Safeguarding public health

Spontaneous reporting: Detecting medication errors and suitability of current systems

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MHRA

1st March 2013

Session objectives

- Experience with reporting medication errors in national pharmacovigilance databases
- How to identify medication errors in signal detection systems

What is a medication error?

'…medication error refers to any unintentional error in the prescribing, dispensing, or administration of a medicinal product while in the control of the healthcare professional, patient or consumer'

GVP Module VI

'Anything to do with a medicine I've been given that causes me harm'

Patient perspective

How do we ask a patient?

Do you think this reaction occurred as a result of an unintentional error in the prescription, dispensing or administration of the medication?

Help

(•) Yes ( ) No

Please provide further details of the medication error required

Step 4. Side Effects Cancel Previous step Continue

A medication error refers to any unintentional error in the prescribing, dispensing or administration of a medicine while in the control of a healthcare professional or the patient. For example this could be a mistake in the dosage of a medicine or how it was taken.

Coding

- Reliant on coding for accurate signal detection

BUT

- Often automated in different ways
- Global issue; different cultures, different systems

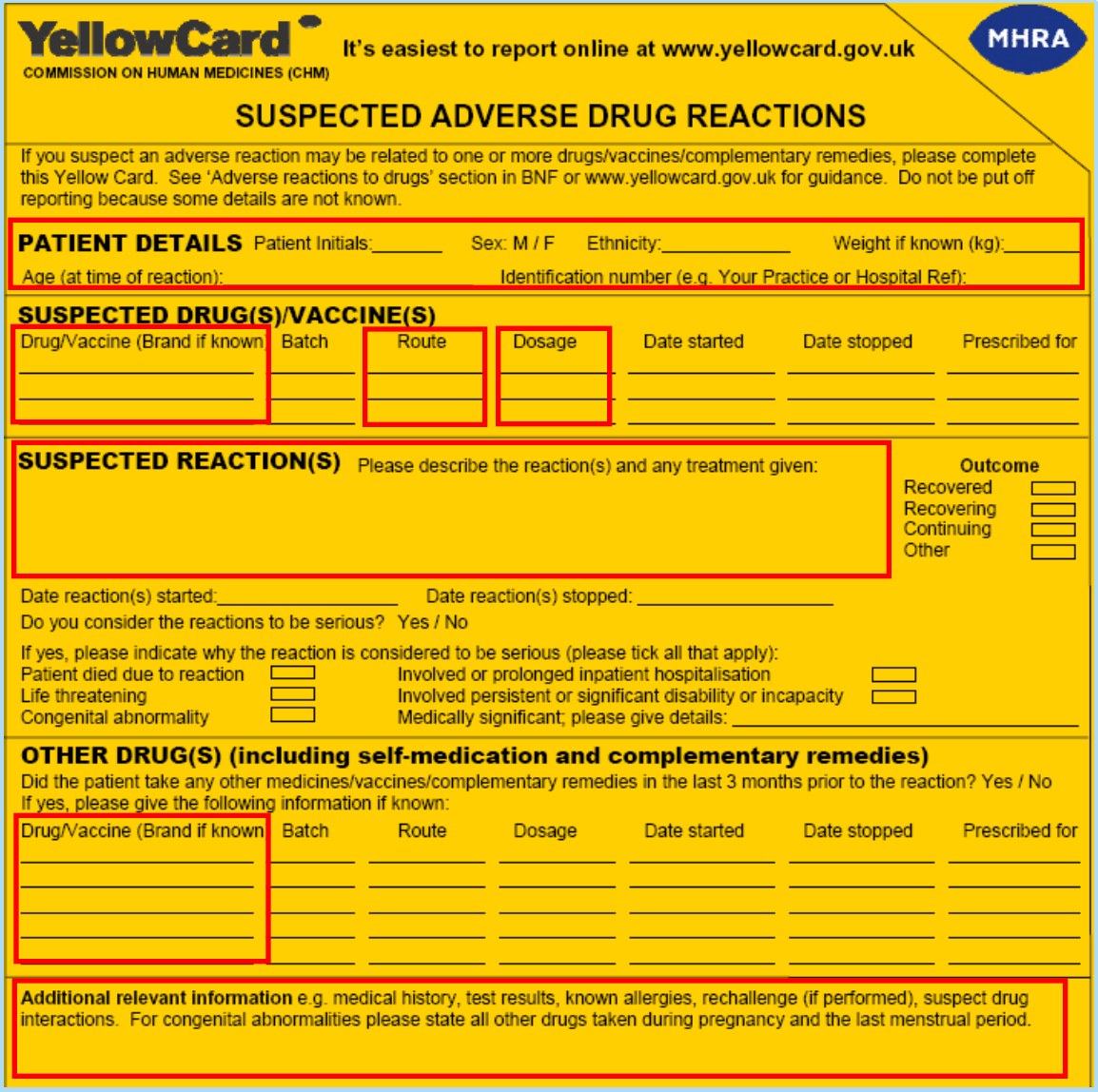
- Is there a right question to ask?
  - Cannot manually screen every report

Spontaneous data

- High volume, but lower strength of evidence
  - ~ 26,000 UK cases received per year
  - > 80% received electronically
  - Patient, health professional and industry cases
- Excellent information on real life use of a product
- Most frequently used signal detection methods identify drug-event combinations (DECs) of interest
  - Is this useful for medication errors?

MEs in spontaneous data

- Patient
- Dose
- Frequency
- Brand
- History
- Route
- Concomitant medications
- Previous allergies



YellowCard
COMMISSION ON HUMAN MEDICINES (CHM)

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

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(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 DRUG(S) (including self-medication and complementary remedies)

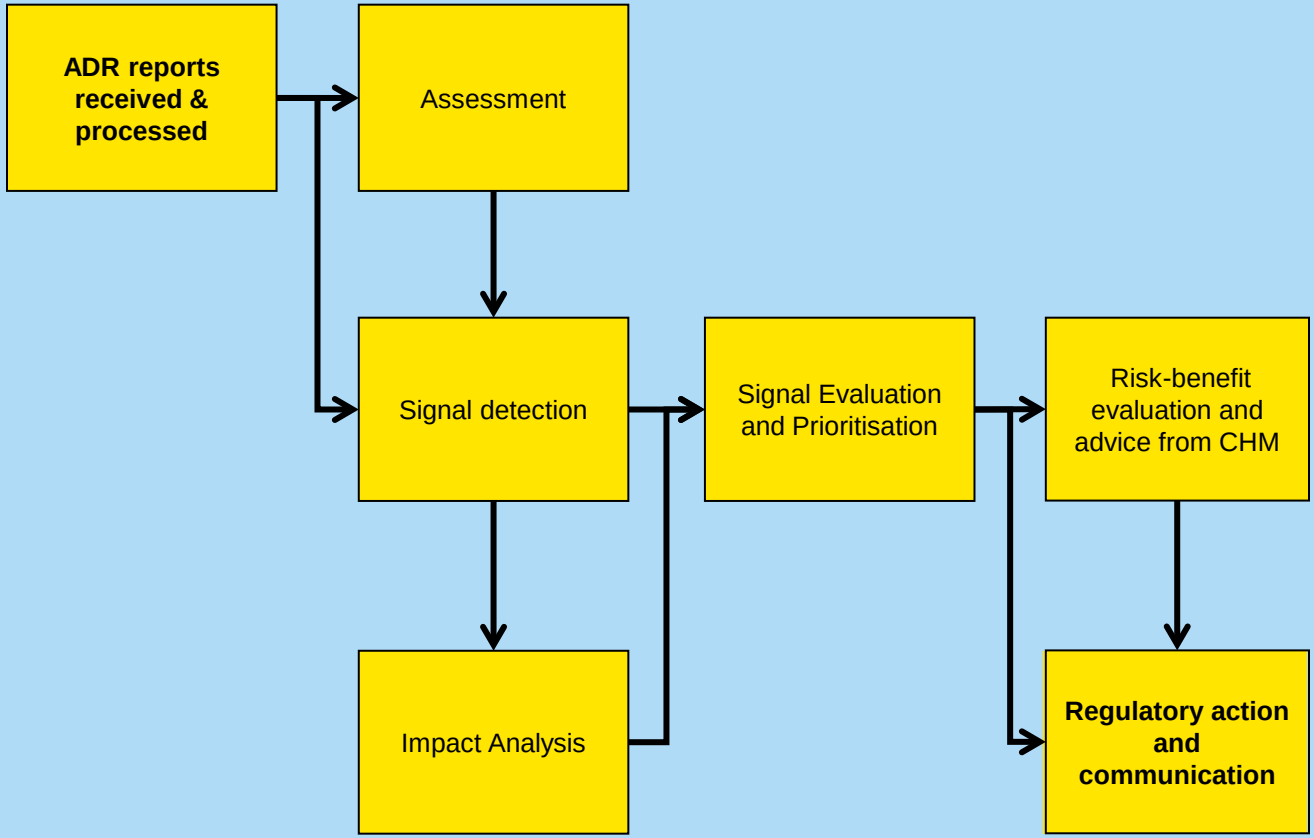
Did the patient take any other medicines/vaccines/complementary remedies in the last 3 months prior to the reaction? Yes / No

If yes, please give the following information if known:

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

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

MHRA Signal Management process



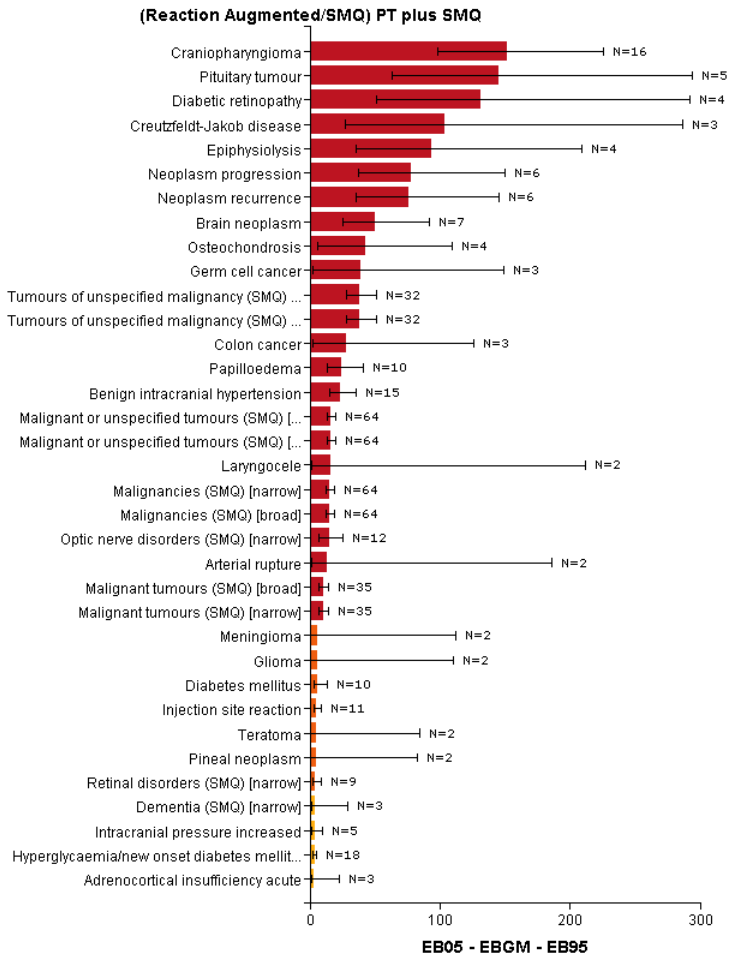
Signal detection methodologies

- Disproportionality methods
- Criteria based
  - Seriousness indicators
  - Population groups
  - Reaction terms of interest

Used predominately to analyse large datasets to filter cases of highest priority

- Individual case review

SOMATROPIN (G) EBGM Confidence Interval Graph



(Some associations excluded due to limit of 35 associations)

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SOMATROPIN (G) Distribution by (Reporter) Qualification

(Reporter) Qualification	N	%
Carer	2	0.52
Chiropodist	0	0.0
Community Pharmacist	0	0.0
Consumer or other non health professional	12	3.15
Consumer or other non-healthcare professional	0	0.0
Coroner	1	0.26
Dentist	1	0.26
GP	17	4.46
Healthcare assistant	0	0.0
Hospital Doctor	158	41.47
Hospital Healthcare Professional	1	0.26
Hospital Nurse	11	2.89
Hospital Pharmacist	1	0.26
Lawyer	0	0.0
Literature	21	5.51
Medical student		
Midwife		
Not Known		
Nurse	2	
Optometrist	0	0.0
Other Healthcare Professional	73	19.16
Other healthcare professional	0	0.0
Paramedic	0	0.0
Parent	1	0.26
Patient	0	0.0
Pharmacist	11	2.89
Pharmacy Assistant	0	0.0
Physician	42	11.02
Pre-reg pharmacist	0	0.0
Radiographer	0	0.0
NULL	4	1.05

View Cases
Create Case Series
Transfer to Case Series
Download Cases
Download Case Details
Reports

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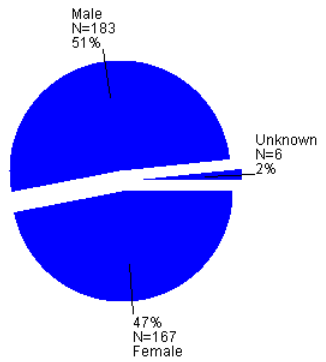
SOMATROPIN (G) Distribution by (Case) Sex



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) Distribution by (Case) Age group cutpoints

(Case) Age group cutpoints	N	%
0	1	0.28
01-02	7	1.97
03-12	116	32.58
13-17	77	21.63
13-18	0	0.0
18-35	25	7.02
19-35	0	0.0
36-65	65	18.26
66+	18	5.06
U	47	13.2
NULL	0	0.0

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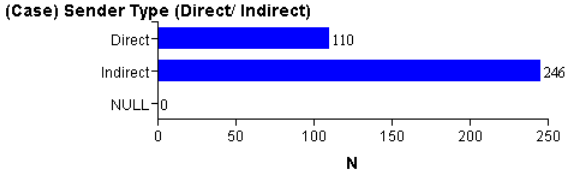
SOMATROPIN (G) Distribution by (Case) Sender Type (Direct/ Indirect)



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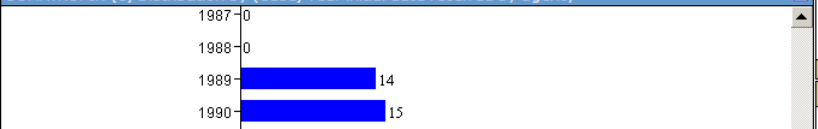
SOMATROPIN (G) Distribution by (Case) Year initial date received by agency



SOMATROPIN (G) Distribution by (Case) Fatal outcome

MEs through signal detection

- Disproportionality against medication error MedDRA terms
- Medication error flagged as an ‘Alert Term’ that is always highlighted for review
    - Reliant on appropriate coding
    - Should always be discussed in signal evaluation
- Often identified outside of these means through cases reviewed as a result of other criteria

Signal Assessment

- Consider whether the event is listed in existing product information
  - Might there be a change in frequency?

- Are there any confounding factors?
  - Patient history
  - Other drugs

- What was the time between taking the drug to the suspected reaction?

- Is the event biologically plausible, or a potential class effect? Is it a potential signal?

Hedrin & ignition issues

- Received as Yellow Cards
  - '…head caught fire…'
  - Identified prior signal processes due to coding issues
  - Fed into signal management process

- Thanks to Jan MacDonald for providing images used in this presentation

Signal Assessment & Meetings

- If the issue merits further discussion will be evaluated at a signal meeting
- Two signal detection meetings each week which includes scientists and assessors of scientific and medical disciplines.
- Signal software used in the meetings to aid assessment
- Should the meeting deem it necessary further evaluation is carried out that week.

RPPS and Impact Analysis

Additional evidence based tools used for further evaluation of signals:

Impact Analysis

- Tool to prioritise possible signals and decide the next step that should be taken. Takes into consideration the strength of evidence as well as the public health implications of the signal.

RPPS

- The Regulatory Pharmacovigilance Prioritisation System. Prioritisation system additionally taking into account public perception of the ADR and Agency obligations.

Fentanyl Patches

Durogesic® *DTrans*® 50 mcg/hr
transdermal patch
fentanyl

One transdermal patch contains 8.4 milligrams of fentanyl
(absorption rate approx 50 micrograms/hour: active surface area 21.0 cm²)

FOR TRANSDERMAL USE
Each patch also contains: polyacrylate adhesive, polyethylene terephthalate/ethyl vinyl acetate film, green printing ink and siliconised polyester film.

POM
C.D.

for external use only

PL 00242/0193 © J-C 2010 GB - 978948

JANSSEN-CILAG Ltd
50-100 Holmers Farm Way
High Wycombe, Buckinghamshire HP12 4EG, UK

Read the leaflet before use. Dosage: as directed by the doctor.

Remove your old patch before applying a new one on a new area of skin. Apply a new patch every 3 days (72 hours).

Opening Instructions

for external use only

- Gently tear or cut open the pouch at the tear notch, shown by the arrow, and remove the edge of the pouch completely (if you use scissors, cut close to the sealed edge of the pouch to avoid damaging the patch)
- Grasp both sides of the opened pouch and pull apart completely
- Take out the patch and use straight away
- Never divide or cut the patch. Do not use the patch if it looks damaged

Keep out of the reach and sight of children.

DISPOSAL AFTER USE: DO NOT throw the pouch away after removing the patch inside. Keep it to put your used patch in. As soon as you take the patch off, fold it firmly in half (sticky sides together) and put it back in the pouch. Put the pouch in the bin with your household rubbish.

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Open

Signal Management

- All signals that warrant further action are discussed at a weekly Signal Management Review Meeting
- Brings together expertise across the Agency including Assessors, Medics and Epidemiologists
- Signals are fully evaluated including assessment of biological plausibility and potential class effects
- Action are discussed and endorsed (including further expert advice required) the priority of the signal is agreed and team allocation is decided

Regulatory Action

There are a number of actions that can be taken with respect to medication errors, just some examples include:

- Updating product information (SPC/PIL)
- Improved packaging
- Warnings in safety bulletins

- Propose changes across EU network

Repevax / Revaxis

Communication

MHRA

Drug Safety Update

Volume 2, Issue 2 **September 2008**

Latest advice for medicines users

Fentanyl patches: serious and fatal overdose from dosing errors, accidental exposure, and inappropriate use

Article date: September 2008

Summary

We have received reports of unintentional overdose of fentanyl due to dosing errors, accidental exposure, and exposure of the patch to a heat source. Fentanyl is a potent opioid analgesic and should be used only in patients who have previously tolerated opioids

Fentanyl patches are licensed for the management of malignant and non-malignant chronic intractable pain. Fentanyl is a controlled drug in the UK and is subject to schedule 2 of the Misuse of Drugs Regulations. Common brands include Durogesic DTrans, Durogesic, Matrifen ▼, and Tilofyl.

Reports of life-threatening adverse reactions and death

We have received spontaneous reports from healthcare professionals, patients, and carers of life-threatening adverse reactions and death after fentanyl overdose in people who were using the patches to control malignant and non-malignant pain.

Factors identified as possibly related to unintentional overdose include dosing errors (by healthcare professionals, patients, or caregivers); accidental exposure (particularly in children); and exposure of the patch to a heat source, possibly resulting in increased fentanyl absorption. These reports also provide some evidence of inappropriate prescribing of fentanyl patches, including prescribing in unlicensed indications and in opioid-naïve patients.

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Conclusions

- A cross-function issue;
- May be identified from many sources
  - Spontaneous data
  - Press
  - Lawyers
  - Patient groups
- Signal detection heavily reliant on accurate and consistent coding conventions
- Different teams and organisations must work closely together throughout the signal management process