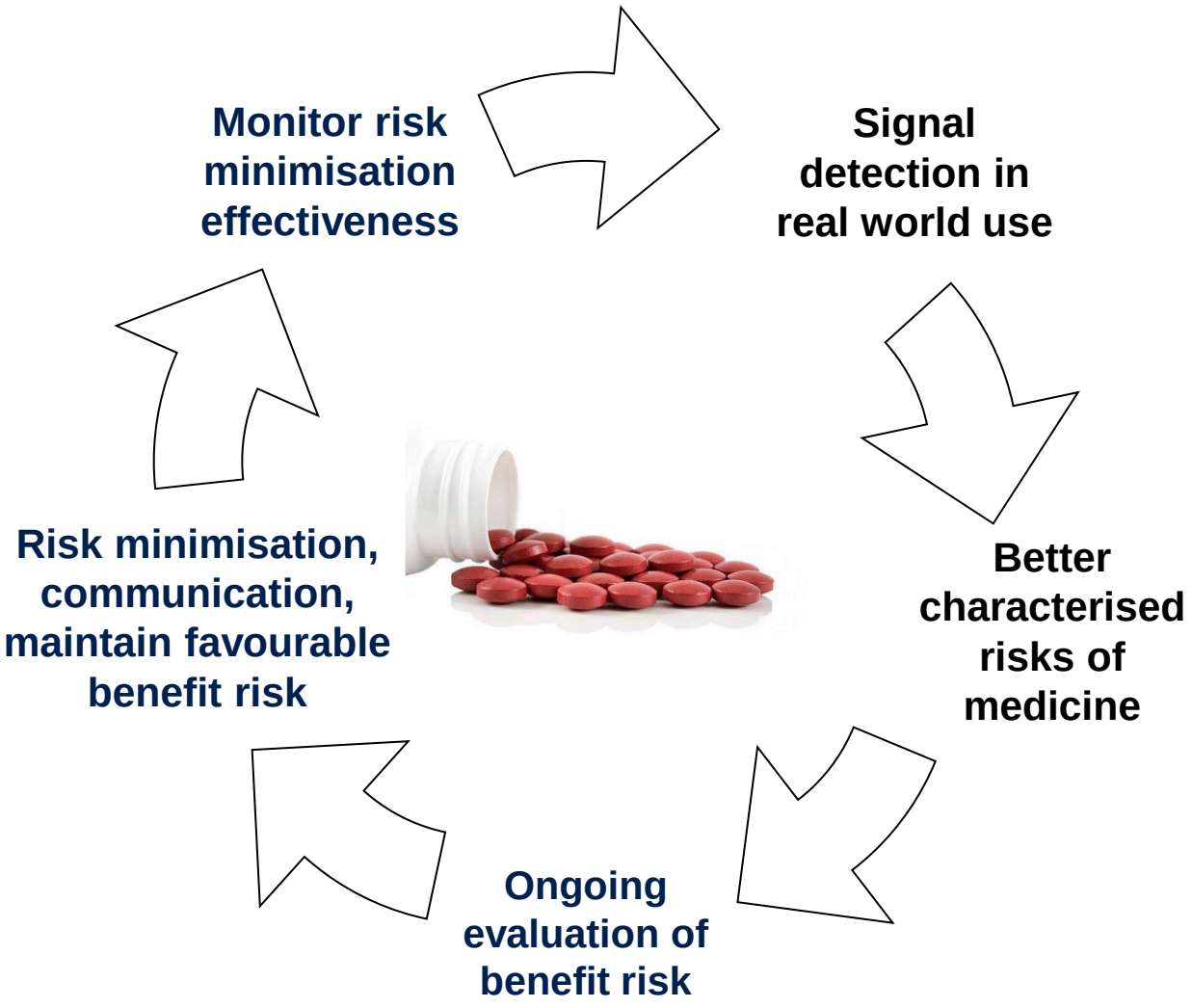


Pharmacovigilance – a definition

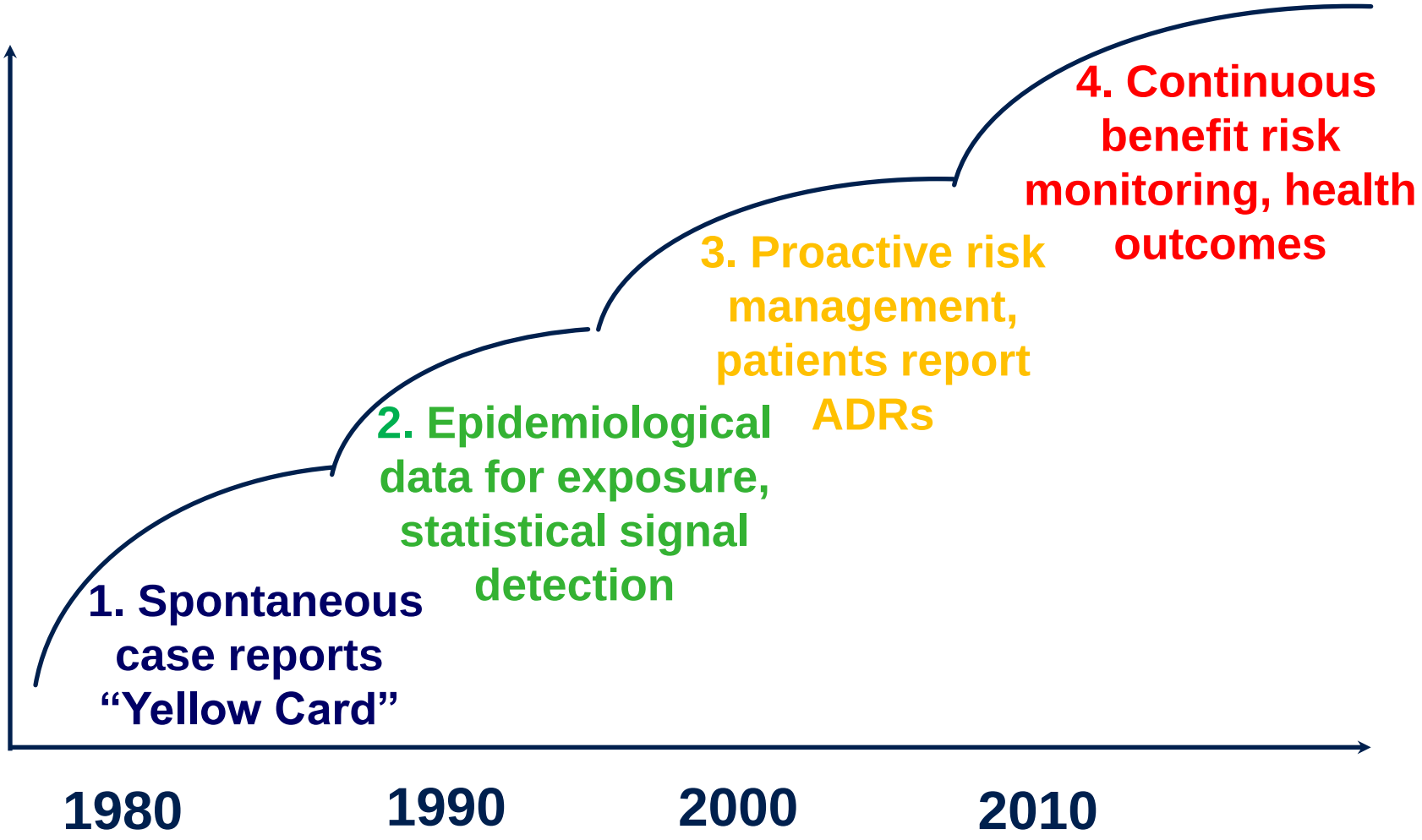
"Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem"

World Health Organization

Pharmacovigilance cycle



Evolution of pharmacovigilance



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Public health impact of ADRs

6.5% hospital admissions in UK relate to adverse drug reactions

ADRs were responsible for death in 0.15%

72% were classified as avoidable

Pirmohamed et al 2004
BMJ 329; 15-19

OPEN ACCESS Freely available online

PLOS | MEDICINE

Number of Patients Studied Prior to Approval of New Medicines: A Database Analysis

Ruben G. Duijnhoven[1,2], Sabine M. J. M. Straus[2,3], June M. Raine[4], Anthonius de Boer[1], Arno W. Hoes[5], Marie L. De Bruin[1,2]*

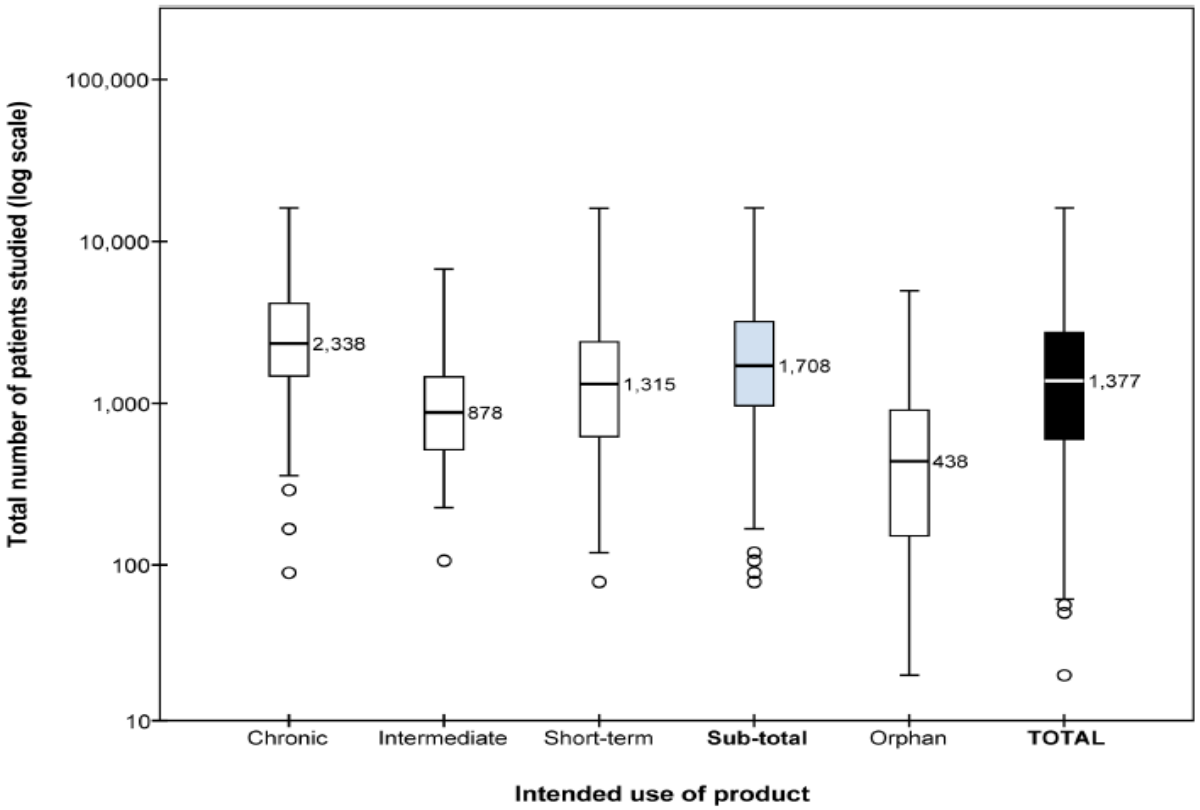
1 Utrecht Institute for Pharmaceutical Sciences, Utrecht University, Utrecht, the Netherlands, **2** Medicines Evaluation Board, Utrecht, the Netherlands, **3** Department of Medical Informatics, Erasmus Medical Center, Rotterdam, the Netherlands, **4** Medicines and Healthcare products Regulatory Agency, London, United Kingdom, **5** Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht, the Netherlands

Abstract

Background: At the time of approval of a new medicine, there are few long-term data on the medicine's benefit–risk balance. Clinical trials are designed to demonstrate efficacy, but have major limitations with regard to safety in terms of patient exposure and length of follow-up. This study of the number of patients who had been administered medicines at the time of medicine approval by the European Medicines Agency aimed to determine the total number of patients studied, as well as the number of patients studied long term for chronic medication use, compared with the International Conference on Harmonisation's E1 guideline recommendations.

Duijnhoven et al PLoS March 2013

Patients studied before approval

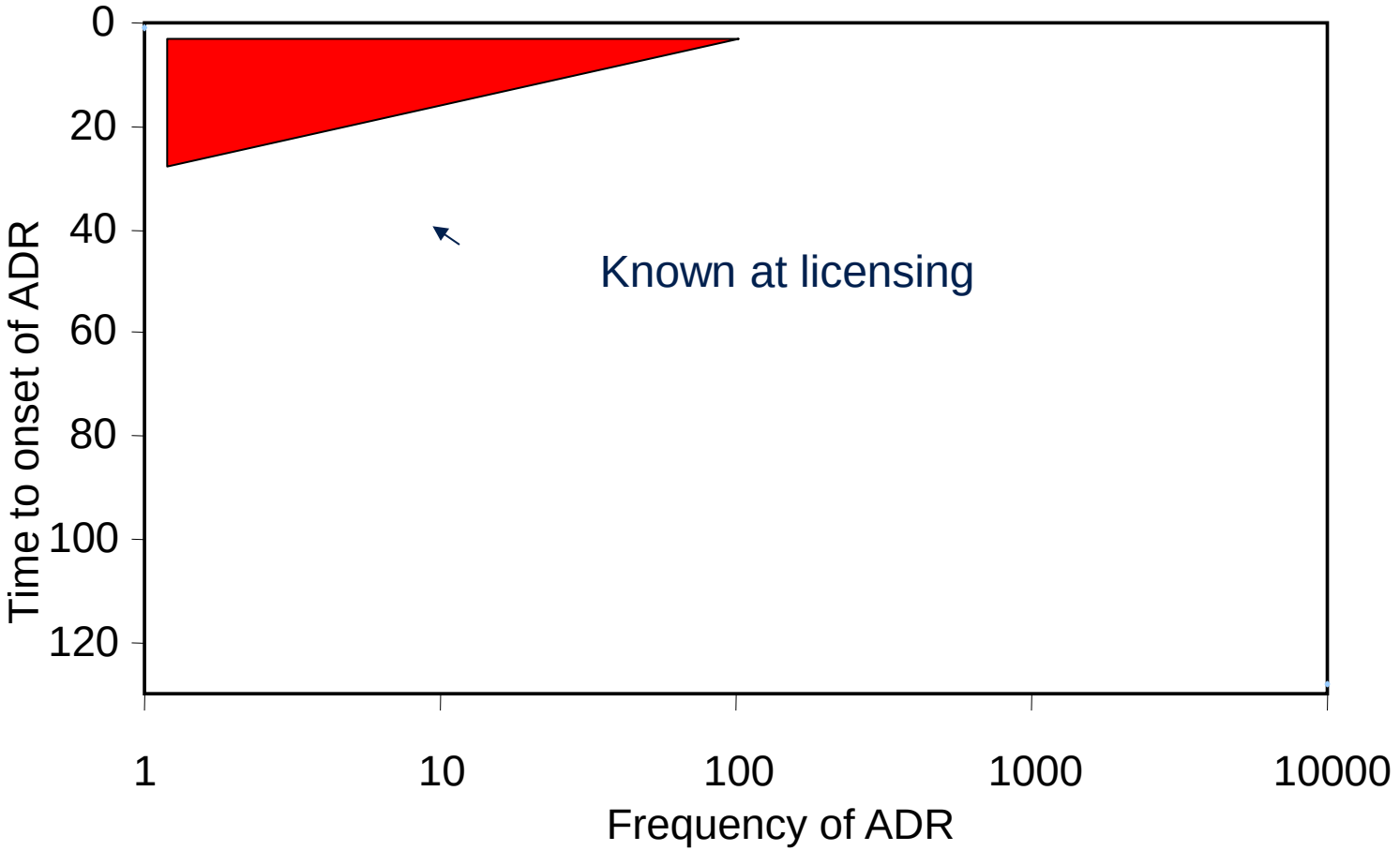


Duijnhoven et al
PLoS March 2013

Patients studied prior to approval of new medicine

For **200** new "standard" medicines between 2000 -2010
median total no patients= **1708**, for orphan drugs = **438** patients
For 84 medicines for chronic use **79.8%** met guidelines for 12 months (at least 100 participants)

Knowledge of ADRs at licensing



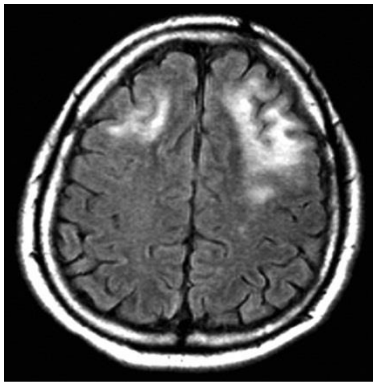
Filling the knowledge gaps

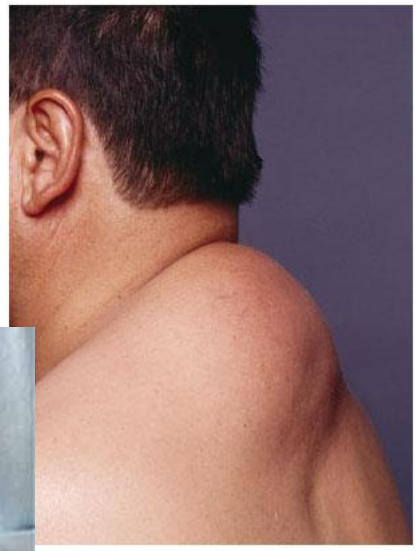
Unidentified ADRs

Long term safety

Special populations

At risk groups





“Landmark” safety issues

Date	Drug / class	Safety concern	Action
1960’s	Thalidomide	Phocomelia	Withdrawn
1970s	Practolol	Oculomucocutaneous Syndrome	Withdrawn
1980’s	Benoxaprofen Aspirin	Phototoxicity Reye’s syndrome	Withdrawn CI in <12’s
1990’s	Oral contraceptives	Venous thromboembolism	Warnings
2000’s	Cerivastatin HRT SSRIs Coxibs Rosiglitazone Gadolinium CAs	Rhabdomyolysis Breast cancer Suicidality- children CVS risk CVS risk Nephrogenic dermopathy/ NSF	Withdrawn Restrictions CI under <18s Warnings Suspended Warnings
2010s	Pandemrix Natalizumab HPV vaccine	Narcolepsy PML Chronic fatigue syndrome	CI under <18s Risk minimisation No evidence

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,[1,2] Gwenaël Huet,[1] Saad Shakir[1,2]

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 report	Animal studies	Case–control	Cohort	RCTs	Meta-analysis	*Others
Rofecoxib	X		x	x	x	X	
Thioridazine	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
Acepromazine+Acepromazine +Clorazepate	X						x
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.

Case reports remain most significant method of pharmacovigilance

Impact of “landmark” safety issues

Shift from reactive to proactive – risk management plans to study known and potential risks for all new medicines

All data sources for critical evaluation – not only case reports

Scientific standards for safety studies – review of protocols by experts

Greater transparency on decisions

-stakeholder involvement

Comprehensive revision of legislation in 2012

Current state of Pharmacovigilance

New approaches to use of evidence

Starting point: a “signal”

“*Information that arises from **one** or **multiple sources** (including observations and experiments)*

*which suggests a **new potentially causal** association, or a new aspect of a known association*

*between an **intervention and an event** or set of related events, either adverse or beneficial*

*which is judged to be of **sufficient likelihood** to justify **verificatory action**”*

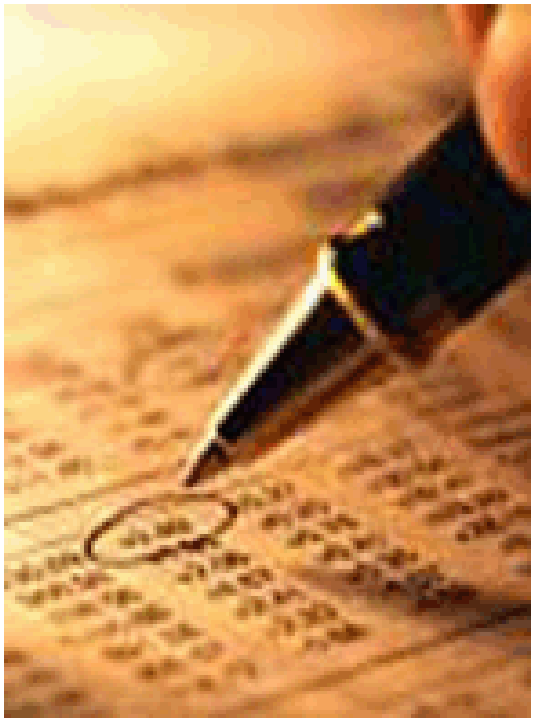
Hauben M, Aronson JK Drug Safety 2009; 32(2) 99-110

MHRA signal detection

Traditional method was reviewing every new case report - but increasing volumes of ADRs make this impractical

Statistical methods to identify drug-ADR combinations disproportionately present in database i.e. observed is greater than expected

Mathematical scoring system aids prioritisation of signals detected from spontaneous ADR data



Strengthening signals from case reports

Yellow Cards are important tool but have limitations

- Differing levels of under-reporting and incomplete data
- Lack of exposure to put reports in context
- Can be too easy to dismiss confounded signals

Electronic healthcare record data is becoming increasing rich and available along with increased computing capabilities

- Already used to study drug utilisation, monitor patient outcomes, pharmacoepidemiological studies to evaluate signals

Key Challenge: To optimise the use of electronic healthcare record data to routinely support and strengthen wider pharmacovigilance providing robust data on risks and benefits as quickly as possible

Clinical Practice Research Datalink

Database of 30 years anonymised NHS records from UK GPs

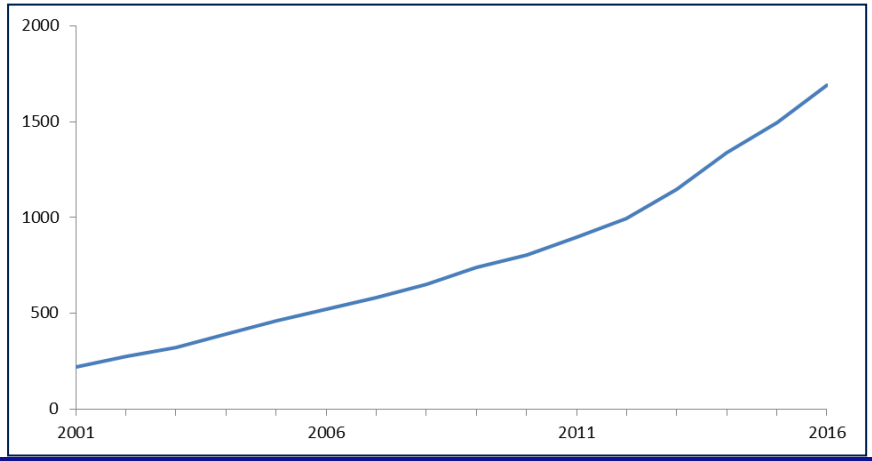
> 22 million patients representative of gender, age & ethnicity

Routine linkage to secondary care (HES), mortality, cancer registry, deprivation datasets

Supporting public health research worldwide

- Drug safety
- Drug use
- Disease epidemiology
- Incidence/prevalence
- Care delivery

1700 peer-reviewed publications using CPRD data



Using CPRD data


PULSE

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Submit your questions for RCGP chair Dr Maureen Baker

Wednesday 28 January 2015

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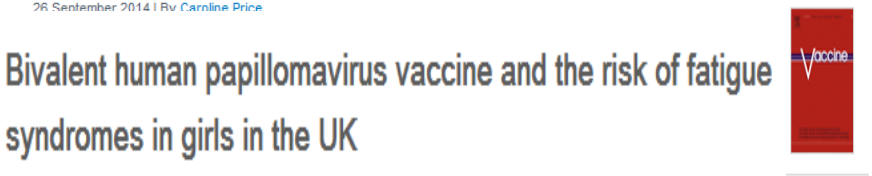
One in seven GP-prescribed antibiotic courses fails, study finds

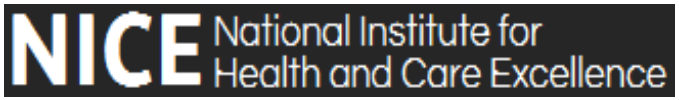
26 September 2014 | By Caroline Price


Bivalent human papillomavirus vaccine and the risk of fatigue syndromes in girls in the UK


THE LANCET

Volume 364, Issue 9438, 11–17 September 2004, Pages 963–969

MMR vaccination and pervasive developmental disorders: a case-control study


NICE National Institute for Health and Care Excellence

Suspected cancer Clinical Guidance

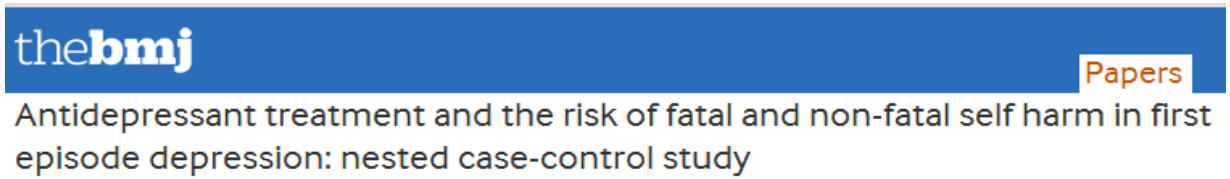
Some NICE cancer guidance exclusively drew evidence from CPRD research

CPRD data is routinely used by MHRA in developing safety guidance


thebmj

RESEARCH

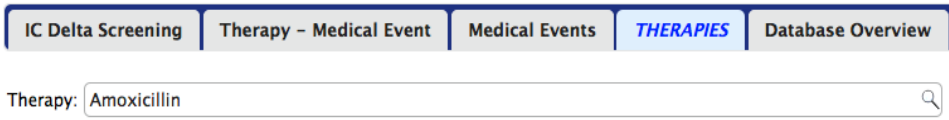
Safety of pertussis vaccination in pregnant women in UK: observational study

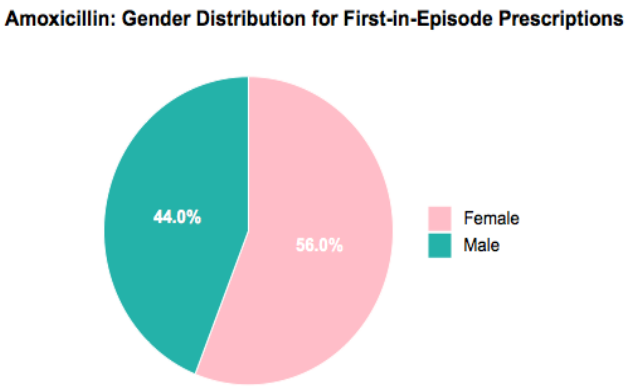

thebmj

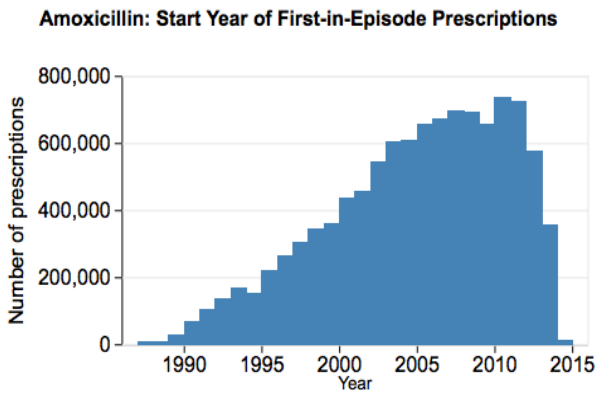
Papers

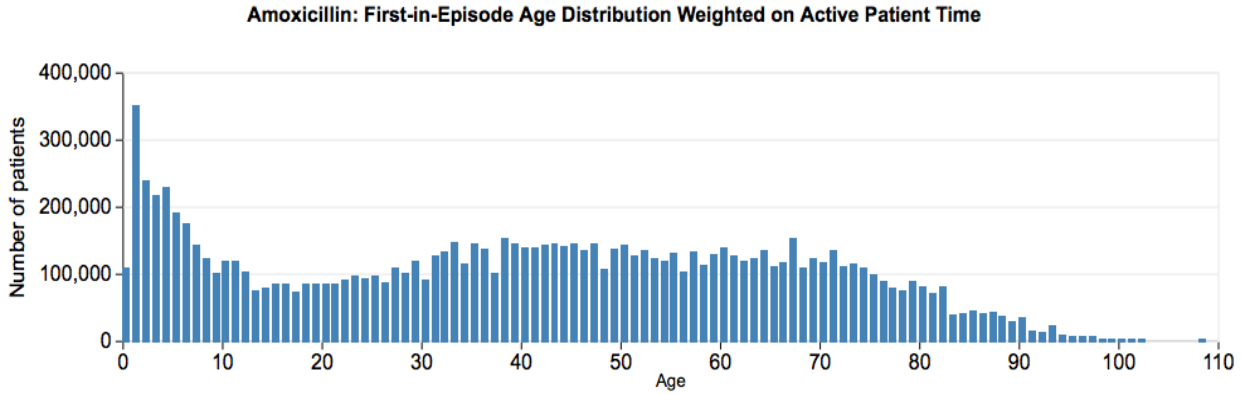
Antidepressant treatment and the risk of fatal and non-fatal self harm in first episode depression: nested case-control study

Following longitudinal drug exposure









- Drug exposure over time and description of treated population
- Frequency of events in population
- Frequency of drug-event combination

→ Put signals into context

Combining ADR case reports & CPRD data

ELSEVIER

Vaccine

Volume 31, Issue 43, 9 October 2013, Pages 4961–4967

14273||

Bivalent human papillomavirus vaccine and the risk of fatigue syndromes in girls in the UK

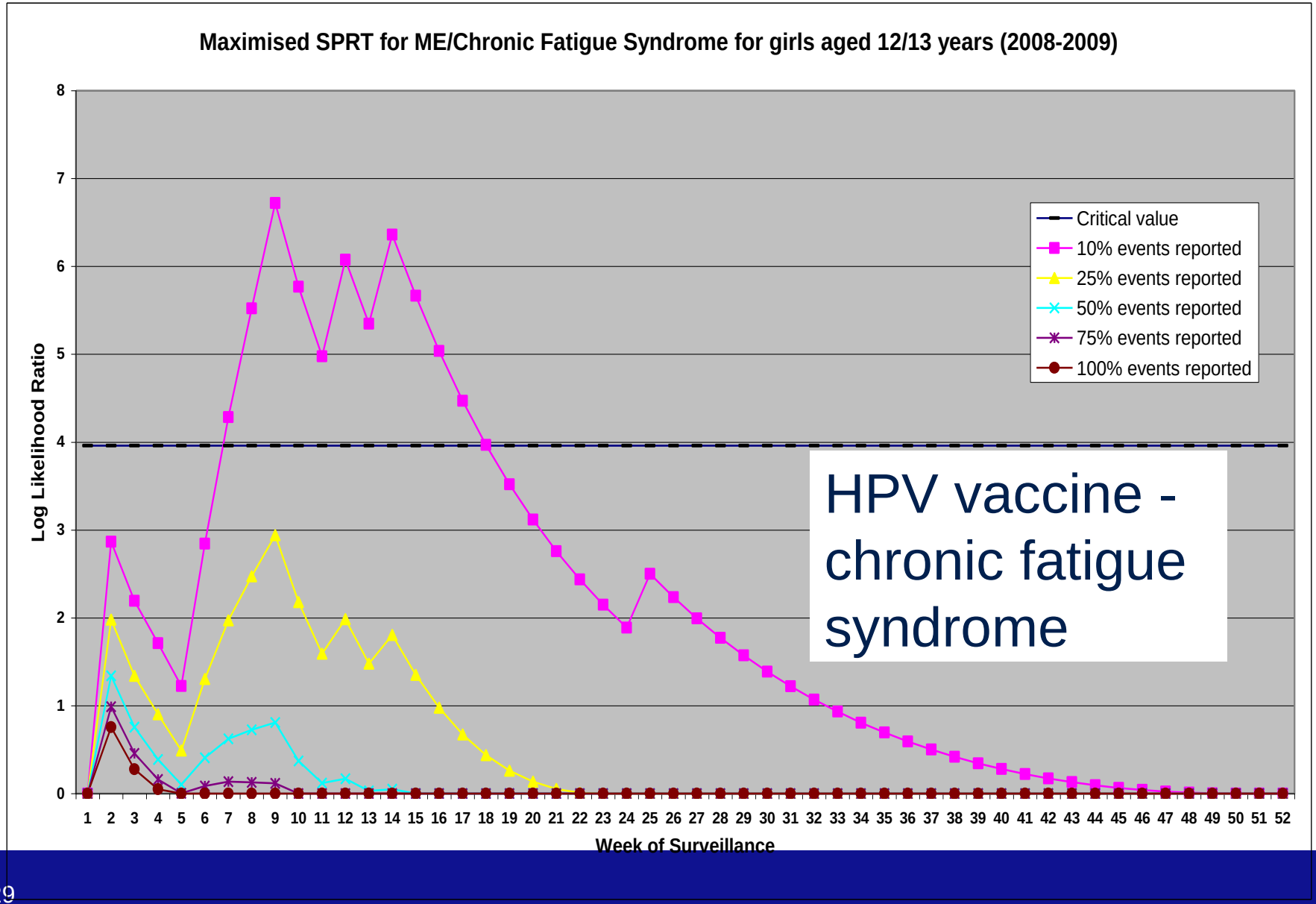
Katherine Donegan, Raphaelle Beau-Lejdstrom, Bridget King, Suzie Seabroke, Andrew Thomson, Philip Bryan

Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency, London, UK

No increase in CFS observed vs expected rates using max sequential probability ratio testing

Donegan et al 2013, Vaccine 31, 43, 4961-7

Example: Observed vs expected analysis



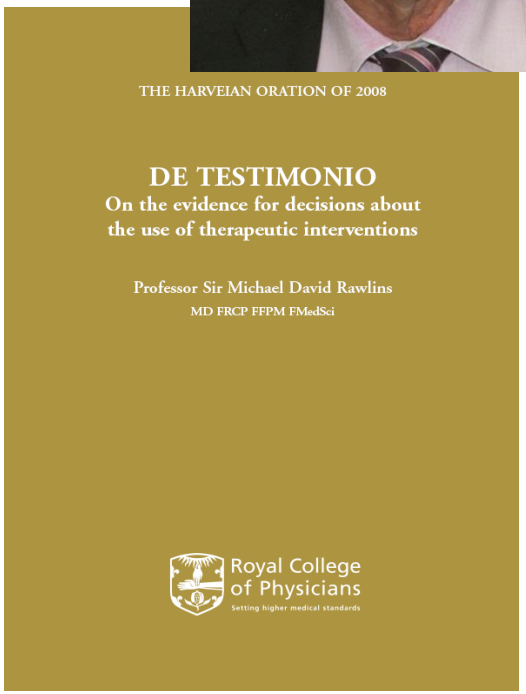
Continually evaluating benefit risk

Critical appraisal of all available evidence taking into account strength of evidence for causality, therapeutic context, treatment alternatives

In-house pharmacoepidemiology capability

- Drug utilisation studies
- Risk evaluation and quantification
- Methodology development

Work with academia & clinical experts



Real world data in pharmacovigilance

Registries (prospective cohorts)

- Eg assess safety profile, health outcomes in clinical use, consider existing infrastructure consider comparator

Database studies

- Eg risk characterisation, investigation of targeted AEs

Drug utilisation studies

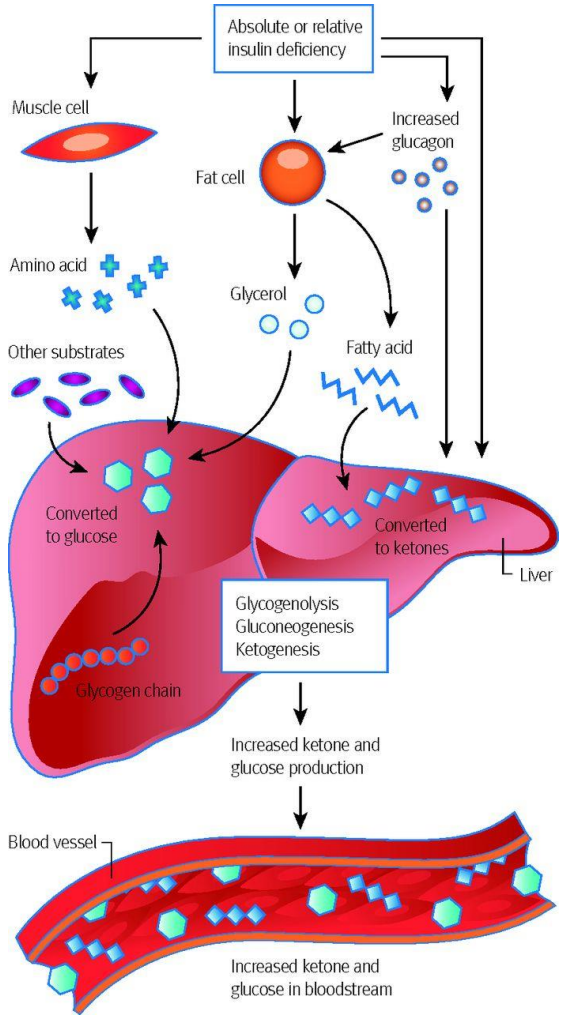
- Eg to assess effectiveness of risk minimisation measures or help plan PAS

Pharmacogenomics

- Eg genome-wide association studies

Pharmacovigilance activity	Example of current issue in pharmacovigilance	Evidence sources
Signal detection and investigation	**SGLT2 inhibitors** and diabetic ketoacidosis	ADR reports mechanistic data
Risk quantification, characterisation	**Fluoroquinolones** - long-term persistent adverse drug reactions	ADR reports, observational data
Benefit risk evaluation	**Gadolinium contrast agents** - tissue accumulation including brain	Pre-clinical data, PK studies, MRI
Risk management	**6-mercaptopurine** - risk of severe leukopenia and alopecia	Pharmaco-genomic data NUDT15 gene
Effectiveness of risk minimisation	**Sodium valproate** in pregnancy - neurodevelopmental disorders	Drug utilisation, patient views

Signal - SGLT2 inhibitors & diabetic ketoacidosis



Case reports of diabetic ketoacidosis associated with SGLT2 inhibitors in Type II diabetes

Prompt communication to HCPs in view of particular characteristic of signal – eugycaemia – related to mechanism of action of SGLT2s

Product information for HCPs and patients updated to include serious and occasionally fatal outcome

Risk characterisation - fluoroquinolones

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Drugs

Home > Drugs > Drug Safety and Availability

Drug Safety and Availability

FDA Drug Safety Communication: FDA advises restricting fluoroquinolone antibiotic use for certain uncomplicated infections; warns about disabling side effects that can occur together

According to a July 26 FDA Drug Safety Communication (www.fda.gov), these medications have been associated with disabling and potentially permanent side effects involving tendons, muscles and/or joints, as well as peripheral nerves and the central nervous system. Some patients may even experience more than one such adverse effect.

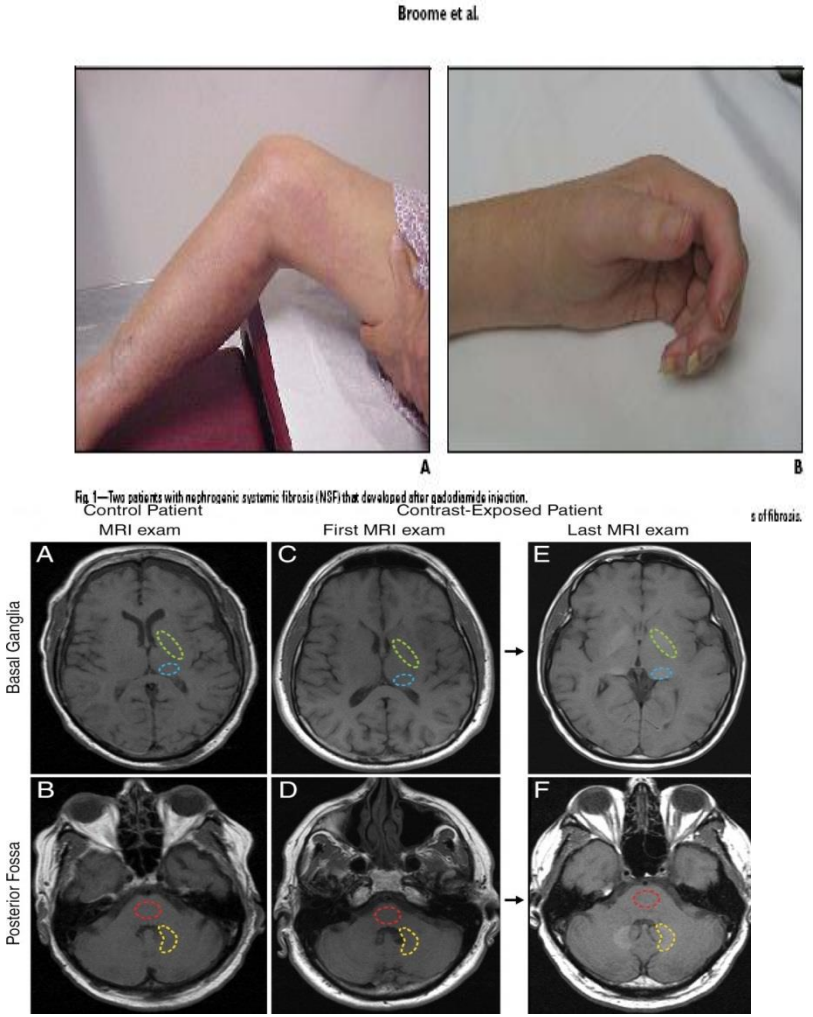
Benefit risk evaluation - Gadolinium contrast agents and tissue accumulation

Regulatory action in 2007 on nephrogenic systemic fibrosis

Growing evidence of brain deposition - publications

Risk appears greater with linear than macrocyclic agents

No evidence of harmful outcome to date



Risk management – 6-mercaptopurine

Mutations in NUDT15 gene result in increased thiopurine-related toxicity
- leukopenia, alopecia

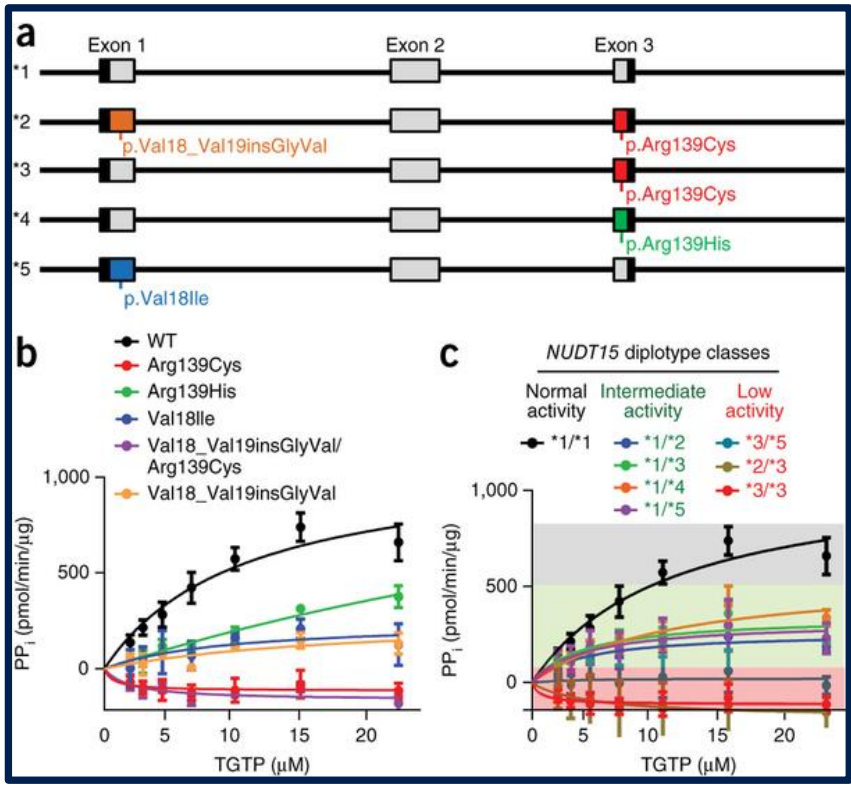
Ethnic variability in frequency of NUDT15.415 C>T

~ 10 % in E Asians

4 % in Hispanics

0.2 % in Europeans

0 % in Africans



Consider dose reduction in patients positive for NUDT15R139 C variant?

Moriyama et al 2016 Nature Genetics

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Risk minimisation effectiveness - valproate

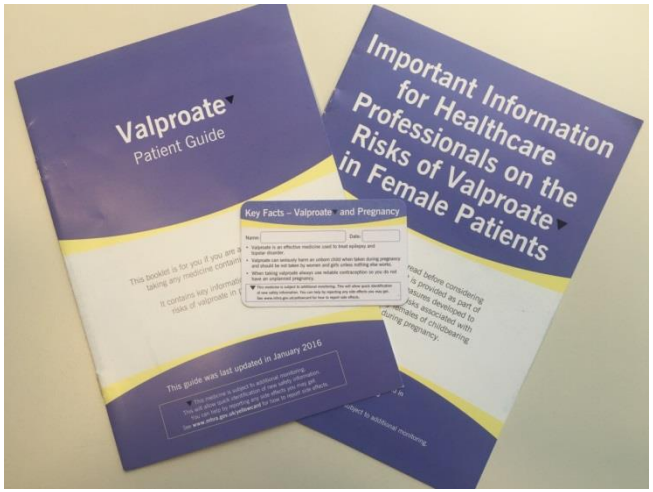
Developmental disorders up to 30 -40% of pre-school children exposed in utero

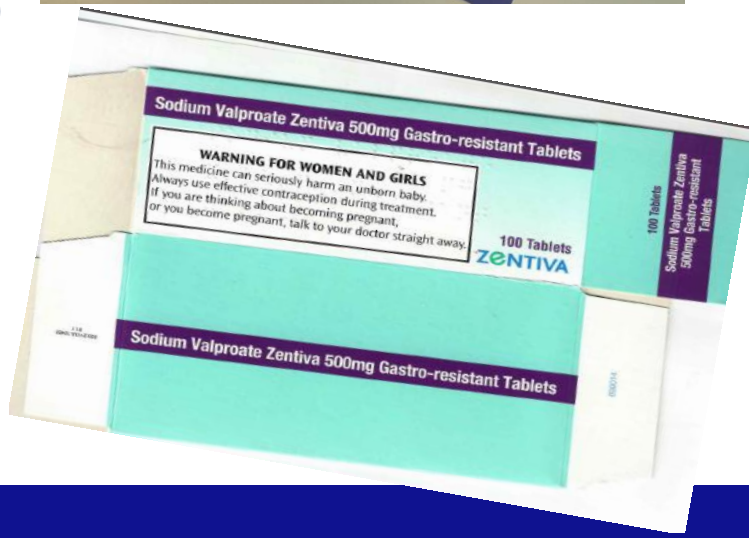
Delayed walking & talking, memory problems, difficulty with speech & language, lower intellectual ability

Increased risk **autistic spectrum disorder** (3X) and **autism** (5X gen pop)

More likely develop symptoms of **ADHD**

In addition to 11% risk of **birth defects**





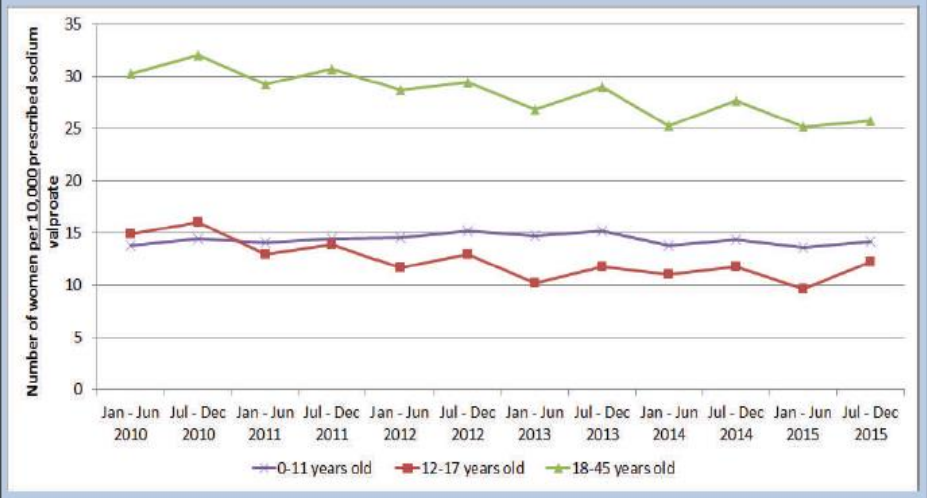
Supporting the safe use of sodium valproate

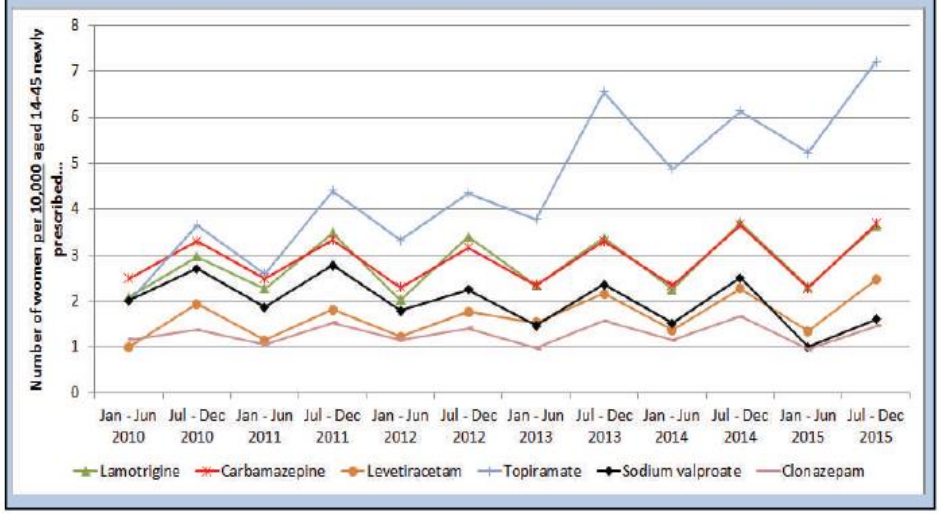
Aims/objectives:

- That sodium valproate is only provided to women who may become pregnant when there is no safe and effective alternative
- That all women who need valproate fully understand the risks associated with pregnancy

Prescribing by GPs *

Target - To reduce use in women aged 14-45 by ~80%





In July—December 2015 for every **10,000** women aged 14-45*at least...

15 were prescribed sodium valproate and had epilepsy

4 were prescribed valproate and had bipolar disorder

4 were prescribed valproate and had migraines

5/10,000 pregnancies

Rate of exposure to sodium valproate in pregnancy in 2015 *

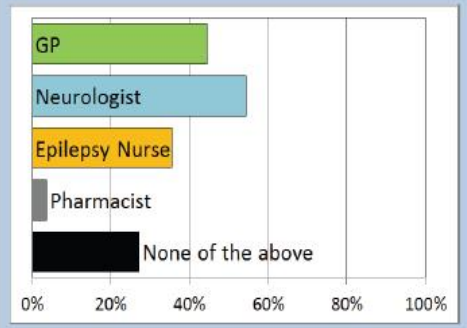
Patient awareness †

Target - 100% awareness & communication

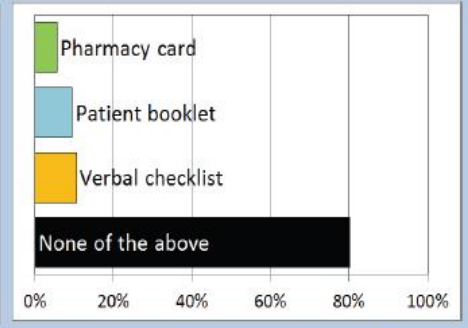
Of 620 epileptic women aged 16-50 currently taking valproate...

80% are aware of any effects on development and/or physical health of a child born to a woman taking sodium valproate

Have ever discussed pregnancy and sodium valproate with a....



Have received the following information...



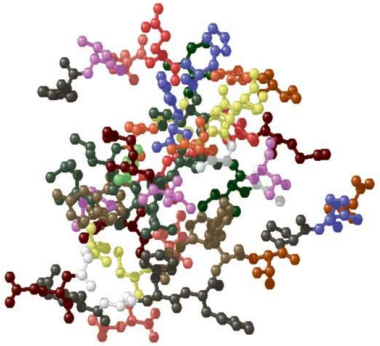
† Data from a survey conducted by Epilepsy Society, Epilepsy Action, and Young Epilepsy

* Data from the UK Clinical Practice Research Datalink (www.cprd.com)

Challenges & opportunities for pharmacovigilance

Challenges for pharmacovigilance

Biological medicines



Earlier access to new medicines and vaccines

Health professional engagement in detecting and managing risk

Greater patient involvement

thebmj

BMJ 2017;357:j1707 doi: 10.1136/bmj.j1707 (Published 2017 April 27)

ANALYSIS

Evolution of biological agents: how established drugs can become less safe

Changes to the manufacturing of biological agents can lead to drugs with different components from the original medicine tested in clinical trials, challenging assumptions about safety, say **David Hunt and colleagues**

Nicole Casadevall *professor of haematology*[1], Oliver Flossmann *consultant nephrologist*[2], David Hunt *honorary consultant neurologist and Wellcome Trust intermediate clinical fellow*[3]

YellowCard
Helping to make medicines safer

MHRA

Report Overview - GB-MHRA-EYC 00100665

Suspect Reaction

Suspect Reactions Added	Outcome of the Reaction	Start Date	End Date
Thrombotic microangiopathy	recovered/resolved with sequelae	11/2012	01/2013

Do you consider the reaction to be serious?
Yes

Reaction severity
Life threatening, Involved or prolonged inpatient hospitalisation, Involved persistent or significant disability or incapacity,

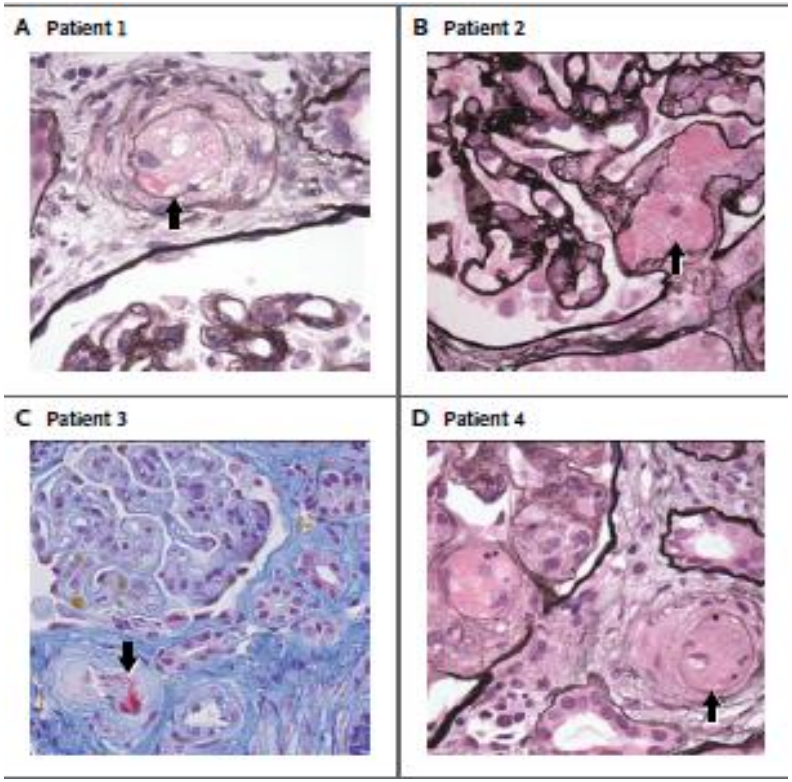
Suspect Drug

Medicine	Brand	Batch No.	Start Date	End Date	Dosage	Indication	Action taken for reaction	Method	Source
rebif	rebif	-	2005	27/12/2012	44mcg 3xwk	Multiple sclerosis	Drug withdrawn	Subcutaneous	Prescription

Additional information

Reaction Description: patient increasingly unwell since end of October 2012 diagnosed with hypertension and acute renal failure requiring hospital admission on the 12/12/2012 found to be thrombocytopaenic clinical picture obscured due to concomitant UTI (E coli) and chest infection kidney biopsy 11/01/2013 showed thrombotic microangiopathy patient became dialysis dependent 31/12/2012 haematological abnormalities normalised by but patient remained dialysis dependent ongoing concerns regarding poor nutrition; patient declined PEG feeding patient died of septic/cardiogenic shock 13/4/2013; no ongoing active microangiopathy but end-stage renal failure contributed to death The patient was taking rebif for: Multiple sclerosis.

Thrombotic microangiopathy & Interferonβ



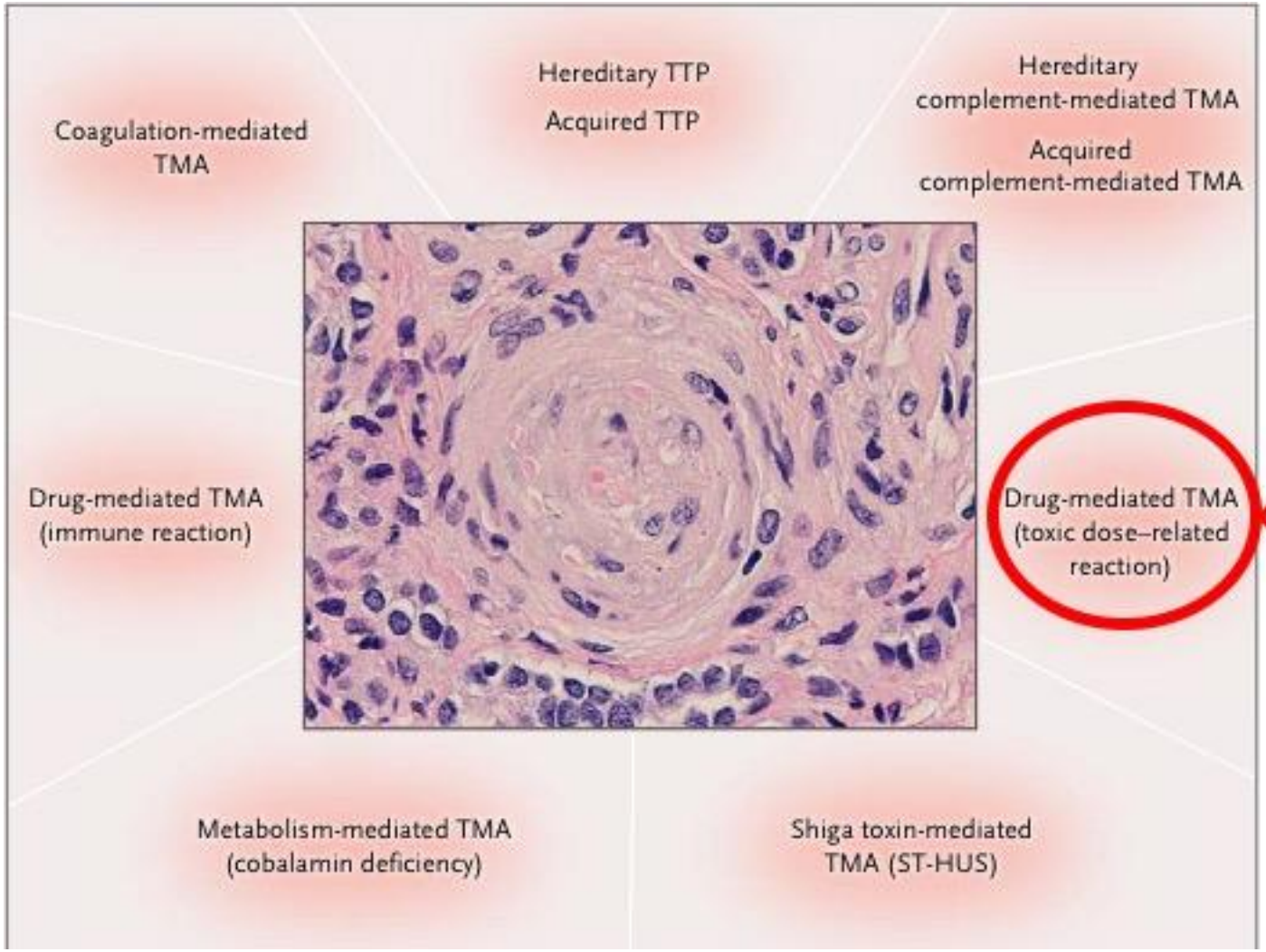
Unexpectedly high number of cases of TMA in MS patients in south Scotland

Common features in renal biopsies

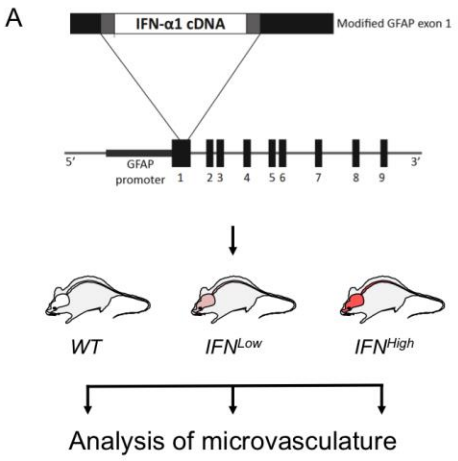
Initial hypothesis was association with common manufacturing source of Interferonβ

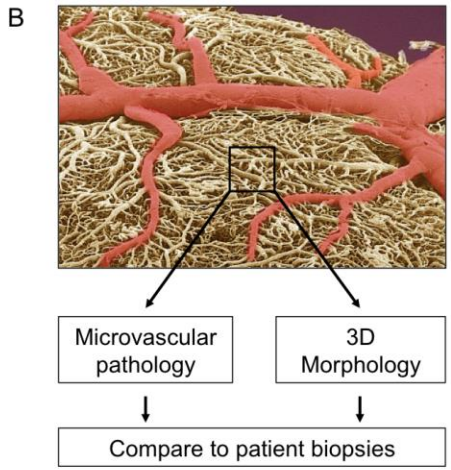
Hunt D et al NEJM March 27,2014

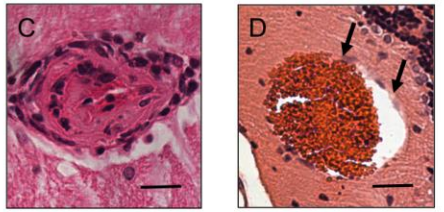
43

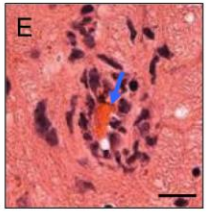

Hereditary TTP
Acquired TTP
Coagulation-mediated TMA
Hereditary complement-mediated TMA
Acquired complement-mediated TMA
Drug-mediated TMA (immune reaction)
Drug-mediated TMA (toxic dose–related reaction)
Interferon-TMA
Metabolism-mediated TMA (cobalamin deficiency)
Shiga toxin-mediated TMA (ST-HUS)

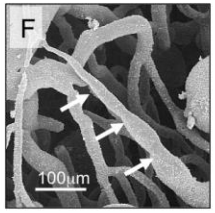
Further investigation in animal studies

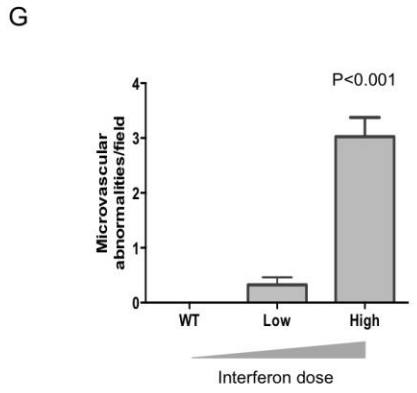












Transgenic overexpression of type I interferon proteins such as IFN alpha & beta shows high levels of interferon cause dose-dependent small vessel damage, including changes seen in patients with TMA

Consistent with a direct effect of interferon protein on small blood vessels

Kavanagh et al Blood 2016

Dr Oliver Flossman & Dr David Hunt
First Dunlop Prize Winners

Clinical observation

- Association of interferon with TMA was suspected from reports of individual patients

Clinical data suggesting a causal association of interferon with TMA

- Frequency of patients identified by a national registry
- Determination of dose-dependent toxicity

Laboratory confirmation of a causal association of interferon with TMA

- Documentation of Type I interferon as the cause of TMA in transgenic mice

Research data applied to clinical practice

- A practice guideline was established to monitor patients treated with Type I interferon
- Identification of early signs of TMA has allowed discontinuation of interferon before irreversible acute kidney injury occurs

Access to innovative medicines

Support for access to new medicines in areas of high unmet medical need

Adaptive licensing pathways under investigation

Aim to reduce uncertainties in benefit risk evaluation via robust risk management plan

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Cancer drug in early access scheme

By PRESS ASSOCIATION

PUBLISHED: 12:47, 11 March 2015 | UPDATED: 12:47, 11 March 2015

Share 29 shares

A cancer drug has become the first to be fast-tracked under a new scheme for patients suffering from life-threatening or seriously debilitating conditions who have no other treatment options available to them.

Pembrolizumab will be offered to those with advanced melanoma under the early access to medicines scheme (EAMS), which was announced by the Government a year ago.

The initiative means researchers can apply for medicines to be made available as soon as the Medicines and Healthcare Products Regulatory Agency (MHRA) signals that the benefits outweigh the risks following an initial scientific assessment, and before they are fully licensed.

BBC Sign in News Sport Weather iPlayer TV Radio

This site is optimised for modern web browsers, and does not fully support your version of Internet Ex

NEWS

Skin cancer drug fast-tracked on NHS

By Michelle Roberts
Health editor, BBC News online

11 March 2015 | Health

Pembrolizumab risk management plan

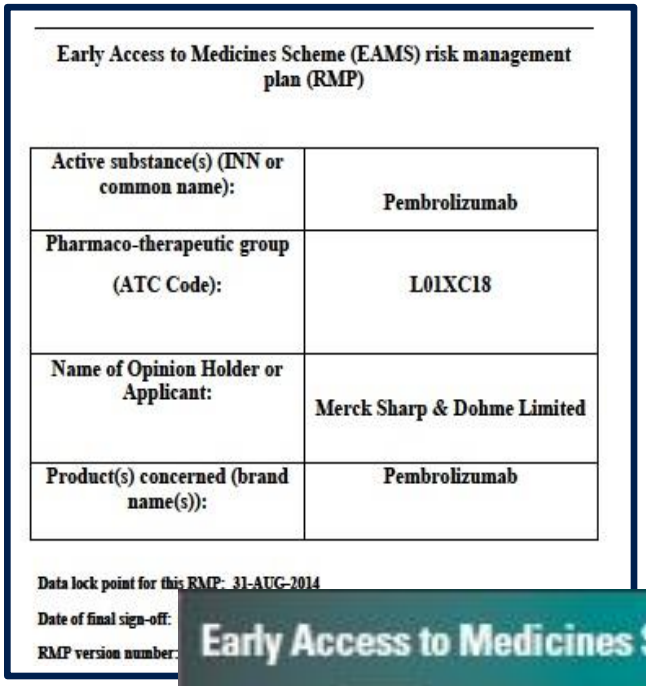
Safety Specification

Pharmacovigilance Plan

- Info collected on all patients before receiving treatment
- Active follow-up for ADRs
- Reporting to MHRA

Risk minimisation measures

- Patient alert card



Early Access to Medicines Scheme (EAMS) risk management plan (RMP)

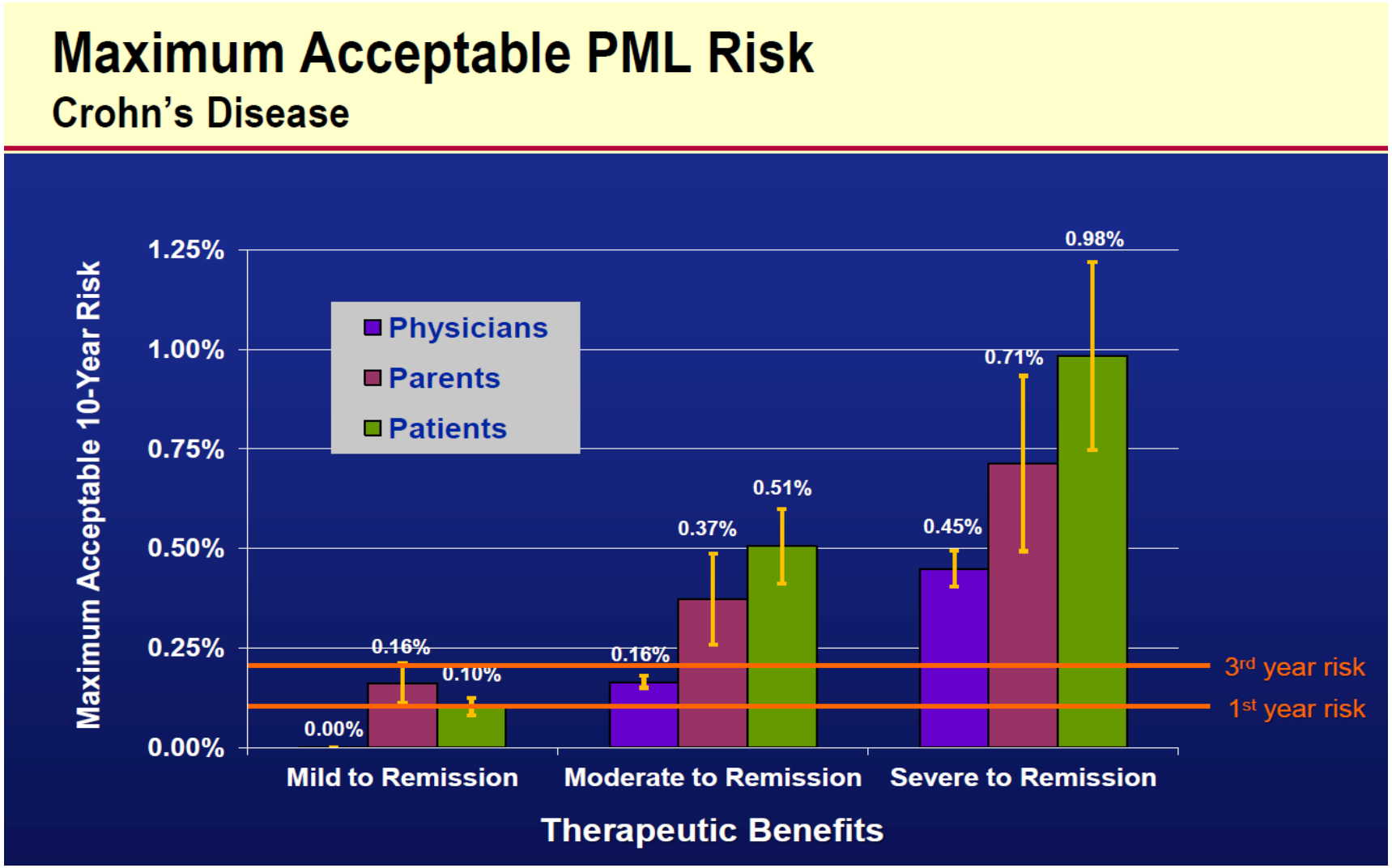
Active substance(s) (INN or common name):	Pembrolizumab
Pharmaco-therapeutic group (ATC Code):	L01XC18
Name of Opinion Holder or Applicant:	Merck Sharp & Dohme Limited
Product(s) concerned (brand name(s)):	Pembrolizumab

Data lock point for this RMP: 31-AUG-2014

Date of final sign-off:

RMP version number:

Understanding patients' risk tolerance



Johnson et al 2010 J Manag Care Pharm

Involving healthcare professionals patients & public in decisions

Interaction with patient and health professional organisations so far only during formal European drug safety reviews

Opportunity of public hearings to be introduced later in 2017

Health professional & patient awareness

Around 15% healthcare professionals have not heard of Yellow Card scheme

Majority of healthcare professionals have never reported a suspected adverse drug reaction

Patient and public awareness of Yellow Card – around 10%

General Medical Council

Working with doctors Working for patients

Enter Sear

About us | Education and training | Registration and licensing | Good medical practice | Concerns about doctors

- Read Good medical practice (2013)
- **Read the explanatory guidance**
- Darllenwch yr arweiniad esboniadol
- 0-18 years
- Accountability in mental health teams
- Acting as a witness in legal proceedings (2013)
- Confidentiality: good practice in handling patient information (2017)

Encouraging a learning culture by reporting errors

22. When something goes wrong with patient care, it is crucial that it is reported at an early stage so that lessons can be learnt quickly and patients can be protected from harm in the future.

23. Healthcare organisations should have a policy for reporting adverse incidents and near misses, and you must follow your organisation's policy.[28]

24. A number of reporting systems and schemes exist around the UK for reporting adverse incidents and near misses.

a. Adverse and patient safety incidents in England and Wales are reported to the National Reporting and Learning System.[29]

b. You must report suspected adverse drug reactions to the UK-wide Yellow Card Scheme run by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Commission on Human Medicines.[30]

c. You must report adverse incidents involving medical devices to the UK-wide MHRA reporting system.[31]

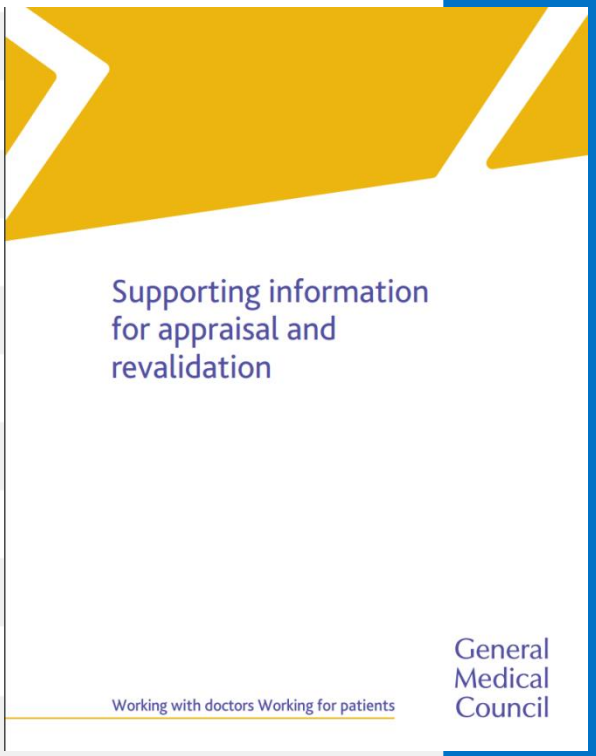
Medical Appraisal Guide (MAG)
Model Appraisal Form
Version 4.2 (updated 2016)

Welcome!

NHS England

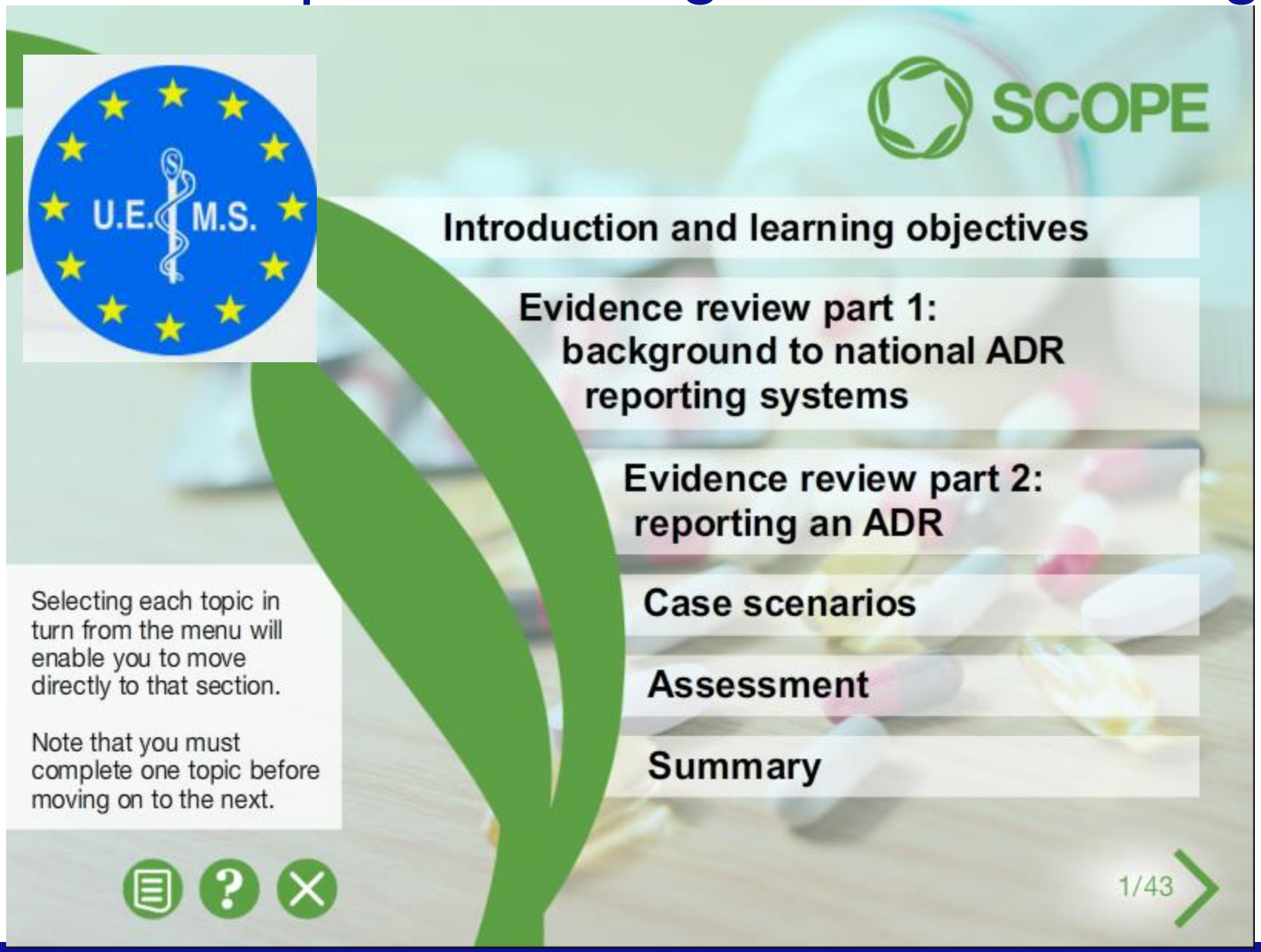
1	Contents
2	Instructions for using this form
3	Personal details
4	Scope of work
5	Record of annual appraisals
6	Personal development plans and their review
7	Continuing professional development (CPD)
8	Quality improvement activity
9	Significant events
10	Feedback from colleagues and patients
11	Review of complaints and compliments
12	Achievements, challenges and aspirations
13	Probity and health statements
14	Additional information
15	Supporting information
16	Review of GMC Good Medical Practice domains
17	Appraisal checklist

Please click on 'Instructions for using this form' and use the helptext bubbles throughout for guidance on how to enter the information required for your appraisal into this form.



Preparation for Appraisal

Accredited pharmacovigilance e-learning



Opportunities for pharmacovigilance

Digital & mobile transformation of pharmacovigilance – integrating risk management into clinician's daily life

Integration of pharmacovigilance data capture into healthcare systems

Using common approaches with other healthcare surveillance systems – defects, counterfeit, blood incidents medical devices incidents

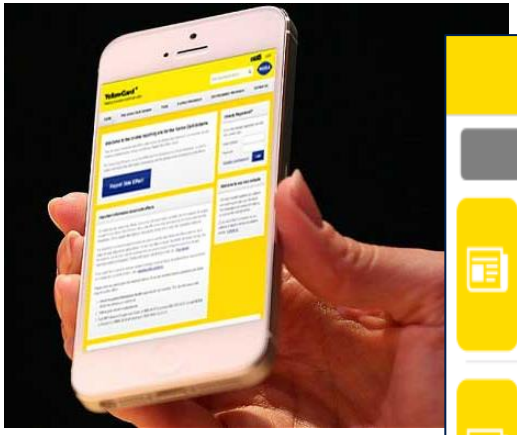
Digital pharmacovigilance transformation

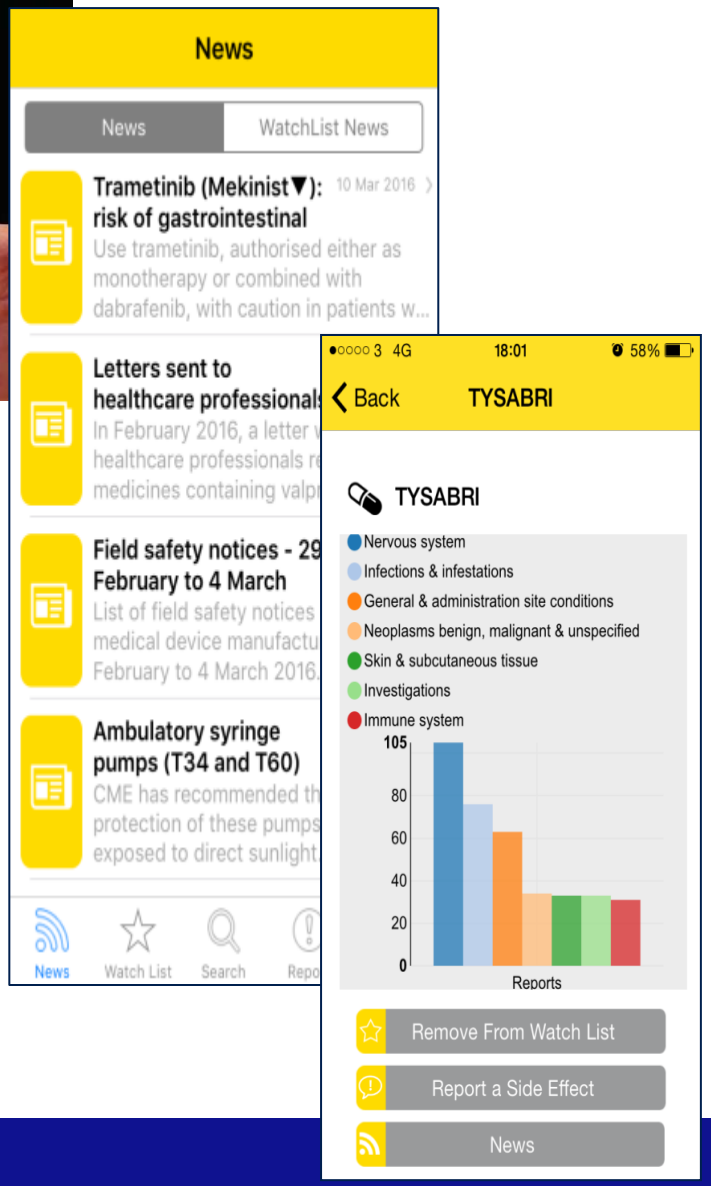
Yellow Card mobile app to report ADRs

Receive drug safety news

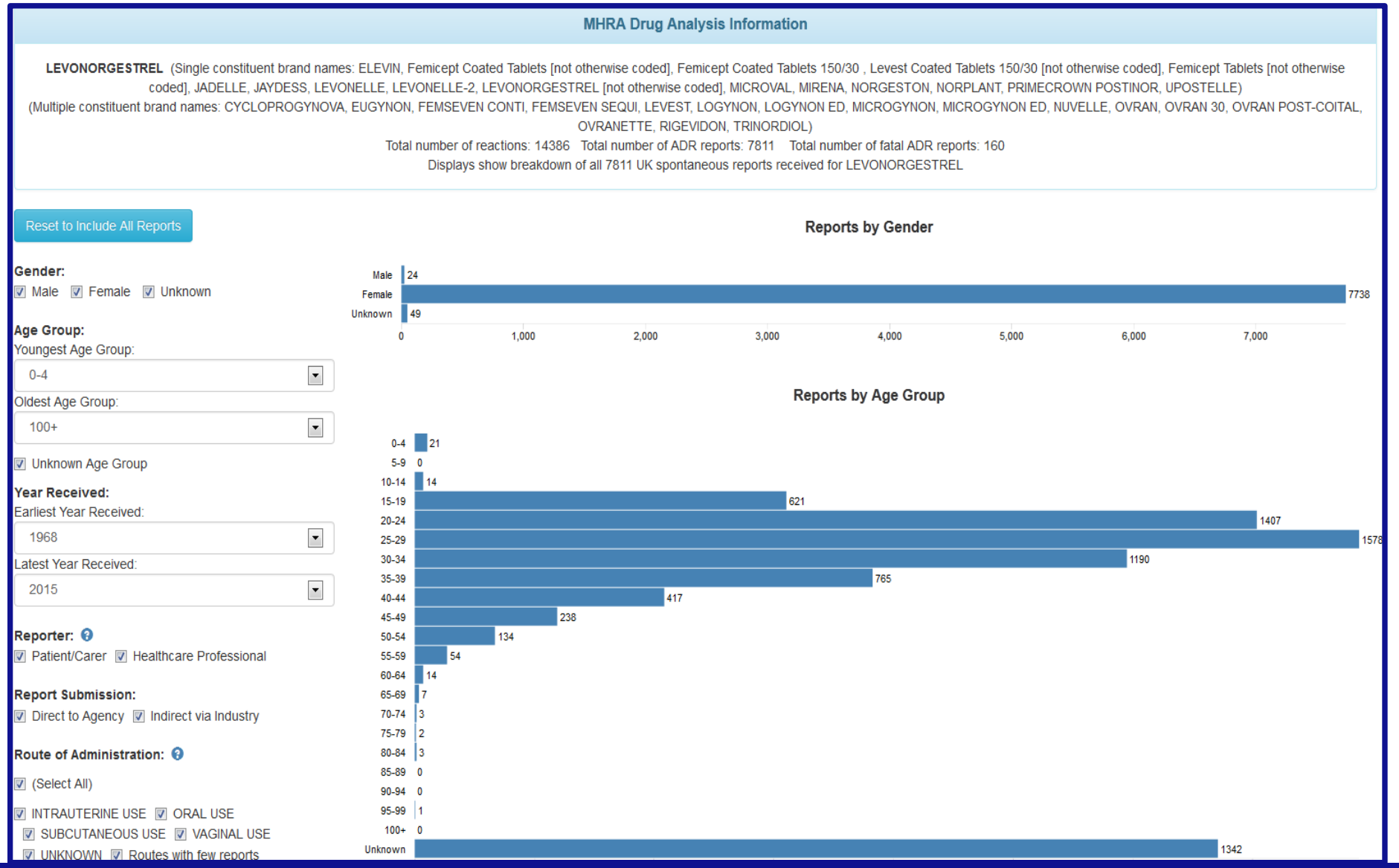
- ✓ General
- ✓ Personalised

View ADR profiles of drugs of interest

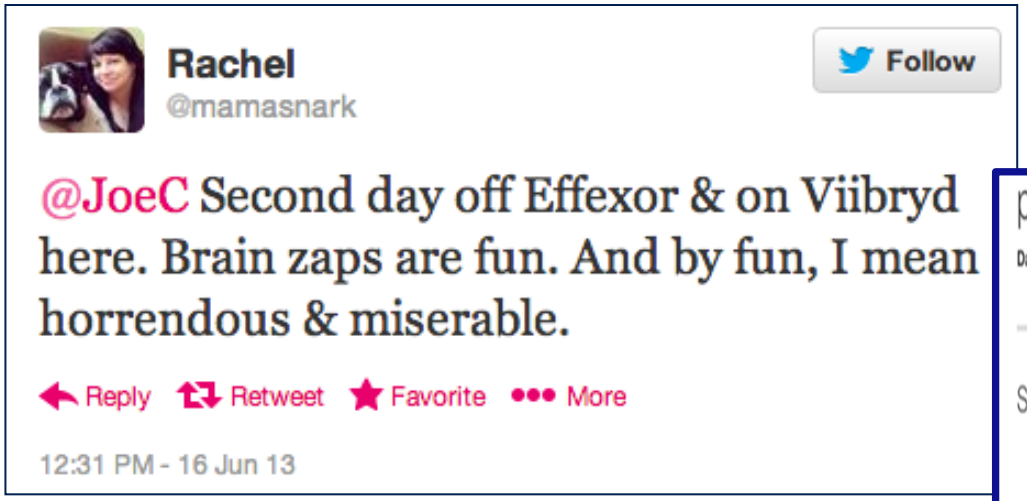


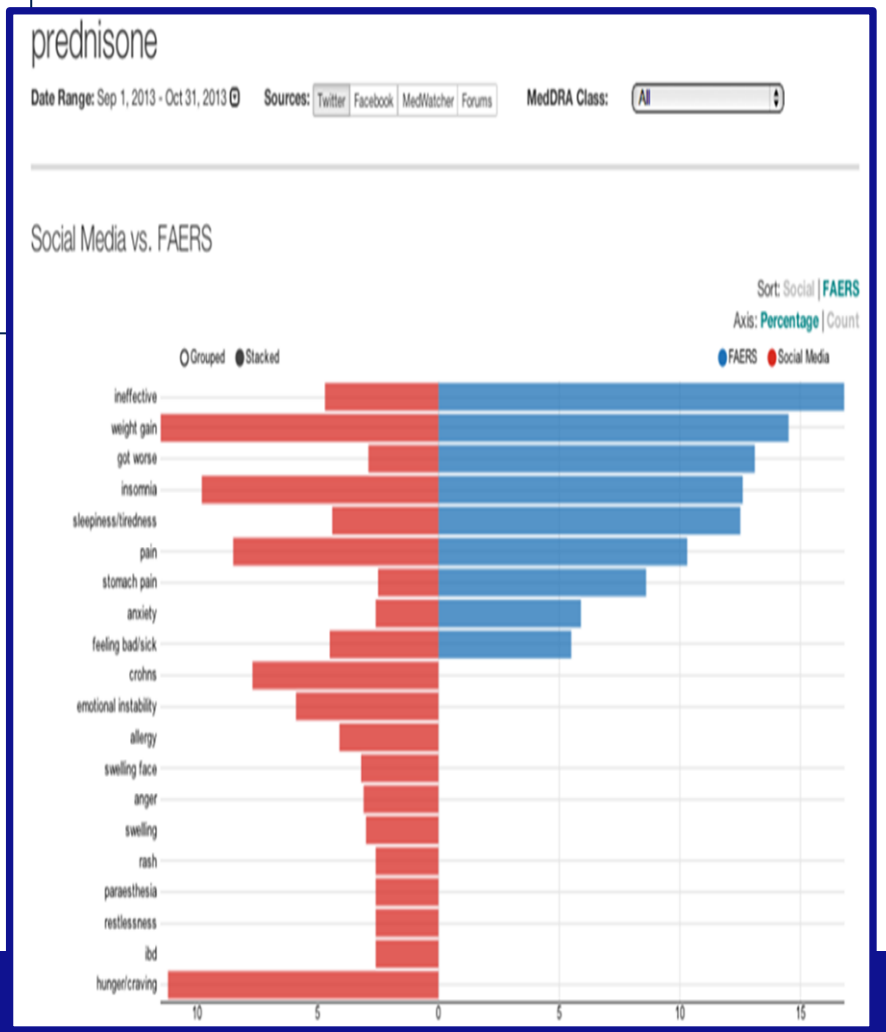


Access interactive PV information



What's to come – using social media?





Will social media data supplement evidence from Yellow Card reports?

Summary

Safety profile of a new medicine only fully characterised in clinical use in wider population

Pharmacovigilance has evolved in response to drug safety issues to become proactive, planning risk management and evaluating effectiveness of risk minimisation measures

Opportunities include maximising use of new technologies & evidence sources, synergies with other surveillance systems

MHRA’s overall goal is vigilance systems which work for all medicines users – to minimise risk and maximise benefits