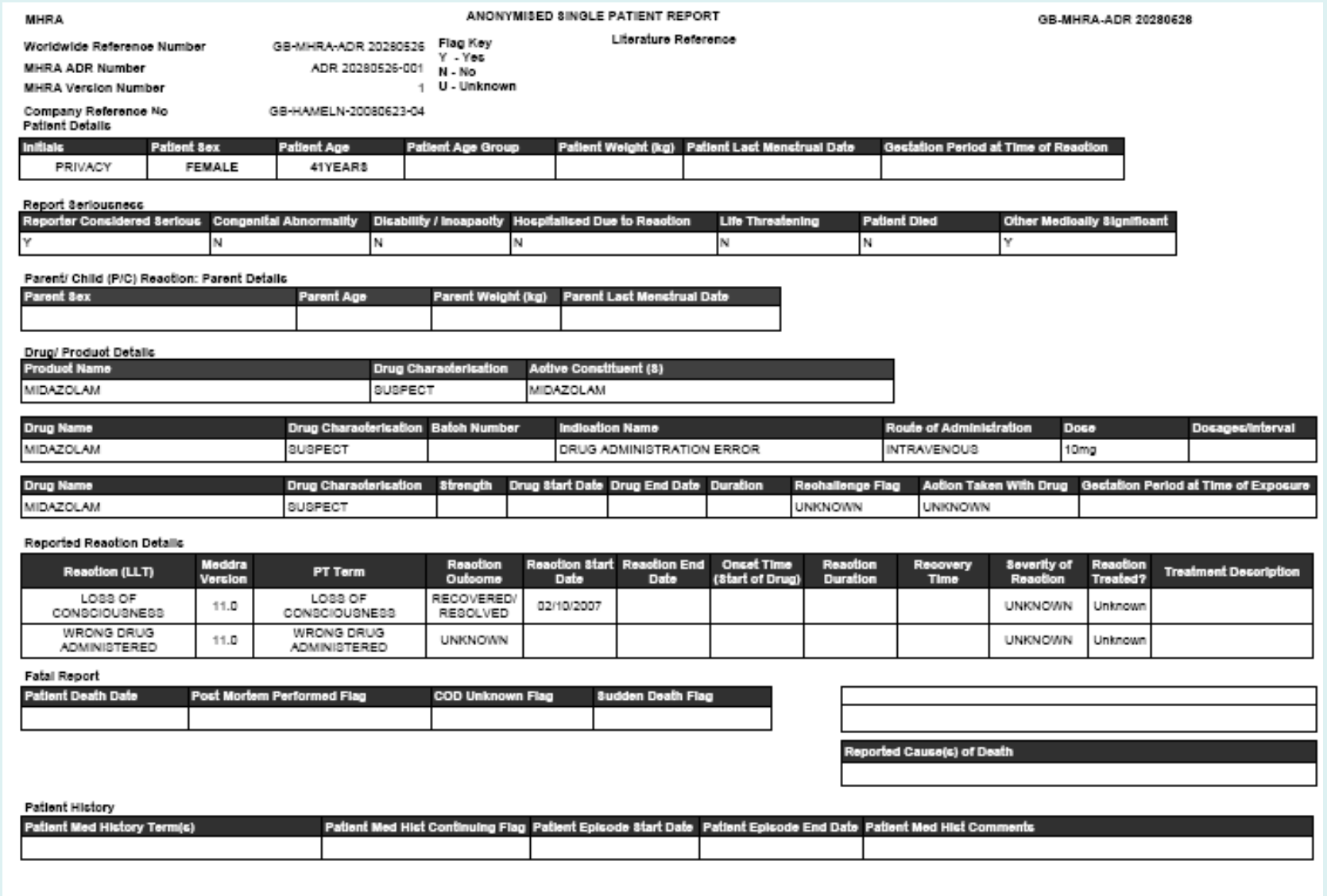
Sharing data from the Pharmacovigilence system in the UK

Weekly sharing of vigilance reports with medication error / human factors issues



MHRA

ANONYMISED SINGLE PATIENT REPORT

GB-MHRA-ADR 20280628

Worldwide Reference Number: GB-MHRA-ADR 20280526
MHRA ADR Number: ADR 20280526-001
MHRA Version Number: 1
Company Reference No: GB-HAMELN-20080623-04

Flag Key
Y - Yes
N - No
U - Unknown

Literature Reference

Patient Details

Initials	Patient Sex	Patient Age	Patient Age Group	Patient Weight (kg)	Patient Last Menstrual Date	Gestation Period at Time of Reaction
PRIVACY	FEMALE	41YEARS				

Report Seriousness

Reporter Considered Serious	Congenital Abnormality	Disability / Incapacity	Hospitalised Due to Reaction	Life Threatening	Patient Died	Other Medically Significant
Y	N	N	N	N	N	Y

Parent/ Child (P/C) Reaction: Parent Details

Parent Sex	Parent Age	Parent Weight (kg)	Parent Last Menstrual Date

Drug/ Product Details

Product Name	Drug Characterisation	Active Constituent (s)
MIDAZOLAM	SUSPECT	MIDAZOLAM

Drug Name	Drug Characterisation	Batch Number	Indication Name	Route of Administration	Dose	Dosages/Interval
MIDAZOLAM	SUSPECT		DRUG ADMINISTRATION ERROR	INTRAVENOUS	10mg	

Drug Name	Drug Characterisation	Strength	Drug Start Date	Drug End Date	Duration	Rechallenge Flag	Action Taken With Drug	Gestation Period at Time of Exposure
MIDAZOLAM	SUSPECT					UNKNOWN	UNKNOWN	

Reported Reaction Details

Reaction (LLT)	Meddra Version	PT Term	Reaction Outcome	Reaction Start Date	Reaction End Date	Onset Time (Start of Drug)	Reaction Duration	Recovery Time	Severity of Reaction	Reaction Treated?	Treatment Description
LOSS OF CONSCIOUSNESS	11.0	LOSS OF CONSCIOUSNESS	RECOVERED/ RESOLVED	02/10/2007					UNKNOWN	Unknown	
WRONG DRUG ADMINISTERED	11.0	WRONG DRUG ADMINISTERED	UNKNOWN						UNKNOWN	Unknown	

Fatal Report

Patient Death Date	Post Mortem Performed Flag	COD Unknown Flag	Sudden Death Flag

Reported Cause(s) of Death

Patient History

Patient Med History Term(s)	Patient Med Hist Continuing Flag	Patient Episode Start Date	Patient Episode End Date	Patient Med Hist Comments

MHRA

ANONYMISED SINGLE PATIENT REPORT

GB-MHRA-ADR 20280526

Patient Drug History

Patient Historic Drug Name	Patient Hist Indication Term(s)	Drug Start Date	Drug End Date	Patient Hist Reaction Term(s)

Parent History

Parent Med History Term(s)	Parent Med Hist Continuing Flag	Parent Medical Start Date	Parent Medical End Date	Parent Med Hist Comments

Parent Drug History

Parent Historic Drug Name	Parent Hist Indication Term(s)	Parent Past Drug Start Date	Parent Past Drug End Date	Parent Hist Reaction Term(s)

Test Results

Test Performed Date	Test Name	Test Result	Low Test Range	High Test Range	Report On File Flag

Additional Test

Reaction Text:

A female nauseous patient was prescribed intravenous metoclopramide 10 mg for nausea. A staff nurse accidentally administered 10 mg of midazolam intravenously and the patient collpased. The nurse became immediately aware of her error and corrective treatment was initiated. The patient made full recovery on the same afternoon.

Reporter Comments:

The reporter considers the existence of three contributing factors: the drugs were allocated in a drug cupboard next to each other, both drugs have similar coloured boxes and begin with M. Contradictorily, the event was assessed as not possibly related to the suspect drug by the reporter.

Worldwide Reference Number GB-GlaxoSmithKline-B0360774A
MHRA ADR Number ADR 20206618-003
MHRA Version Number 3
Company Reference No GB-GlaxoSmithKline-B0360774A

Flag Key
Y - Yes
N - No
U - Unknown

Literature Reference

Patient Details

Initials	Patient Sex	Patient Age	Patient Age Group	Patient Weight (kg)	Patient Last Menstrual Date	Gestation Period at Time of Reaction
PRIVACY	FEMALE	22YEARS				

Report Seriousness

Reporter Considered Serious	Congenital Abnormality	Disability / Incapacity	Hospitalised Due to Reaction	Life Threatening	Patient Died	Other Medically Significant
Y	N	N	N	N	N	Y

Parent/ Child (P/C) Reaction: Parent Details

Parent Sex	Parent Age	Parent Weight (kg)	Parent Last Menstrual Date

Drug/ Product Details

Product Name	Drug Characterisation	Active Constituent (s)
PAROXETINE HYDROCHLORIDE	SUSPECT	PAROXETINE
RISPERIDONE	SUSPECT	RISPERIDONE
AMITRIPTYLINE	OTHER	AMITRIPTYLINE
CITALOPRAM	OTHER	CITALOPRAM
DIAZEPAM	OTHER	DIAZEPAM
DIHYDROCODEINE	OTHER	DIHYDROCODEINE
DOSULEPINE	OTHER	DOTHIEPIN
DULOXETINE	OTHER	DULOXETINE
EFEXOR	OTHER	VENLAFAXINE HYDROCHLORIDE
FLUOXETINE	OTHER	FLUOXETINE
GAMANIL	OTHER	LOFEPRAMINE HYDROCHLORIDE
LORAZEPAM	OTHER	LORAZEPAM
LORMETAZEPAM	OTHER	LORMETAZEPAM
METHADONE	OTHER	METHADONE
MIRTAZAPINE	OTHER	MIRTAZAPINE
ORLISTAT	OTHER	ORLISTAT
PROTHIADEN	OTHER	DOTHIEPIN HYDROCHLORIDE
QUETIAPINE	OTHER	QUETIAPINE
REBOXETINE	OTHER	REBOXETINE
ROACCUTANE	OTHER	ISOTRETINOIN
TRAZODONE	OTHER	TRAZODONE

MHRA

Drug Name	Drug Characterisation	E
PAROXETINE HYDROCHLORIDE	SUSPECT	
RISPERIDONE	SUSPECT	
AMITRIPTYLINE	OTHER	
CITALOPRAM	OTHER	
DIAZEPAM	OTHER	
DIHYDROCODEINE	OTHER	
DOSULEPINE	OTHER	
DULOXETINE	OTHER	
EFEXOR	OTHER	
FLUOXETINE	OTHER	
GAMANIL	OTHER	
LORAZEPAM	OTHER	
LORMETAZEPAM	OTHER	
METHADONE	OTHER	
MIRTAZAPINE	OTHER	
ORLISTAT	OTHER	
PROTHIADEN	OTHER	
QUETIAPINE	OTHER	
REBOXETINE	OTHER	
ROACCUTANE	OTHER	
TRAZODONE	OTHER	

Reported Reaction Details:

Reaction (LLT)	Meddra Version	PT Term	Reaction Outcome	Reaction Start Date	Reaction Dat
AGGRESSION	11.0	AGGRESSION	UNKNOWN	13/08/1999	
AGITATION	11.0	AGITATION	UNKNOWN	13/08/1999	
BALANCE DIFFICULTY	11.0	BALANCE DISORDER	UNKNOWN	08/1999	
BLURRED VISION	11.0	VISION BLURRED	UNKNOWN	13/08/1999	
CONFUSION	11.0	CONFUSIONAL STATE	UNKNOWN	13/08/1999	
DELIBERATE SELF-HARM	11.0	INTENTIONAL SELF-INJURY	UNKNOWN	12/10/2006	
DIARRHEA	11.0	DIARRHOEA	UNKNOWN	13/08/1999	
DIZZINESS	11.0	DIZZINESS	UNKNOWN	03/1999	
ELECTRIC SHOCK SENSATION	11.0	PARAESTHESIA	UNKNOWN	13/08/1999	
FATIGUE	11.0	FATIGUE	UNKNOWN	13/08/1999	
FLU SYMPTOMS	11.0	INFLUENZA	UNKNOWN	13/08/1999	
HAIR DISORDER	11.0	HAIR DISORDER	UNKNOWN	07/1999	
HEAD INJURY	11.0	HEAD INJURY	UNKNOWN	06/1999	
JERKINESS	11.0	DYSKINESIA	UNKNOWN	13/08/1999	
LETHARGY	11.0	LETHARGY	UNKNOWN	13/08/1999	
LOW MOOD	11.0	DEPRESSED MOOD	UNKNOWN	13/08/1999	
MEMORY DEFICIT	11.0	MEMORY IMPAIRMENT	UNKNOWN	13/08/1999	
OVERDOSE	11.0	OVERDOSE	UNKNOWN	12/10/2006	
OVERDOSE	11.0	OVERDOSE	UNKNOWN	20/06/2006	
PANIC ATTACK	11.0	PANIC ATTACK	UNKNOWN	08/1999	
SCALP INJURY NOS	11.0	SKIN INJURY	UNKNOWN	06/1999	
SLEEP DISTURBANCE	11.0	SLEEP DISORDER	UNKNOWN	13/08/1999	
SLEEPINESS	11.0	SOMNOLENCE	UNKNOWN	06/2002	
SUICIDAL BEHAVIOR	11.0	SUICIDAL BEHAVIOUR	UNKNOWN	13/08/1999	
SUICIDAL IDEATION	11.0	SUICIDAL IDEATION	UNKNOWN	13/08/1999	
SWEATING	11.0	HYPERHIDROSIS	UNKNOWN	13/08/1999	
VERTIGO	11.0	VERTIGO	UNKNOWN	13/08/1999	
VIOLENCE	11.0	AGGRESSION	UNKNOWN	13/08/1999	
VOMITING	11.0	VOMITING	UNKNOWN	13/08/1999	
WITHDRAWAL REACTION	11.0	WITHDRAWAL SYNDROME	UNKNOWN	13/08/1999	

Patient History

Patient Med History Term(s)
ACNE
ALCOHOL ABUSE
DEPRESSION
DRUG ABUSE
DRUG ABUSE
ECZEMA
OVERDOSE
OVERDOSE
OVERDOSE
SELF ESTEEM DECREASED
STRESS

Patient Drug History

Reaction Text:

This case was reported by a lawyer (in relation to alleged 'withdrawal') and described the occurrence of withdrawal in a female patient who received paroxetine. This narrative has been written after review of medical notes provided as part of the action received on 15th August 2005:This patient has a history of acne and eczema managed by a dermatologist. "She has a history of depression relating to previous skin problems". After trying amitriptyline and Edronax which were not tolerated, the patient was switched to paroxetine 20mg daily on 29/04/1998.Out of hours service notes 26-03-1999: stopped paroxetine 'Monday' and 'feels dizzy etc'.Out of hours service notes 13-08-1999: weaning off paroxetine but experiencing problems with panic attacks and loss of balance. "Happened before when came off". (NOS)There appears to have been an interaction between the patient and a solicitor regarding a claim "for damages arising out of damage to her hair which occurred in July 1999" which seems to have occurred when the patient was weaning herself off paroxetine. "She suffered considerable damage to her scalp and head in June 1999 and this caused her further depression" (solicitor's letter to GP). (The GP responded that the patient was treated for dandruff.) Another letter from the GP to the solicitor states that the patient had contacted the surgery on 21/06/1999 and 14/08/1999 to say that she couldn't cope without her paroxetine and low doses (unclear) were continued.On 28/06/2002, the patient had low mood, her dose of paroxetine was increased to 40mg daily and she requested amphetamines -declined. The patient appears to have been switched to venlafaxine in April 2003 as she was feeling very low and too sleepy on paroxetine.She was seen In A&E following overdose of 20 x 75mg venlafaxine on 21-08-2004 but took her own discharge against medical advice. In March 2005, she had an urgent referral for suicidal ideation without intent (having come off venlafaxine 5 months earlier).A letter from psychiatrist dated 20/04/2005 says that the patient now felt that her depression had started after the birth of her child 8 years earlier; had been on several antidepressants which worked for a while; "felt that paroxetine 'did something funny to her' and she has since become amotivated and lethargic". The psychiatrist did not feel that the patient needed input from the mental health team.The patient took an overdose and attended A&E on 25/07/2005 but did not wait to be seen by doctor. (Her drugs were not specified but the other notes suggest that she would have been taking lofepramine at the time.)Follow up information received on 05 May 2006:No additional relevant information was identified in this set of hospital notes.This case was received as part of a legal action- medical records available on request.Follow-up received on 03 January 2008.A Claimant Schedule of Information, completed and signed by the claimant, was received by GSK from the claimant's lawyers.Pre-prescription medical conditions were listed as depression. The claimant stated that there were not any pre-existing conditions of a nature relevant or similar to the alleged injuries.Seroxat was first prescribed on 29 April 1998 and was subsequently prescribed at various dates between 16 September 1998 and 04 October 2005. Other anti-depressant medication taken during this period by the patient included venlafaxine hydrochloride, lormetazepam, lorazepam, diazepam, lofepramine hydrochloride and dothlepin hydrochloride.Alleged injuries included agitation, confusion, diarrhoea, electric zaps, jolting, aggression, sweating, vertigo, 'server' sleep disturbance, flu symptoms, fatigue, suicidal, blurred vision, dizziness, vomiting, lethargy, poor memory and violent outburst. The date of first onset (not further specified) was 13 August 1999 and date of first diagnosis (not further specified) was 13 August 1999. The duration of the alleged injuries was 6 years.Additional information from medical records received 23 May 2008.The patient had a family history of mental illness with her mother, an aunt and two of her brothers being treated for depression and another aunt and a cousin having committed suicide by taking overdoses. The patient had variously claimed to have been depressed since a teenager or since the birth of her only child in November 1996. She had always noted a strong association with her menstrual cycles, being at her worst mood-wise for a week before menstruation. The patient was treated twice with roaccutane in 1997 and 1998. This caused pruritis and a worsening of her eczema. The patient received at least two antidepressants (amitriptyline in October 1997 and fluoxetine in January 1998) prior to paroxetine.Paroxetine was prescribed from 29 April 1998 to 29 January 2003 when it was noted that she was "very low and too sleepy with fleeting thoughts of self harm". She was changed to venlafaxine and propranolol and subsequently has had a significant number of antidepressants (including dosulepine April 2005, quetiapine July 2005, duloxetine May 2006, reboxetine July 2006 which caused sweating, citalopram December 2006 which caused vomiting, trazodone December 2006, mirtazapine February 2007, risperidone May 2007 which seemed to produce worsening of suicidal ideation when discontinued suddenly, fluoxetine again in November 2007). She was prescribed orlistat for weight loss in 2004. She has been described as a long standing depressive with underlying poor self esteem and poor self worth with poor coping strategies. Her care had been compromised by her frequent non-attendance at appointments, referrals and therapeutic interventions. She had taken a number of overdoses at times of stress (August 2004, September 2004, July 2005, November 2005, June 2006, October 2006 and July 2007). Her care has been further complicated by substance abuse (cannabis at school leading to paranoia, amphetamines for weight loss before 2004, ecstasy, cocaine, dihydrocodeine in 2006, diazepam in 2005 and methadone in 2006). She has also abused alcohol with excessive consumption noted in 2006 (2x diazepam detoxifications required and 2 occasions of injury whilst intoxicated) and in 2007 it was noted she had a weekly intake of about 100 units. A letter dated 9 October 2007 reported "suicidal thoughts on and off for 2 years, last around a week then go away... worse... with... menstrual cycle approximately one week before period. Hearing one voice which she recognises as her own. Denies illicit drug use since Feb 2007 diagnosis situational crisis and mild depressive mood."On 6 May 2008 she was reported to be taking amitriptyline 10mg 1-2 at night with fluoxetine 40mg having been dispensed on 14 April 2008. She was complaining of abdominal pain in the right iliac fossa and had a negative pregnancy test. She also admitted to a low mood and to hearing a voice (her own, inside her head).The outcome of the events is unknown. These medical records were received as part of a legal action and are available on request.The following information was obtained from medical records received 24 June 2008:On 20 June 2006, the patient ingested an overdose of 14 Valium tablets and 14 dosulepin tablets, with 2 cans of beer; there was also a "possibility of overdose of codyramol". She was treated in A&E where it was noted that she "expresses suicidal ideation". The patient was also agitated and aggressive and required sedation. The psychologist noted that she had taken the overdose "in response to on-going low mood and recent relationship breakdown", and "did deny any further active suicidal ideation".On 12 October 2006, the patient was treated in A&E following an alleged overdose of reboxetine and alcohol, recorded as "deliberate self-harm". She also had injuries to her face and stomach and a broken tooth, as a result of an "alleged assault".

MHRA incident 14/7/08

- *“Due to the patient's poor eyesight, a nurse administered the daily insulin glargine.*
- *On the day of the ADRs, the nurse who came to administer the insulin glargine had not seen the patient or the Opticlik before and had not received any training on the use of the Opticlik.*
- *When the nurse attempted dialling the Opticlik, the pen jammed. The next Opticlik pen she tried also jammed. The nurse then drew up the insulin glargine from within the Opticlik cartridge system with a needle and syringe.*

- *The nurse then drew up the insulin glargine from within the Opticlik cartridge system with a needle and syringe.*
- *The syringe was not an insulin syringe, and the nurse misread what she was supposed to administer.*
- *The patient was supposed to receive 36 units. The nurse injected three times, until the cartridge became empty, and then withdrew an additional 60 units from a second cartridge and injected this.*
- *The patient received a total of 360 units of insulin. Two to three hours later the patient was falling asleep in the car with a friend. The patient became hot, flushed, and did not feel well. She required assistance getting out of the car, and fell to the floor.*
- *The paramedics were called, and the patient died. It was reported that the patient had hypoglycaemia and her heart had stopped. The pens were independently tested due to this being a criminal case, and they were*

Search of NPSA incident database

- Search date: 01Jan05 to 01Apr08
- Search Terms: 2 NRLS searches run
- 1/ “syringe” AND “insulin” AND “mls” (generated 102 incidents, of these 11 were found to be related)
- 2/ “not an insulin syringe" or "non-insulin syringe" or "non insulin syringe" (generated 1 incident)

NRLS Report

Degree of harm	Frequency	Validated
Death	0	0
Severe	0	0
Moderate	3	1
Low	3	6
No harm	6	5

Case report 1

- Comments by student midwife that midwife may have inadvertently given 0.8mls of insulin in a 1ml syringe with an orange needle.
- 8 iu were prescribed.
- Woman had severe hypo requiring dextrose and a sliding scale insulin. She reported her concerns to the midwife who came on duty on the next shift.
- Moderate

Case report 2

- Nurse was performing morning drug round preparing IM injections - one for injection of Insulatard (60 units - 1ml - 100units) and one heparin injection (5000units - 1ml - 5000units).
- Two syringes were on nurses' station, "an insulin syringe for Insulatard and a 10mls syringe for heparin.
- Nurse took three calls whilst standing "/ "preparing injections.
- Insulatard drawn up mistakenly in 10mls syringe - amount drawn up 6 mls instead of 0.6mls. Staff nurse started to give, realised mistake after approx 3-4 mls given. Moderate

Case Report 3

- *When setting up GKI infusion used wrong syringe*
- *added incorrect amount of insulin - 1.2 mls instead of 12 units.*

Case report 4

- Sliding scale insulin for patient.
- Drugs added label incorrect.
- Drug added actrapid, quantity 10mls.
- The correct dose for sliding scale is 50 units of actrapid not 10mls.

Last Updated: Monday, 3 September 2007, 13:08 GMT 14:08 UK

E-mail this to a friend Printable version

Doctor gives fatal insulin dose

A 92-year-old man died of a heart attack after a junior doctor gave him a drugs overdose, an inquest has heard.

Mr Johnston was being treated at Belfast City Hospital

Walter Kenneth Johnston was injected with 100 times the correct dose of insulin by a junior doctor at Belfast City Hospital.

Dr Nuzaimin Ahmad claimed he did not know how to treat him.

He used the wrong syringe to administer the drug in the early hours of 25 February 2005. Dr Ahmad no longer practises in the UK.

Belfast Coroner's Court heard he had only been working at the hospital for three weeks.

A letter from the doctor read out in court said he believed that "one unit of insulin was equivalent to one millilitre".

"I have not received any previous instruction in the handling of insulin," it said.

News Front Page

Africa
Americas
Asia-Pacific
Europe
Middle East
South Asia
UK
England
Northern Ireland
Scotland
Wales
UK Politics
Education
Magazine
Business
Health

Last Updated: Tuesday, 26 July, 2005, 16:24 GMT 17:24 UK

E-mail this to a friend Printable version

Patient given 'insulin overdose'

Doctors in NI are to receive fresh guidance on how to administer insulin.

The incident happened at Belfast City Hospital four years ago

It follows an inquest into the death of an elderly woman who was given ten times the dose of insulin she needed.

The inquest heard Sarah Smith, 90, from Whiterock Parade in Belfast, became semi-conscious and died after choking on food. It happened four years ago.

The inquest was told it had emerged later that the junior doctor treating her at Belfast City Hospital had not been shown how to measure insulin.

RELATED
Departm
Services
The BBC i
content o

TOP NOR
Police at
Joyriders
Tourists

Ne

Last Updated: Wednesday, 1 February 2006, 07:02 GMT

Hospitals admit insulin overdoses

Hospitals in Northern Ireland have said staff gave wrong dosages of insulin to patients 33 times in recent years.

Two patients received fatal overdoses at Belfast City Hospital

Two patients received fatal overdoses at Belfast's City Hospital. On another two occasions, incorrect amounts were administered to patients.

The Royal Victoria Hospital had nine cases of incorrect doses and seven hospitals had one to four incidents.

All NI hospitals were asked to check records for insulin overdoses over 10 years. Most were unable to do so.

BBC NI's health correspondent Dot Kirby said that last year, an inquest was held into the death of an elderly woman in the City Hospital in Belfast.

"She died in 2001 because a junior doctor gave her too much insulin. After her death, the hospital said they immediately instigated a number of measures to ensure that 'such events would not happen again,'" she said.

Agency for Healthcare Research and Quality
web M&M Morbidity & Mortality Rounds on the Web

Primary Care | August 2006

It's All in the Syringe

The Case

A 33-year-old man with type 2 diabetes presented to his physician's office to discuss his diabetes management. The patient admitted not taking his medications or checking his blood sugars regularly. In the office, his blood sugar was 335 mg/dL, so the nurse practitioner (NP) ordered 6 units of regular insulin to administer.

After the medical assistant brought the insulin and syringe, the NP prepared the medication and injected the insulin. Immediately after the injection, the NP discovered that a tuberculin syringe was used instead of an insulin one. As a result of the error, the patient inadvertently received 60 units of insulin rather than 6 units. The patient was given orange juice, a sandwich, and his blood sugars were closely monitored for 4 hours with no significant events.

NHS
National Patient Safety Agency

Rapid Response Report

NPSA/2008/RRR001

From reporting to learning

22 January 2008