

eHealth - The road towards more efficient and integrated care solutions for patients

Mick Foy

Vigilance and Risk Management of Medicines

15th May 2015



Agenda



The MHRA

What is pharmacovigilance

Yellow Card reporting

Use of mobile apps and social media

The role of the patient in pharmacovigilance

Summary

Primary objective to enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe

- UK Competent Authority for regulating: Medicines, Medical Devices, Blood & Blood Components, Good Practice: Research, Manufacturing, Clinical, Pharmacovigilance
- Home of the Clinical Practice Research Datalink and National Institute for Biological Standards & Control
- Yellow Card Scheme collects reports of adverse drug reactions
- Underpins MHRA pharmacovigilance work

PHARMACOVIGILANCE





this
 child's life

may depend on the safety of 'Distaval'

Consider the common expense in a case such as this—but the trouble contained a conventional barbiturate. Year by year, the legislation claims a mounting toll in childhood deaths. Yet it is simple enough to get a sedative and hypnotic which is both highly effective...and substantially safe. 'Distaval' has been prescribed for over three years in the country, where the accidental poisoning rate is substantially high but there is no case reported in which even gross overdoses with 'Distaval' has had harmful results.

'DISTAVAL' 12 hrs. tablets	
PAGE	PRICE PER
Tablet of 25	2s. 6d.
Box of 100	4s. 4d.
250	8s. 9d.
1,000	27s. 6d.

'DISTAVAL' 60/75/90 mg. tablets	
PAGE	PRICE PER
Tablet of 15	3s. 6d.
Box of 100	55s. 4d.
250	85s. 8d.
1,000	295s. 0d.

'DISTAVAL'

THE DISTILLERS COMPANY (MARKET) LIMITED
 Broadland House, The Broadway, Whitechapel, London, E.1 in Telephone: 224675 3000



The UK wide scheme since 1964

Acts as a vital early warning system

Monitoring a medicine throughout the lifecycle in clinical use

Reports submitted in confidence

Causality does not need to be established – we ask for reports of “suspicions” of ADRs

Voluntary – professional obligation

The image displays the Yellow Card reporting system in three forms: a physical form, a promotional flyer, and a digital interface on a laptop.

Physical Form (Top Right): Titled "YellowCard REPORT OF SUSPECTED ADVERSE DRUG REACTIONS". It includes fields for Patient Details (Name, Sex, Age, Weight, etc.), Suspected Drug(s)/Vaccine(s) (Name, Batch, Route, etc.), and a section for the reaction(s) and any treatment given. It also has checkboxes for "Recovered", "Continuing", and "Other".

Promotional Flyer (Middle): Features the Yellow Card logo and the text "A side effect of your medicine? Report it using Yellow Card". It includes a call to action: "If you think the medicine you are taking may have caused a side effect, you can report it using Yellow Card." and the MHRA logo.

Laptop Screen (Bottom Right): Shows the online reporting portal. It has a header with "YellowCard" and "MHRA". The main content area includes a "Report a side effect" button, a "Already registered?" section with a login button, and a "Report" section with a "Report" button. The footer contains the MHRA logo and contact information.

Why are ADRs a problem?



Because....

- they account for around 5% of hospital admissions
- they cause death in 1 in 1000 medical inpatients
- they complicate drug therapy
- they decrease compliance and delay cure

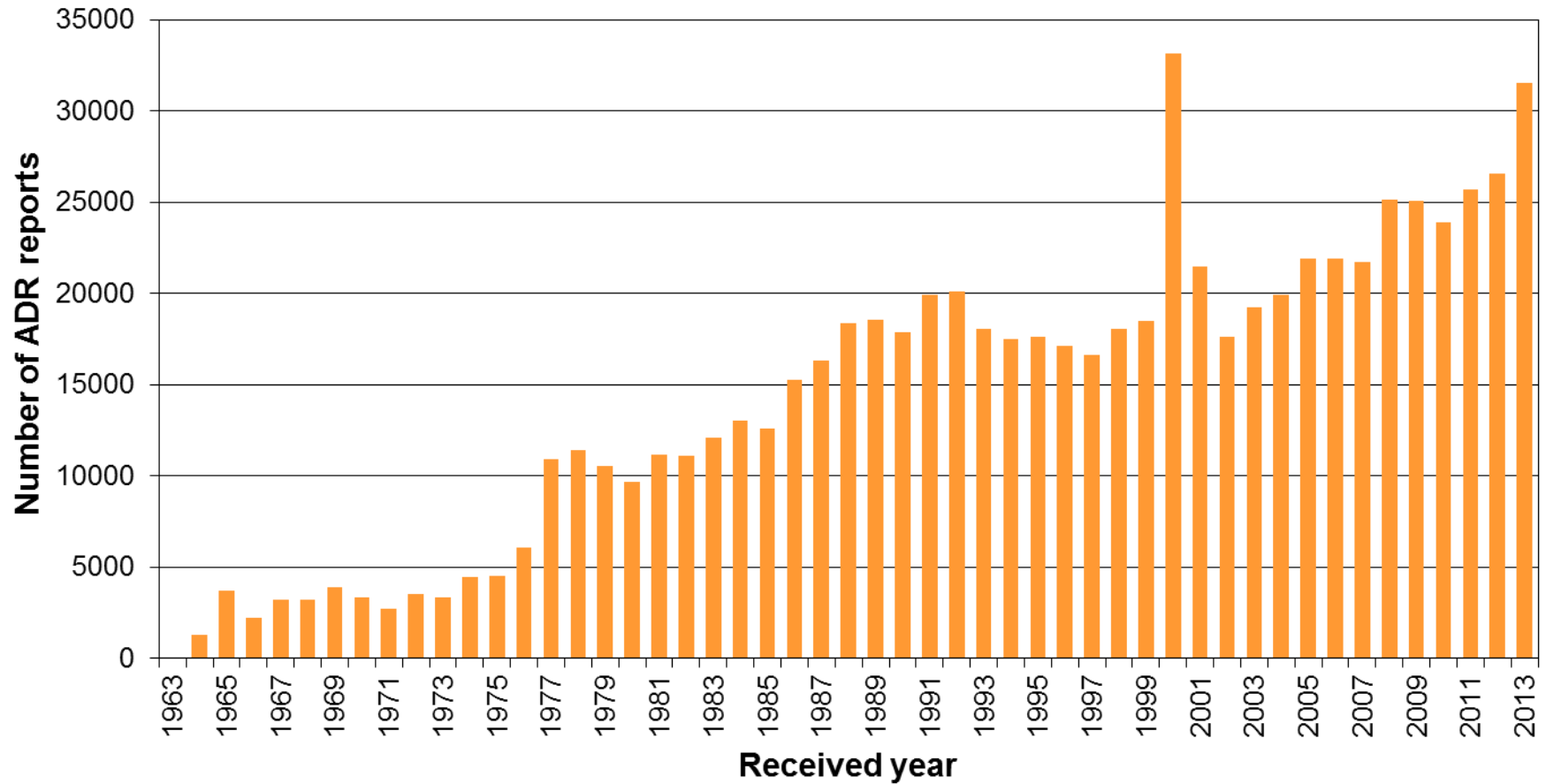
How common are ADRs?

- Up to 40% patients in the community experience ADRs
- In the UK Non Steroidal Anti-Inflammatory Drug (NSAID) use alone accounts for¹
 - 65,000 emergency admissions/year
 - 12,000 ulcer bleeding episodes/year
 - 2,000 deaths/year
- ¹*Blower et al. Emergency admissions for upper gastrointestinal disease and their relation to NSAID use. Aliment Pharmacol Ther 1997; 11: 283-291*

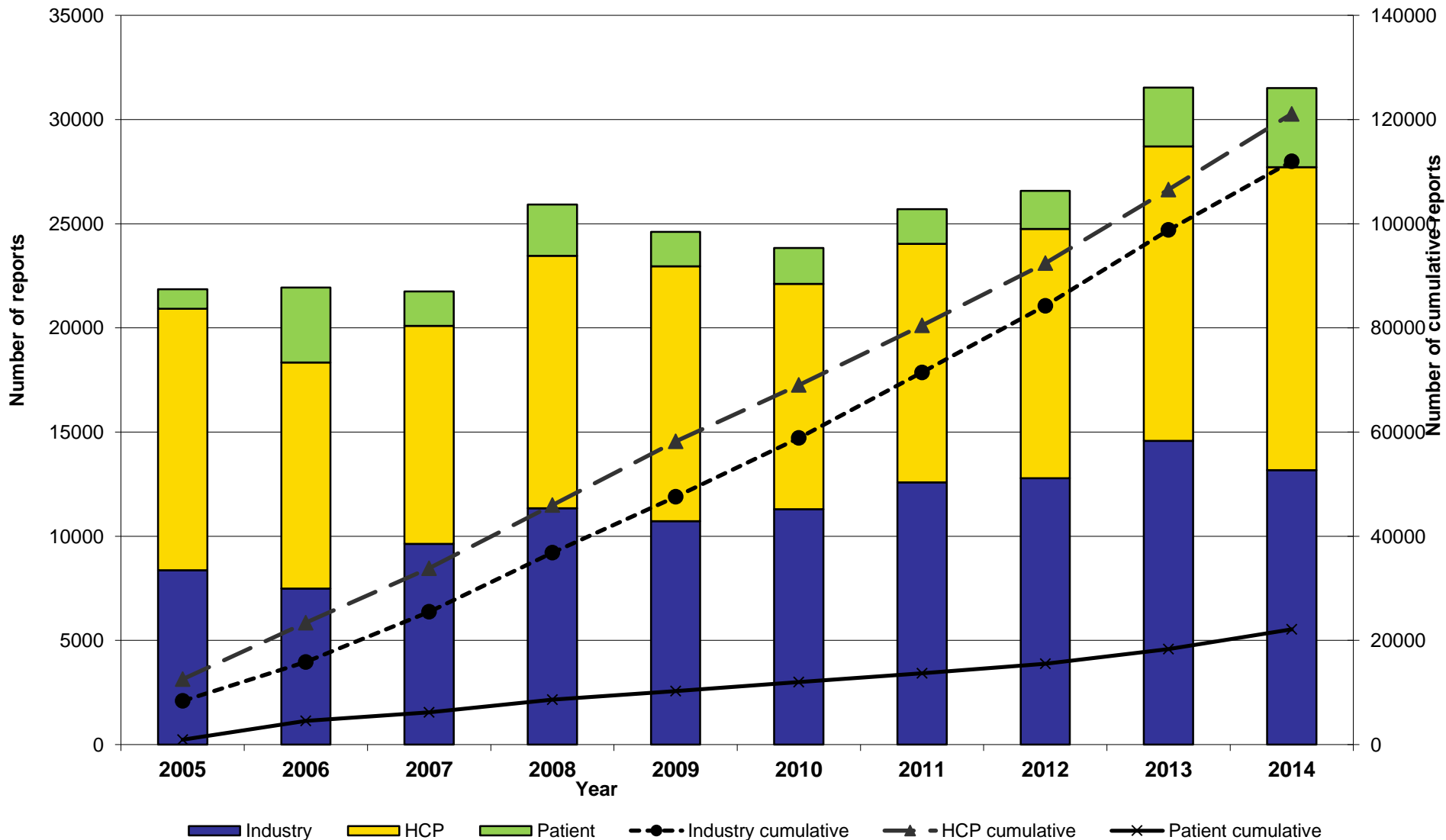
Who is most at risk from ADRs?

- Patients who;
 - very young, or elderly
 - are taking multiple therapies
 - 50% of patients on 5 drugs or more
 - have more than one medical problem
 - have a history of allergy or a previous ADR

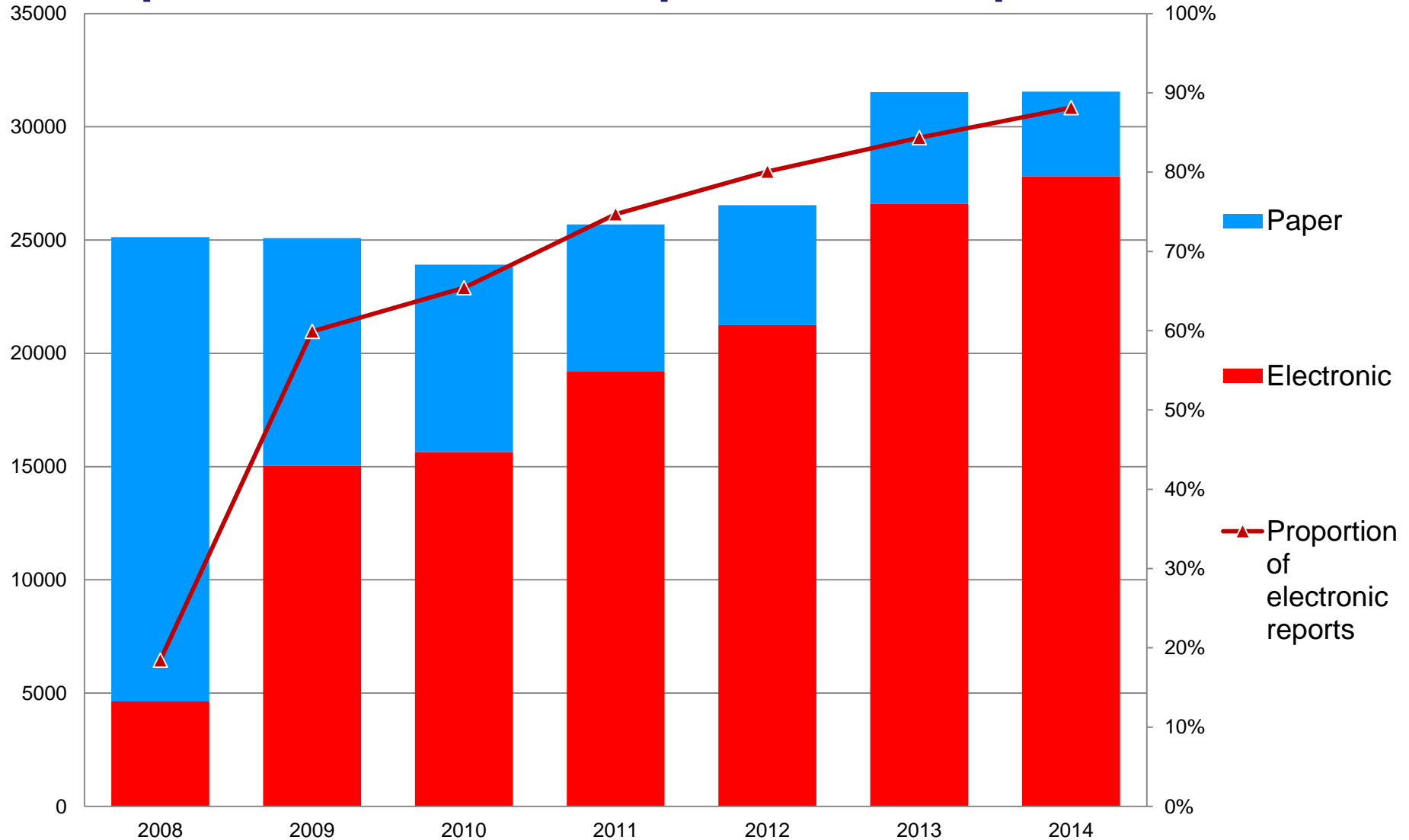
ADR Volumes



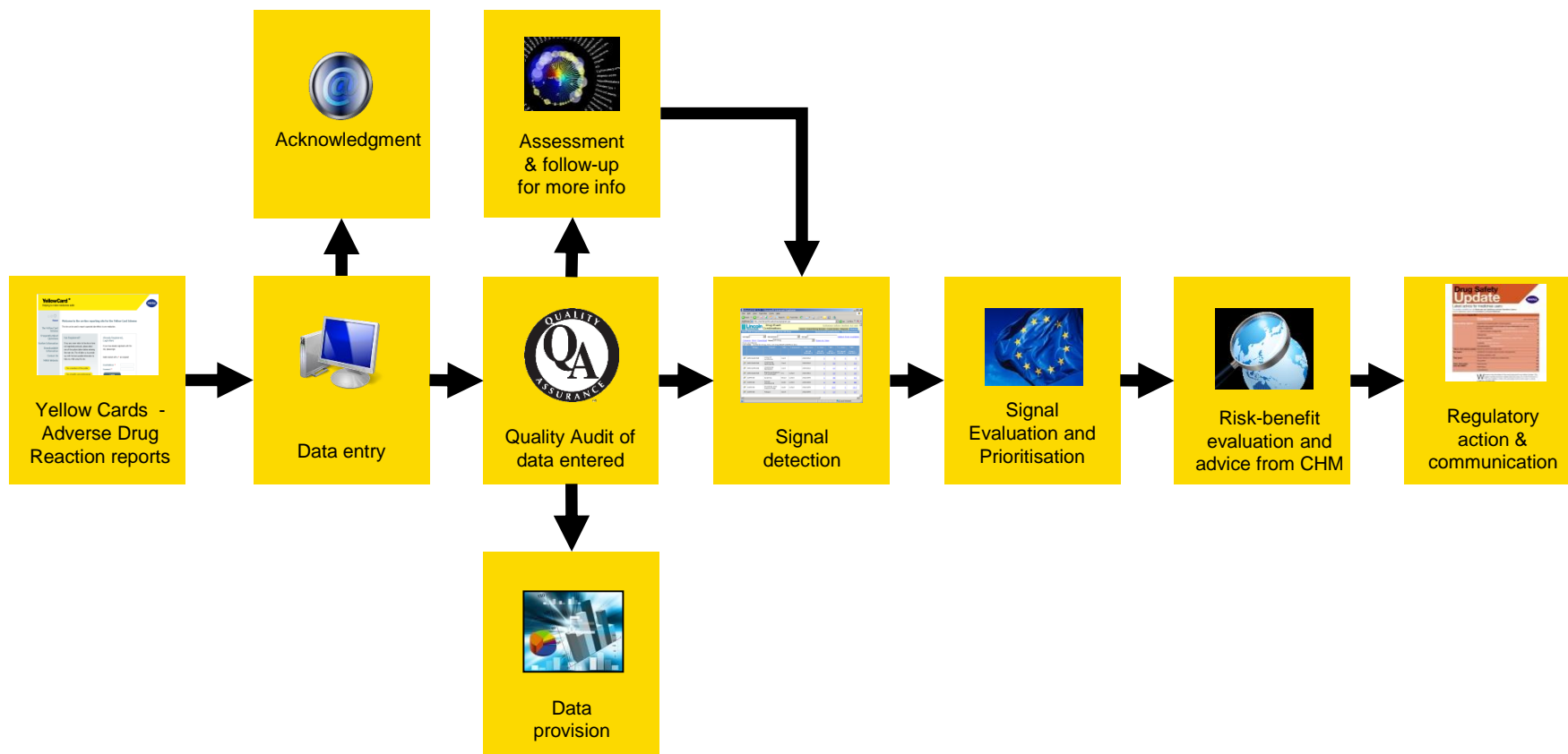
ADR reporting by source over the last 10 years



Paper and electronic suspected ADR reports



Yellow Card Workflow



Yellow Card Strategy



- To raise awareness and understanding of the Yellow Card Scheme
- Two complementary sets of activities - healthcare professionals and the public

Facilitation

Increasing access to the scheme to meet the needs of reporters e.g. electronic reporting

Education

On the importance of Yellow Card reporting

Motivation

Approaches to make reporters more likely to report

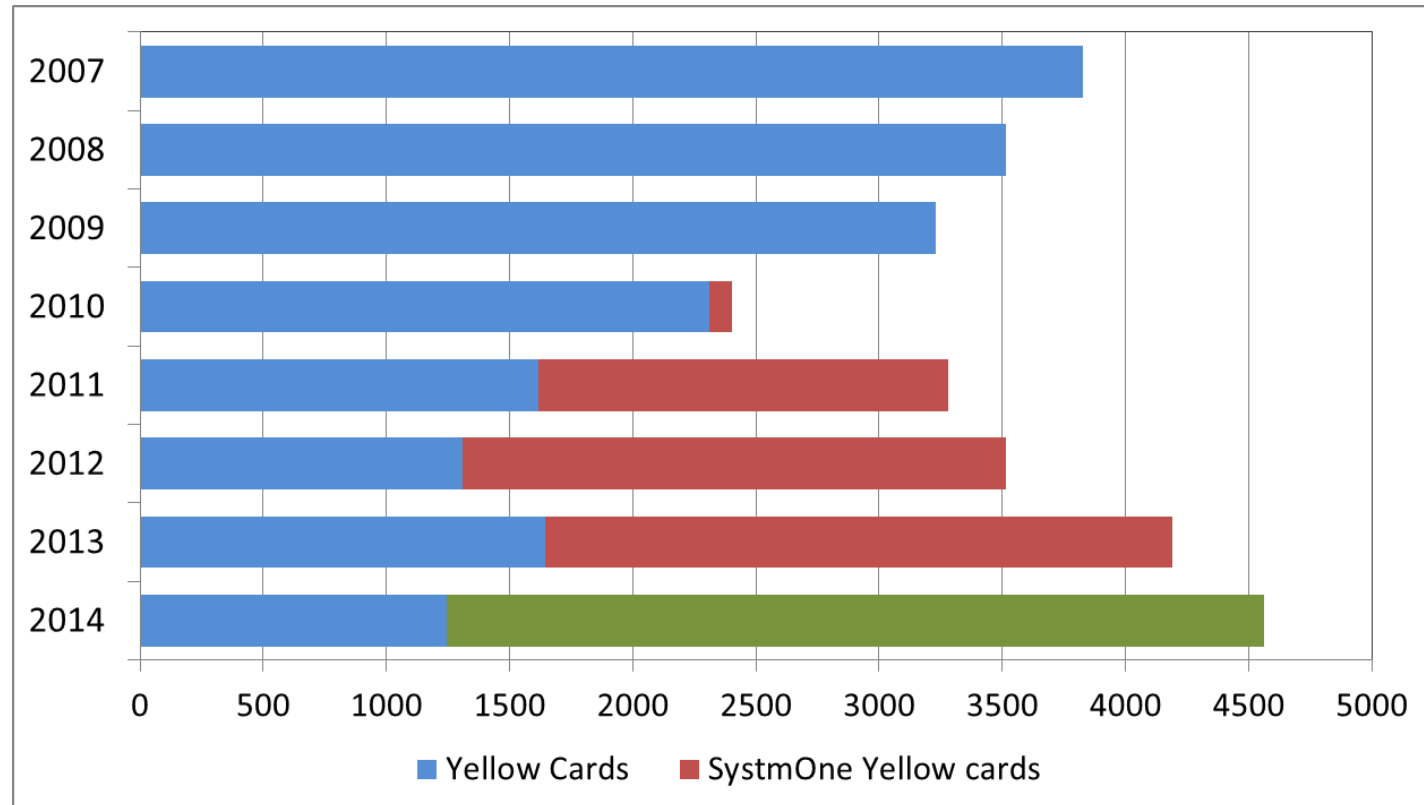
Promotion

Develop and maintain promotion and communication strategies for the scheme

Reporting direct from clinical systems



- Electronic Yellow Card reporting now being introduced via GPSoC into all clinical systems
- SystmOne GP system (below) - 20% of GP practices
- InPS, EMIS and Microtest to go live this year





Innovative Medicines Initiative

IMI-GB-DEC-2013-13
Annex 1

9th Call for Proposals 2013

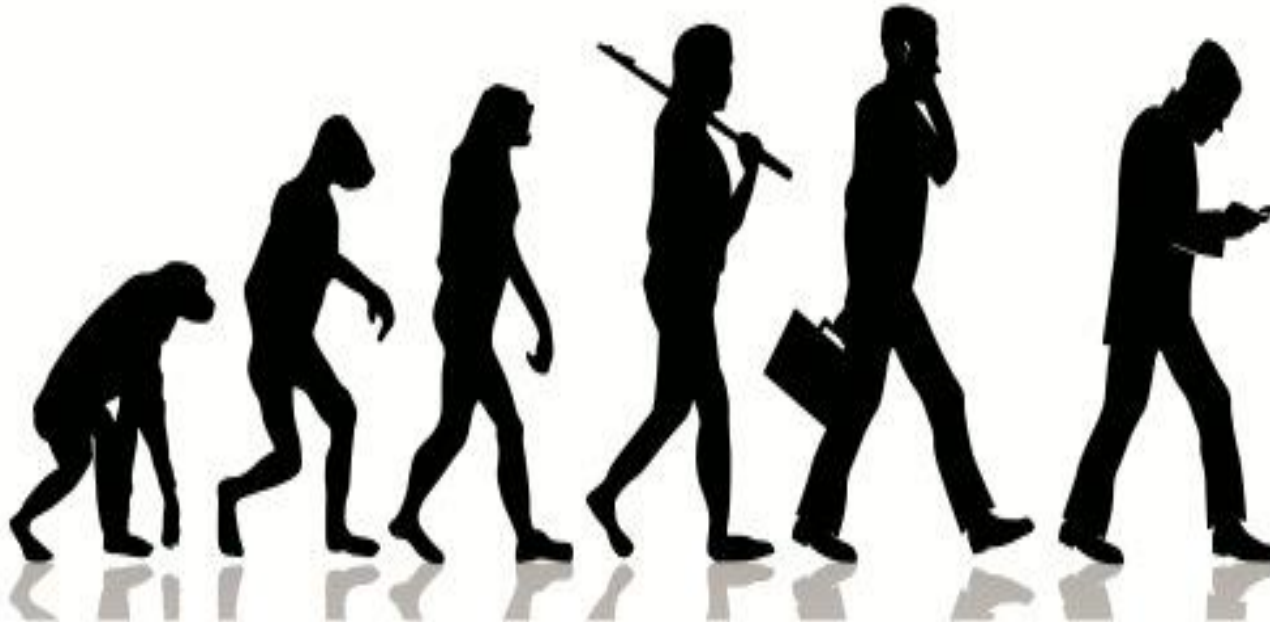
Innovative Medicines Initiative

Version 2

TABLE OF CONTENTS

GENERAL PRINCIPLES	2
1. WEBAE - LEVERAGING EMERGING TECHNOLOGY FOR PHARMACOVIGILANCE	6

Evolution of technology

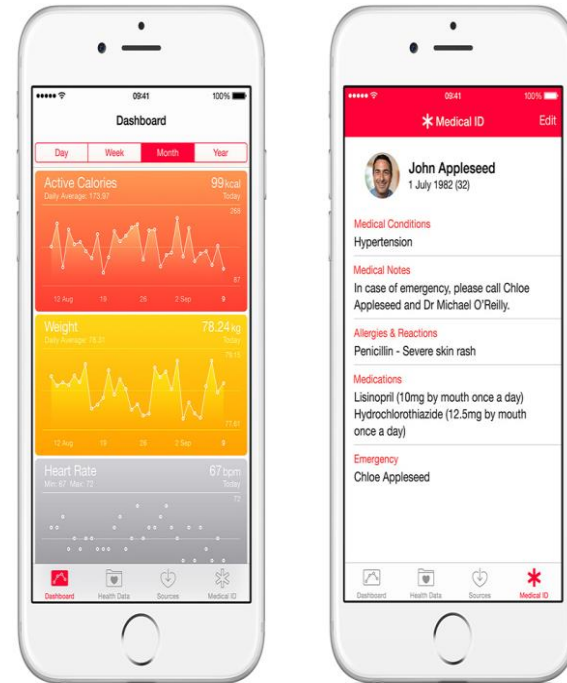


- What does personal computing look like in 2014?
- Personal and work devices have begun to merge together
- Handheld devices are more powerful than the desktop PCs of only a couple of years
- Social media is fully integrated and always on

Smartphones and mobile apps



- 1.75 billion smartphones in use worldwide
- 34.6 million in the UK
- 62% of UK adults and 53% of households have a smartphone (24% also have a tablet)

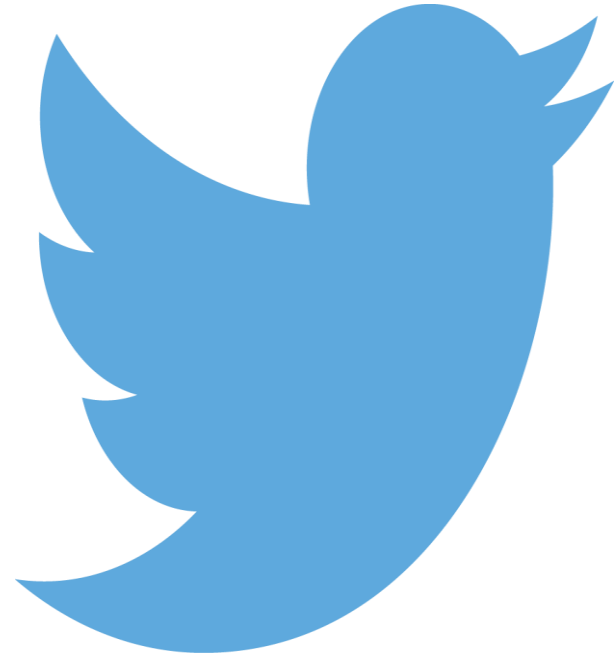


- 1.3 million apps available for android users (1.2 million for iOS)
- Around 6,000 health related apps
- NHS has its own app store

Social media



- 1.35 billion active Facebook users
- 680 million on mobile devices
- 48% log on every day
- 25-34 largest age group



- 284 million active Twitter users
- 80% active on mobile
- 500 million tweets per day worldwide

Questions for Pharmacovigilance

- How can we make best use of these new technologies to enhance PV?
- Can the use of social media be harnessed to support our activities?
- What are the legal & ethical implications?
- What are our obligations (industry & regulators)
- Is it all just noise?

The Evolution of ADR reporting

YellowCard™ It's easiest to report online at www.yellowcard.gov.uk
(0800 033 6666) (0800 033 6666)

SUSPECTED ADVERSE DRUG REACTIONS

If you suspect an adverse reaction may be related to one or more drugs, please complete this Yellow Card. One Yellow Card should be filled in for each drug. Do not fill in more than one Yellow Card for the same drug. Do not fill in more than one Yellow Card for the same patient.

PATIENT DETAILS Patient's name: _____ Sex: M / F _____ Weight of knowledge: _____
Age of last of reaction: _____ Identification number (e.g. Your Practice or Hospital Ref): _____

SUSPECTED DRUG(S)/VACCINE(S)
Drug name (Brand name), Route, Dose, Date started, Date stopped, Prescribed for: _____

SUSPECTED REACTION(S) Please describe the reaction(s) and any treatment given: _____
Date reaction(s) started: _____ Date reaction(s) stopped: _____
Do you consider the reaction(s) to be serious? Yes / No: _____
If you consider the reaction(s) to be serious, please fill in all the boxes: _____
Patient died due to reaction: ☐ Death occurred at or near the time of reaction: ☐
Life-threatening: ☐ Hospitalized or prolonged hospitalization: ☐
Congenital abnormality: ☐ Disability or significant disability or incapacity: ☐
Other: _____

OTHER DRUG(S) (including self-medication and complementary remedies)
If you suspect one or more other suspected adverse reactions to the drug(s) listed above, please fill in this box: _____
If you suspect one or more other suspected adverse reactions to the drug(s) listed above, please fill in this box: _____
Drug name (Brand name), Route, Dose, Date started, Date stopped, Prescribed for: _____

Additional relevant information (e.g. medical history, test results, known allergies, medical conditions, pregnancy, current drug reactions). For congenital abnormalities please state all other drugs taken during pregnancy and the last menstrual period: _____

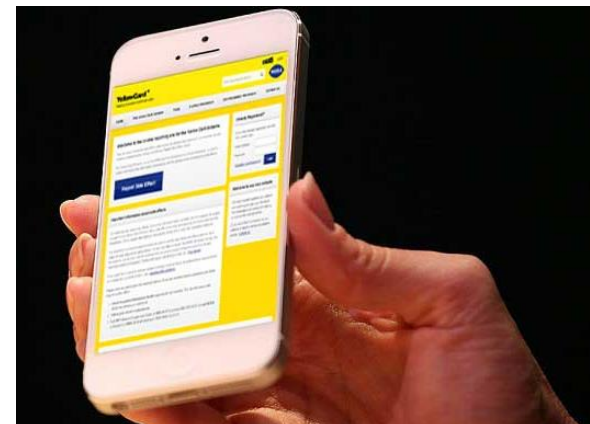
Please list any medicines obtained from the internet: _____

REPORTER DETAILS Name and Professional Address: _____
Postcode: _____ Tel No: _____
Email: _____
Signature: _____ Date: _____

CLINICIAN (if not the reporter) Name and Professional Address: _____
Postcode: _____ Tel No: _____
Email: _____
Signature: _____ Date: _____

Information on adverse drug reactions is collected by the MHRA and is available at www.mhra.gov.uk.
The Yellow Card is the only way to report an adverse reaction to a medicine. Do not fill in a Yellow Card if you are not a healthcare professional or if you are not a patient.

Please attach additional pages if necessary. Send to: PREPOST YELLOW CARD Box 100, London W1A 0AL.



Access to information

Drug Analysis Print Drug name: INTERFERON BETA

Drug name:	INTERFERON BETA	Report type:	Spontaneous
Report run date:	31-Mar-2015	Report origin:	UNITED KINGDOM
Data lock date:	30-Mar-2015 19:00:09	Route of admin:	ALL
Period covered:	01-Jul-1963 to 30-Mar-2015	Reporter type:	ALL
Earliest reaction date:	11-Mar-1996	Reaction:	ALL
MedDRA version:	MedDRA 17.1	Age group:	ALL

System Organ Class	Single active constituent		Multiple active constituent		Total unique reports ^a	
	All	Fatal	All	Fatal	All	Fatal
Blood disorders	65	0	0	0	65	0
Cardiac disorders	77	6	0	0	77	6
Congenital disorders	9	0	0	0	9	0
Ear disorders	12	0	0	0	12	0
Endocrine disorders	16	0	0	0	16	0
Eye disorders	31	0	0	0	31	0
Gastrointestinal disorders	135	0	0	0	135	0
General disorders	543	16	0	0	543	16
Hepatic disorders	25	1	0	0	25	1
Immune system disorders	25	0	0	0	25	0
Infections	224	3	0	0	224	3
Injuries	94	1	0	0	94	1
Investigations	195	0	0	0	195	0
Metabolic disorders	22	1	0	0	22	1
Muscle & tissue disorders	126	0	0	0	126	0
Neoplasms	115	11	0	0	115	11
Nervous system disorders	396	5	0	0	396	5
Pregnancy conditions	51	0	0	0	51	0
Psychiatric disorders	201	2	0	0	201	2
Renal & urinary disorders	42	0	0	0	42	0
Reproductive & breast disorders	33	0	0	0	33	0
Respiratory disorders	88	2	0	0	88	2
Skin disorders	132	0	0	0	132	0
Social circumstances	6	0	0	0	6	0
Surgical & medical procedures	29	1	0	0	29	1
Vascular disorders	52	0	0	0	52	0
TOTAL NUMBER OF REACTIONS	2744	49	0	0	2744	49

New Yellow Card App

●●○○○ 3 4G 18:04 57%

← Back Medicines

TYSABRI

Batch Number TY8468

Dosage Unknown

Route Unknown

Place where medicine was obtained

Unknown

Reason for taking medicine

Multiple sclerosis

Action taken with medicine Unknown

Has the medicine caused a similar reaction before? ☒

●●●●● 3 4G 18:00 58%

← Back TYSABRI

TYSABRI

Showing adverse drug reaction reports submitted to the MHRA for the active ingredient: **NATALIZUMAB**.

Organ System	Number of Reports
Nervous system	105
Infections & infestations	75
General & administration site conditions	65
Neoplasms benign, malignant & unspecified	0
Skin & subcutaneous tissue	0
Investigations	0
Immune system	0

Remove From Watch List

Report a Side Effect

News

The Future Patient Journey?

Search internet for medicine information and side effect – find Yellow Card information and directed to App store

Download App, scan package to auto populate, add other information, attach photos

ADR report sent to MHRA

Patient receives advice, information on medicine, directed to PIL, DAP, other important safety information

Patient can register for updates on medicine so future alerts are received directly to phone

Social Media



Public Profiles



All Public

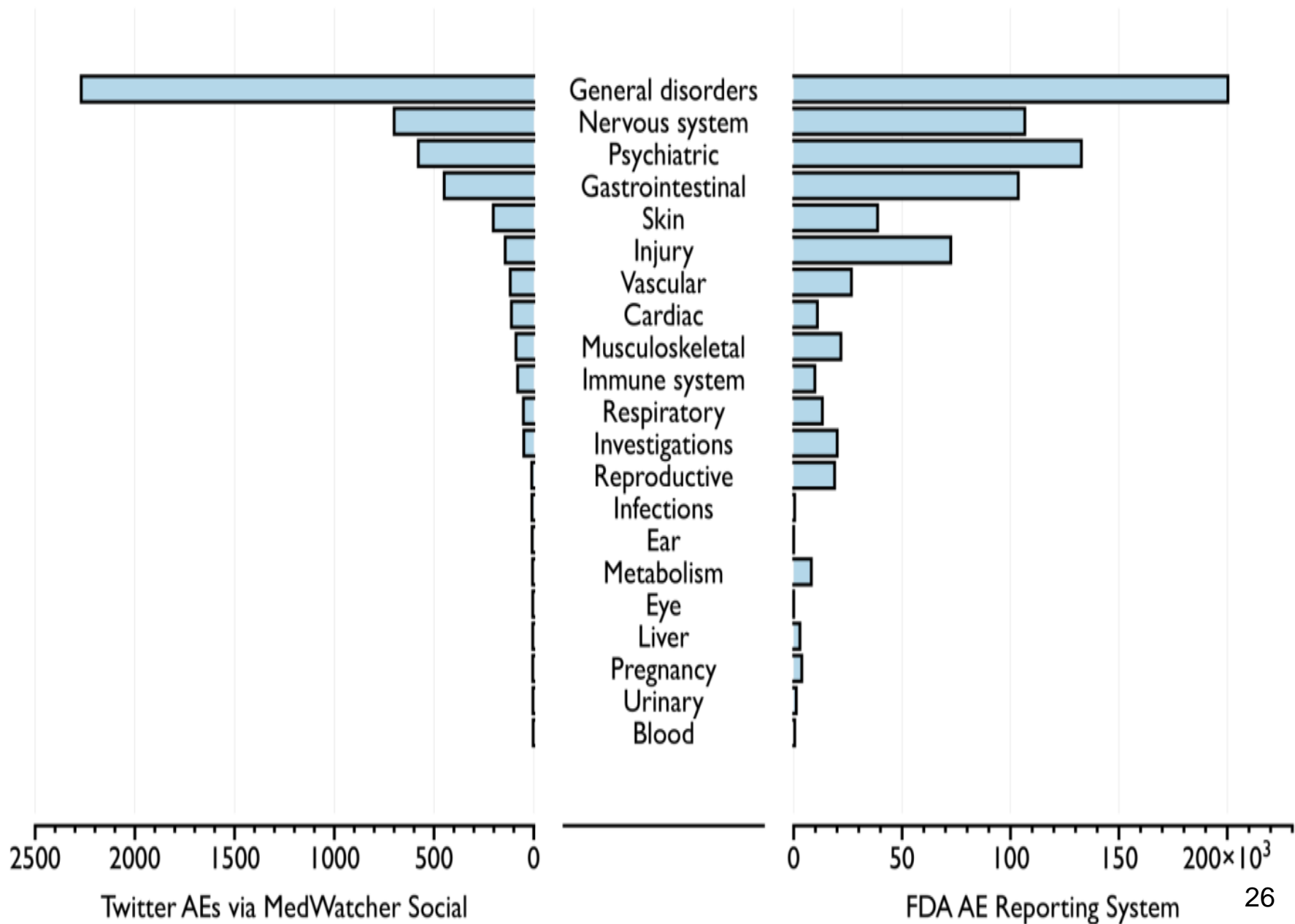


Public & Health related



Public & Health related

All Medical Products



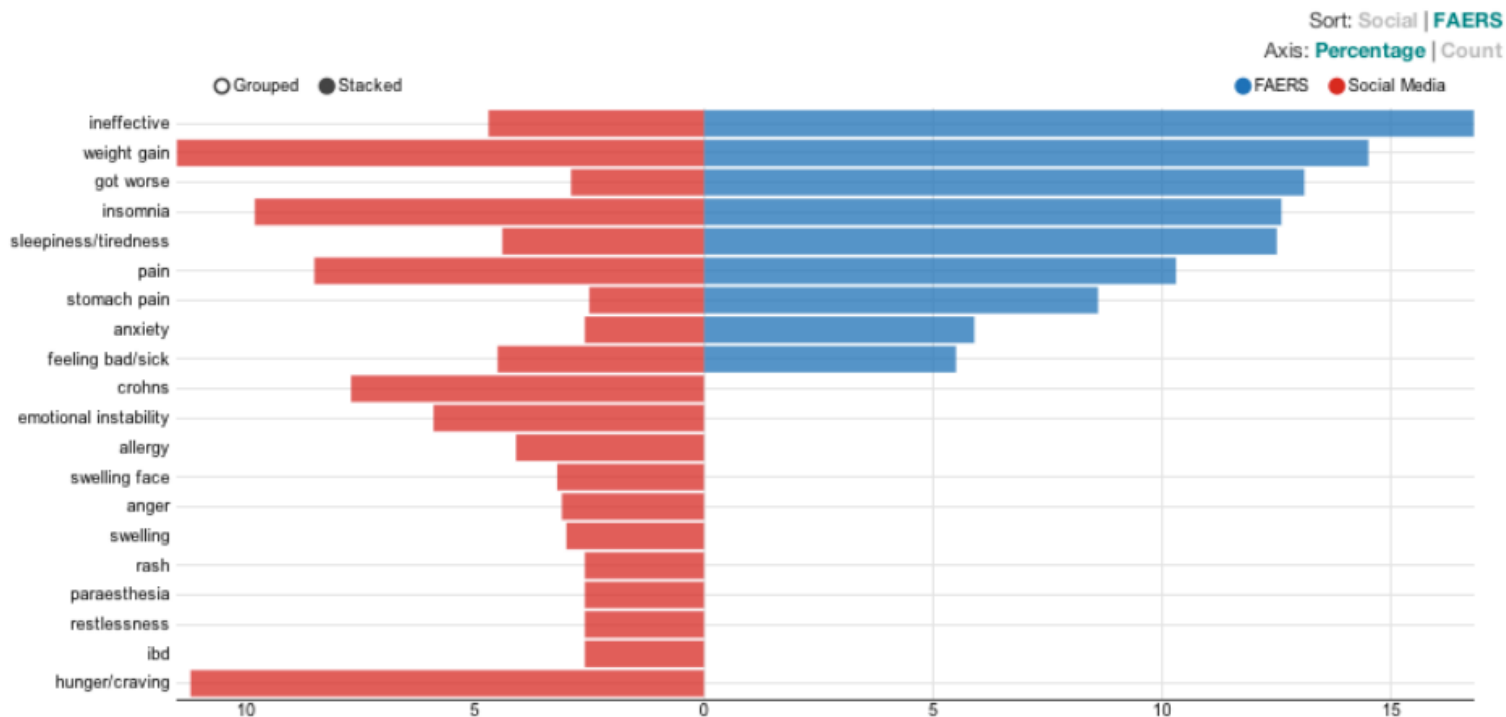
prednisone

Date Range: Sep 1, 2013 - Oct 31, 2013

Sources: [Twitter](#) [Facebook](#) [MedWatcher](#) [Forums](#)

MedDRA Class: [All](#)

Social Media vs. FAERS



prednisone sucks and turns me into a scared little baby I watched the intro to AHS Asylum and now I'm freaked out	12/15/2013	<input type="button" value="⬆"/>
Prednisone + breathing treatment = me still awake ! ☐	12/15/2013	<input type="button" value="⬆"/>
This prednisone is f***** my emotions up	12/15/2013	<input type="button" value="⬆"/>
I'm really mad that they put me on Prednisone	12/15/2013	<input type="button" value="⬆"/>
I am pleased to announce that my face is no longer swollen #allergies #hydroxyzine # prednisone # swollen #3weekslater	12/15/2013	<input type="button" value="⬆"/>
In other news, I am STARVING . Stupid Prednisone . But at least I can have an apple instead of leftover cake. #fb	12/15/2013	<input type="button" value="⬆"/>
@user omg when I was on prednisone I ate *all the things* and gained 20lbs in one month. Be careful! And feel better.	12/15/2013	<input type="button" value="⬆"/>
@user class="symptom-class" id="tag130" title="symptom - Psychiatric - Irritability">CrankyAmy Yeeeeeep. Prednisone . Are you saying it's RAGE + THE EVIL MUNCHIES ? Because that is FOUL.	12/15/2013	<input type="button" value="⬆"/>
Oh prednisone , my lungs thank you, but my nerves, head and stomach would appreciate a speedy exit.	12/14/2013	<input type="button" value="⬆"/>
Careful on pronunciation. RT @user me: I don't like prednisone ; it makes me full of rage . dr.: Would you rather be full of puss?	12/14/2013	<input type="button" value="⬆"/>
Apparently prednisone makes you really b***** . Sorry to all innocent bystanders.	12/14/2013	<input type="button" value="⬆"/>
So I am apparently a walking infection . me: I don't like taking prednisone ; it makes me full of rage . dr.: Would you rather be full of puss?	12/14/2013	<input type="button" value="⬆"/>
prednisone and fever => http://t.co/Td7fRRRnTa	12/14/2013	<input type="button" value="⬆"/>
Loving this one Linda ~ Perfect picture to describe the hunger when on Prednisone ! You rocked this! http://t.co/SkZTLWWQ4y	12/14/2013	<input type="button" value="⬆"/>
Thanks to the doc who put me on 5x the normal dose of prednisone I can't stop throwing up and I feel like c*** #asthamproblems	12/14/2013	<input type="button" value="⬆"/>
50 mg of prednisone doesn't even help that much, that 10 mg was crucial :(12/14/2013	<input type="button" value="⬆"/>
@user class="symptom-class" id="tag118" title="symptom - Gastrointestinal - Crohn's Disease">Crohns My surgeon said I was a mess.I had no fever because I was on prednisone .	12/14/2013	<input type="button" value="⬆"/>
HELLO THERE, SWOLLEN PREDNISONE MOON-FACE . NICE TO HAVE YOU BACK.	12/13/2013	<input type="button" value="⬆"/>
I hate prednisone !!!! I just wanna eat everything..... ☐☐	12/13/2013	<input type="button" value="⬆"/>

The Future Patient Journey?

Patients posts on social media about a side effect to a medicine

WEB-RADR social media screening identifies this as a possible ADR

All similar posts are identified – marked as “labelled” or “unlabelled” PRRs determined

Information used to support signal detection?
Or signal validation?
Or signal assessment?

What is the role of the patient beyond the tweet/post. Do we engage or not?

- Awareness of MHRA and the Yellow Card Scheme is only around 10%
- MHRA need to continue to make reporting more accessible
- Electronic reporting via apps and other media is important
- Access to information is key to success
- Engagement with patient groups helps to “spread the word”

- Pharmacovigilance is a key public health protection system
- The Yellow Card Scheme underpins UK pharmacovigilance activities
- New technologies offer new possibilities for pharmacovigilance
- Traditional ADR reporting and signal management methods are changing
- WEB-RADR seeks to investigate, develop tools and recommend policy
- Patient engagement is key to success