

Cases Count: 23

**Case Number : 232065** 

Gender: F

Data Entry Date: 16/08/2007 Weight (kg): 0

Hospitalisation: Age: 84Y

Onset Date : DOB :

Outcome: 12/08/2007 Causality: Causality possible

Recovered with sequelae

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Psychotic disorder Caused or prolonged

inpatient hospitalisation Psychosis, due to lithium dose increase or addition of other antipsychotics (

not specified).

**Medicine details:** 

LITHIUM CARBONATE (Suspected) Reason :

Tablet 750 Milligram Daily

**Batch**: **Started**: 01/08/2007 **Stopped**: 05/08/2007

AROPAX (Other drug) Reason :

Tablet 20 Milligram Daily

Batch: Started: Stopped:

BETALOC (Other drug) Reason :

Tablet 50 Milligram 2 times

Batch: Started: Stopped:

COLGOUT (Other drug) Reason :

Tablet 500 Microgram Daily

Batch: Started: Stopped:

DI-GESIC (Other drug) Reason :

Tablet 2 3 times

Batch: Started: Stopped:

MADOPAR (Other drug) Reason :

Tablet 62.5 Milligram Daily

Batch: Started: Stopped:

OROXINE (Other drug) Reason :

Tablet 150 Microgram Daily

Batch: Started: Stopped:

Ostevit D (Other drug) Reason :

Tablet 1000 Unit Daily

Batch: Started: Stopped:

PLAVIX (Other drug) Reason :

Tablet 75 Milligram Daily

Batch: Started: Stopped:

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Medicine details :						
TEMAZEPAM (Other drug)		Re	ason :			
Tablet		10 Milligram	Daily			
Batch :	Started :			Stopped :		
ZYLOPRIM (Other drug)		Re	ason :			
Tablet		200 Milligram	Daily			
Batch :	Started :			Stopped :		
ZYPREXA (Other drug)		Re	ason :			
Tablet		5 Milligram	Daily	Oral		
Batch :	Started :			Stopped :	0	

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Cases Count: 23

Case Number: 232364 Gender: F

Data Entry Date: 22/08/2007 Weight (kg): 0

Hospitalisation: Age: 43Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: the reporting healthcare practitioner suspected that the event may be due to lithium

overdose but was unsure.

Reaction:

Preferred Term Severity Report Description Treatment

Renal failure acute Patient experienced acute

renal failure.

Medicine details:

CLOZAPINE (Suspected) Reason :

Tablet 200 Milligram Daily Oral

Batch: Started: Stopped:

LITHIUM CARBONATE (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 23

Gender: M

Case Number: 233948

**Data Entry Date**: 02/10/2007 **Weight (kg)**: 0

Hospitalisation: Age: 23Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: The patient underwent pre-clozapine investigations, including an electrocardiogram,

echocardiograph, full blood count, hepatic and renal function tests, creatine kinase and troponin I, a CT scan of the brain and electroencephalograph, all of which were normal. Varambally S, Howpage P. Acute myocarditis associated with clozapine. Australian

Psychiatry; Aug 2007, 15(4): 343-346.

Reaction :		
Preferred Term	Severity	Report Description
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, chest pain, heart rate increased, tachycardia, chest discomfort, body temperature increased, troponin increased, blood creatine phosphokinase increased, C-reactive protein increased, dyspnoea, white blood count increased.
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation	
Body temperature increased	Caused or prolonged inpatient hospitalisation	
C-reactive protein increased	Caused or prolonged inpatient hospitalisation	
Chest discomfort	Caused or prolonged inpatient hospitalisation	
Chest pain	Caused or prolonged inpatient hospitalisation	
Dyspnoea	Caused or prolonged inpatient hospitalisation	
Heart rate increased	Caused or prolonged inpatient hospitalisation	
Neutrophil count increased	Caused or prolonged inpatient hospitalisation	
Tachycardia	Caused or prolonged inpatient	

hospitalisation

### **Treatment**

All psychiatric medications were ceased. He was placed on low doses of bisoprolol and ramipril by the cardiac team.

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Reaction:

Preferred Term Severity Report Description Treatment

Troponin I increased Caused or prolonged

inpatient

hospitalisation

Weight increased Caused or prolonged

inpatient

hospitalisation

White blood cell count

write blood cell court

increased

Caused or prolonged

inpatient hospitalisation

Medicine details:

CLOPINE (Suspected) Reason: Unspecified schizophrenia

12.5 Milligram Daily

Batch: Started: Stopped: 0

FLUOXETINE HYDROCHLORIDE (Suspected) Reason : Depression

Batch: Started: Stopped:

LITHIUM CARBONATE (Suspected) Reason : Depression

Batch: Started: Stopped:

OLANZAPINE (Other drug) Reason :

15 Milligram

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Heart Rate Heart rate 160/min

Temperature Body temperature 38.4

Troponin Troponin I 10.37 (range up to 0.1).

Creatine Creatine kinase 259 (range up to 171).

phosphokinase

C-Reactive Protein C-Reactive protein 43.2 (range up to

5.0).

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Cases Count: 23

Lithium was temporarily ceased.

**Case Number : 235290** 

Gender: F

**Data Entry Date**: 14/11/2007 **Weight (kg)**: 60

 Hospitalisation :
 Age :

 Onset Date :
 24/10/2007

 DOB :
 30/09/1952

Outcome: 30/10/2007 Causality: Causality possible

Recovered

Information: She has had previous acute organic brain disorder/syndrome secondary to Cabaser in

past.i

Reaction:

Preferred Term Severity Report Description Treatment

Mental disorder due to a Caused or prolonged general medical condition inpatient

hospitalisation

Patient has Parkinson's disease and history of stable bipolar disorder. She was seen by her

psychiatrist the week preceding the study commencement, and had her dose of Lithium increased. She commenced placebo rivastigmine on 23/10/07. She developed what has been diagnosed as an "acute organic brain"

syndrome" secondary to Litium toxicity.

### Medicine details:

LITHIUM CARBONATE (Suspected) Reason : Unspecifid affective psychosis

Tablet 1 Gram Daily Oral

**Batch**: **Started**: **Stopped**: 24/10/2007

RIVASTIGMINE (Suspected) Reason :

Capsule 3 Milligram Daily Oral

**Batch**: **Started**: 23/10/2007 **Stopped**: 24/10/2007

CABASER (Other drug) Reason :

1 Dose Unspec Daily

Batch: Started: Stopped:

MADOPAR (Other drug) Reason : Paralysis agitans

1 Dose Unspec Daily

Batch: Started: L TERM Stopped:

SYMMETREL (Other drug) Reason : Paralysis agitans

Capsule 200 Milligram Daily Oral

Batch: Started: L TERM Stopped:

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Cases Count: 23

Case Number: 235737

Gender: F

**Data Entry Date**: 28/11/2007 **Weight (kg)**: 0

Hospitalisation: Age:

**Onset Date**: 05/06/2007 **DOB**: 01/08/1967

Outcome: Causality: Causality possible

Recovered

**Information:** Patient was consuming approximately 10Lit of coke per day.

Reaction:

Preferred Term Severity Report Description Treatment

nephrogenic diabetes insipidus. ? Ziprasidone induced hyperglycaemia.

(? Psychogenic polydipsia). Hyperosmolar

non-ketotic coma?

Hyperglycaemia Life threatening
Nephrogenic diabetes Life threatening

Nephrogenic diabetes insipidus

Medicine details:

LITHIUM CARBONATE (Suspected) Reason :

Tablet 1.5 Gram Daily Oral

Batch: Started: L TERM Stopped: 05/06/2007 0

Ziprasidone (Suspected) Reason : Diabetes mellitus

Capsule 160 Milligram Daily Oral

Batch: Stopped: 05/06/2007

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Serum glucose = 63mmol/L

Sodium Na + = 152 mmol/L.

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Cases Count: 23

**Case Number: 236769** 

Gender: F

**Data Entry Date**: 08/01/2008 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Thinking abnormal Caused or prolonged "I felt my brain was Lithium stopped. Now on Epilim.

inpatient BLOCKED. I couldn't think hospitalisation straight or creatively".

Severe chest pain leading

to collapse.

Chest pain Caused or prolonged

inpatient hospitalisation

Poverty of thought content Caused or prolonged

inpatient hospitalisation

Thought blocking Caused or prolonged

inpatient hospitalisation

Medicine details:

LITHIUM CARBONATE (Suspected) Reason : Unspecifid affective psychosis

Tablet Oral

Batch: Started: L TERM Stopped: 0

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Cases Count: 23

**Case Number : 237529** 

Gender: M

**Data Entry Date**: 04/02/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date: 21/12/2007

**DOB**: 30/05/1969

Outcome:

Causality: Causality probable

Not yet recovered

Information:

Reaction:

Preferred Term Severity

Report Description

**Treatment** 

Drug eruption

Caused or prolonged

d Herpetiform rash on trunk.
Confluent maculopapular

inpatient hospitalisation

Caused or prolonged

ion rash on arms.

inpatient

hospitalisation

Rash vesicular

Rash maculo-papular

Caused or prolonged

inpatient

hospitalisation

**Medicine details:** 

LITHIUM CARBONATE (Suspected)

Reason: Unspecifid affective psychosis

Batch :

Started :

STERM

Stopped:

0

ATENOLOL (Other drug)

Reason: Essential benign hypertension

25 Milligram

Daily

Batch :

Started :

**S TERM** 

Stopped:

**MIRTAZAPINE (Other drug)** 

**Reason:** Unspecifid affective psychosis

45 Milligram

Daily

Batch:

Started :

L TERM

Stopped:

**Laboratory Investigations:** 

Type

Range

Date Tested Result

Details

Skin biopsy

Confirmed reaction to lithium on skin

biopsy

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Cases Count: 23

Case Number: 238757

Gender: F

Data Entry Date: 10/03/2008 Weight (kg): 0

Hospitalisation: Age: 22Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Electrocardiogram QT electrocardiogram QT prolonged interval abnormal:

corrected QTc >500ms

ogram QT Zeldox ceased

Medicine details:

LITHIUM CARBONATE (Suspected) Reason :

Batch: Started: Stopped:

Zeldox (Suspected) Reason :

Capsule 400 Milligram Daily Oral

Batch: Started: Stopped: 0

QUETIAPINE (Other drug) Reason :

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

QT interval QTc greater than 500ms

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Cases Count: 23

**Case Number : 239203** 

Gender: M

**Data Entry Date**: 25/03/2008 **Weight (kg)**: 0

Hospitalisation: Age: 64Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

### Reaction:

Preferred Term
Drug interaction

### Severity

Caused or prolonged inpatient hospitalisation

### Report Description In Sep/Oct 2007, the

patient's Lithium levels

increased to 0.8 (unit and reference range unspecified). The patien's renal function drecreased (unspecified). In late 2007 the patient developed hypothyroidism. On an unspecified date the patient experienced parkinsonian syndrome, cognitively "dull", "catatonic" with arms hanging down and open mouth. Suspected Lithium toxicity. The Lithium was discontinued (date unspecified) and the risperdone was decreased to 0.5mg daily and the valproate continued (dose unspecified). The patient's

lithium level was 3 (value unspecified) (normal reference range unspecified) prior to

cessation.

On an unspecified date (late 2007 or early 2008) the patient fell over and was hospitalised with renak failure. The litium level dropped to 1 but, the patient remained "Parkinsonian" It was suspected that the patient was experiencing encephalopathy due to a suspected drug interaction between lithium and risperidone.

Fall Caused or prolonged

inpatient hospitalisation

#### **Treatment**

Lithium was withdrawn, risperidone was reduced.

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Reaction:

Renal failure

Preferred Term Severity Report Description Treatment

Hypothyroidism Caused or prolonged

inpatient

hospitalisation

Parkinsonism Caused or prolonged

inpatient hospitalisation

Caused or prolonged

inpatient

hospitalisation

Renal impairment Caused or prolonged

inpatient

hospitalisation

Toxic encephalopathy Caused or prolonged

inpatient

hospitalisation

Medicine details:

LITHIUM CARBONATE (Suspected) Reason :

1 Gram

Daily

Batch: Started: Stopped:

RISPERDAL (Suspected) Reason: Unspecifid affective psychosis

1 Milligram Daily

Batch: Started: Stopped: 0

SODIUM VALPROATE (Suspected) Reason :

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Serum drug level Lithium Lithium Lithium level was 3 (value unspecified)

(normal range unspecified) prior to cessation (date unspecified).
Lithium level dropped to 1 (value

unspecified) (normal range unspecified)

(date ununspecified)>

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Cases Count: 23

**Case Number : 239352** 

Hospitalisation: Admitted to hospital Age:

Onset Date: 04/03/2008 DOB: 01/11/1952

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Depressed mood Caused or prolonged

inpatient hospitalisation

Gradual worsening of depressed mood over the past six weeks, to the point of feeling suicidal and at risk of harming herself.

Medicine details:

ACETYLCYSTEINE (Suspected) Reason: Unspecifid affective psychosis

Batch: Started: Stopped:

EFEXOR (Suspected) Reason: Unspecifid affective psychosis

375 Milligram Daily

Batch: Started: Stopped: 0

LITHIUM CARBONATE (Suspected) Reason : Unspecifid affective psychosis

Tablet 900 Milligram Daily Oral

Batch: Started: Stopped: 0

**VALIUM (Suspected)** Reason: Unspecifid affective psychosis

10 Milligram Daily

Batch: Started: Stopped:

ZYPREXA (Suspected) Reason: Unspecifid affective psychosis

30 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 23

**Case Number : 240070** 

Gender: F

**Data Entry Date:** 16/04/2008 Weight (kg): 0

**Hospitalisation: Age:** 46Y

**Onset Date:** DOB:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

**Preferred Term** Severity **Report Description Treatment** Hyperparathyroidism

Hyperparathyroidism, nephrolithiasis and renal

cyst.

Ceased Lithium

Nephrolithiasis

Renal cyst

Medicine details:

LITHIUM CARBONATE (Suspected) Reason:

L TERM Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Calcium Calcium levels were found to be raised

> (2.63 mmol/L, normal range 2.10-2.60). Increased urinary calcium excretion. Calcium levels normalised after Lithium

was ceased.

Other data Raised parathyroid horme (PTH) of 13 1.6-6.9

pmol/L

PTH remained elevated at 9.7 after

Lithium was ceased.

Ultrasound Renal ultrasound revealed small calculi.

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Cases Count: 23

Age:

**Case Number : 240325** 

Gender: F

**Data Entry Date: 23/04/2008** Weight (kg): 2.88

Hospitalisation: Admitted to hospital

Onset Date: 09/02/2008 **DOB**: 09/02/2008

Outcome: Causality: Causality possible

Not yet recovered

Information: Secretariat comment: F/N.

Reaction:

**Preferred Term** Severity **Report Description Treatment** 

Pulmonary valve stenosis Caused or prolonged

> inpatient hospitalisation

Baby born to a mother taking lithium for bipolar disorder. Diagnosed with critical pulmonary vaive stenosis. Duct dependent and requires cardiac surgery at hospital.

Drug exposure during

pregnancy

Caused or prolonged

inpatient

hospitalisation

Pulmonary valve stenosis

congenital

Batch:

Caused or prolonged

inpatient hospitalisation

Medicine details:

LITHIUM CARBONATE (Suspected) Reason:

Tablet 450 Milligram Oral Daily

Batch: Started: Stopped:

FLUOXETINE HYDROCHLORIDE (Other drug) Reason:

> Oral 40 Milligram

Batch: Started: Stopped:

FOLIC ACID (Other drug) Reason:

Started:

5 Milligram Oral

Reason:

Stopped:

**MULTIVITAMINS (Other drug)** 

1 Dose Unspec Oral

Batch: Started: Stopped:

THYROXINE SODIUM (Other drug) Reason:

Oral **Tablet** 100 Microgram Daily

Batch: Started: Stopped:

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Cases Count: 23

**Case Number : 242396** 

Gender: F

**Data Entry Date**: 30/06/2008 **Weight (kg)**: 0

**Hospitalisation**: Admitted to hospital Age:

**Onset Date**: 10/06/2008 **DOB**: 13/06/1962

Outcome: 14/06/2008 Causality: Causality probable

Recovered

Information: Previous serotonin syndrome several years ago when commenced on amisulpride

(resolved when amisulpride ceased).

Reaction:

Preferred Term Severity Report Description Treatment

Hyperreflexia Caused or prolonged Hy

inpatient hospitalisation

Hyper reflexia, ankle clonus, tremor, dilated pupils, tachycardia, increasing agitation and

restlessness, sweating.

Ziprasidone & phenelzine

0

stopped.

Agitation Caused or prolonged

inpatient

hospitalisation

Clonus Caused or prolonged

inpatient hospitalisation

Hyperhidrosis Caused or prolonged

inpatient hospitalisation

Neuroleptic malignant

syndrome

Tremor

Caused or prolonged inpatient

hospitalisation

.....

Restlessness Caused or prolonged

inpatient hospitalisation

Tachycardia Caused or prolonged

inpatient hospitalisation

Caused or prolonged

inpatient

hospitalisation

Medicine details:

LAMOTRIGINE (Interaction) Reason : Unspecified schizophrenia

400 Milligram Daily

Batch: Started: L TERM Stopped:

LITHIUM CARBONATE (Interaction) Reason: Unspecified schizophrenia

675 Milligram Daily

Batch: Started: L TERM Stopped: 0

PHENELZINE SULPHATE (Interaction) Reason: Unspecified schizophrenia

90 Milligram Daily

Batch: Started: L TERM Stopped: 0

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Medicine details: **QUETIAPINE** (Interaction) Reason: Unspecified schizophrenia 100 Milligram Daily LTERM Stopped: Batch: Started: Reason: Unspecified schizophrenia Ziprasidone (Interaction) 160 Milligram Daily Batch: Started: 05/06/2008 **Stopped**: 12/06/2008 0 **ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)** Reason: 40 Milligram Daily L TERM Started: Stopped: Batch: **INDAPAMIDE HEMIHYDRATE (Other drug)** Reason: 40 Milligram Daily Started : Stopped: Batch: **LEVLEN ED (Other drug)** Reason: 40 Milligram Daily

L TERM

Stopped:

Batch:

Started:

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**Cases Count: 23** 

Case Number: 243355

Gender: F

**Data Entry Date**: 31/07/2008 **Weight (kg)**: 0

Hospitalisation: Age: 21Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

**Information:** Patient had no history of neuroleptic malignant syndrome.

Reaction:

Preferred Term Severity Report Description Treatment

Neuroleptic malignant

syndrome

Dose of Seroquel was All three medications Ceased increased to 800mg daily as the lower dose was not

effective. In addition pt was on Epilim and Lithium. Pt developed neuroleptic malignant syndrome

Medicine details:

EPILIM (Suspected) Reason: Unspecifid affective psychosis

Tablet Oral

Batch: Started: Stopped: 0

LITHIUM CARBONATE (Suspected) Reason: Unspecifid affective psychosis

Tablet Oral

Batch: Started: Stopped: 0

SEROQUEL (Suspected) Reason : Unspecifid affective psychosis

Tablet 800 Milligram Daily Oral

Batch: Started: Stopped: 0

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Cases Count: 23

Case Number: 243368 Gender: F

**Data Entry Date**: 31/07/2008 **Weight (kg)**: 0

**Hospitalisation**: Required a visit to the doctor Age:

Onset Date: 15/01/2008 DOB: 27/01/1965

Outcome: Causality: Causality probable

Recovered

Information:

2	2	<b>~+</b> 1	$\sim$	n	
Re	aı	υu	v		•

Preferred Term Severity Report Description Treatment

Hypercalcaemia Sweats, rapid pulse, leg Lithium withdrawn.

cramps, constipation and blurred vision.

Blood parathyroid hormone

increased Constipation

Heart rate increased

Hyperhidrosis

Muscle spasms

Vision blurred

### Medicine details:

LITHIUM CARBONATE (Suspected) Reason: Unspecifid affective psychosis

Tablet 900 Milligram Daily Oral

Batch: Started: Stopped:

ACIMAX (Other drug) Reason :

Batch: Started: Stopped:

Adefin XL (Other drug) Reason :

Batch: Started: Stopped:

CARTIA (Other drug) Reason :

Batch: Started: Stopped:

COVERSYL PLUS (Other drug) Reason :

Batch: Started: Stopped:

LAMOTRIGINE (Other drug) Reason :

Batch: Started: Stopped:

MINIPRESS (Other drug) Reason :

Batch : Started : Stopped :

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Medicine details :			
SEROQUEL (Other drug)		Reason:	
Batch :	Started :		Stopped:

Laboratory Investigations	is:
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Range Туре Date Tested Result Details

Nuclear magnetic resonance Nuclear medicine scan negative

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Cases Count: 23

Case Number: 243844

Gender: F

**Data Entry Date**: 15/08/2008 **Weight (kg)**: 0

**Hospitalisation**: Required a visit to the doctor Age:

Onset Date: 15/02/2008 DOB: 12/11/1929

Outcome: Causality: Causality certain

Recovered

Information: CERT

Reaction:

Preferred Term Severity Report Description Treatment

Diarrhoea Usual lithium levels (for Ketoprofen tablets were ceased

years) 0.6mmol/L. Patient was noted to be

experiencing diarrhoea,

slurred speech,

drowsiness, unsteady gait and persistent low grade nausea. It had been attributed to her history of reflux and new oxycontin. Lithium level when tested

was 1.4mmol/L.

Ataxia

Dysarthria

Nausea

Somnolence

**Medicine details:** 

LITHICARB (Interaction) Reason : Unspecifid affective psychosis

2 Dose Unspec Daily

Batch: Started: Stopped:

ORUVAIL SR (Interaction) Reason : Pain

200 Milligram Daily Oral

**Batch**: **Started**: 15/01/2008 **Stopped**: 15/02/2008

ACIMAX (Other drug) Reason :

20 Milligram Daily

Batch: Started: Stopped:

KALMA (Other drug) Reason :

1 Milligram Daily

Batch: Started: Stopped:

Lexapro (Other drug) Reason :

20 Milligram Daily

Batch: Started: Stopped:

OXYCONTIN (Other drug) Reason : Pain

10 Milligram Daily

Batch: Started: 15/12/2007 Stopped:

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**Medicine details:** 

PANAMAX (Other drug) Reason :

6 Dose Unspec Daily

Batch: Started: Stopped:

VALPRO (Other drug) Reason : Unspecifid affective psychosis

1000 Milligram Daily

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Other data

Usual lithium levels 0.6 mmol/L.

Lithium result 1.4 mmol/L.

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Cases Count: 23

Case Number: 244638

Gender: M

Data Entry Date: 15/09/2008

Weight (kg): 0

**Hospitalisation:** 

Age:

Onset Date: 20/04/2007

**DOB**: 20/10/1960

Outcome:

Causality: Causality possible

Not yet recovered

Information: HIV +ve

Reaction:

Preferred Term Severity Report Description Treatment

Nephrogenic diabetes diabetes insipidus ceased lithium therapy,

insipidus (nephrogenic) switched to olanzapine therapy

Medicine details:

LITHIUM CARBONATE (Suspected) Reason: Unspecifid affective psychosis

750 Milligram

**Batch: Started: Stopped:** 17/12/2007

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Cases Count: 23

Case Number: 244731

Gender: M

**Data Entry Date**: 18/09/2008 **Weight (kg)**: 0

**Hospitalisation**: Admitted to hospital **Age**: 99u

Onset Date : DOB :

Outcome: Causality: Causality certain

Recovered

Information: Concurrent medical conditions included hypomanic episode and hypertension. Patient

had a family history of bipolar disorder in two first-degree relatives.

Parker G. Alert: Inaccurate Lithium Assay Results. Aus & NZ Journal of Psychiatry. 2008; 42: 643-645

The author's considered the events were related to treatment with Lithium carbonate. The author's commented that "on further testing, they established that when a serum level was high, the assay (provided by an independent major pharmaceutical company) performs an 'automatic dilution' that can then generate a falsely low value...Thus, patients with high lithium levels and at risk of toxicity are, paradoxically, most likely to generate a spuriousl;y low (and false) value, and therefore be at risk of inappropriate

clinical management".

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$\mathbf{r}$	50	L.L		

Preferred Term	Severity	Report Description	Treatment
Mania	Caused or prolonged inpatient hospitalisation	A patient who had experienced bipolar disorder for over 20 years and who had been euthymic for most of that period while highly compliant with lithium, had falsely low lithium levels reported over two periods, 6 years apart, and was actually lithium toxic on the most recent occasion. At that latter time the spuriously low lithium levels reported on the assay risked dispelling any clinical suspicion of lithium toxicity, although toxicity was later confirmed.	
Agitation	Caused or prolonged inpatient hospitalisation		
Anaemia	Caused or prolonged inpatient hospitalisation		
Blood creatinine increased	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		
Depression	Caused or prolonged inpatient hospitalisation		

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Reaction: **Preferred Term** Severity **Report Description Treatment** Caused or prolonged Depressive symptom inpatient hospitalisation Elevated mood Caused or prolonged inpatient hospitalisation Caused or prolonged Hepatic enzyme increased inpatient hospitalisation Caused or prolonged Laboratory test interference inpatient hospitalisation Caused or prolonged Neutropenia inpatient hospitalisation Pallor Caused or prolonged inpatient hospitalisation Stress Caused or prolonged inpatient hospitalisation Therapeutic agent toxicity Caused or prolonged inpatient hospitalisation Tremor Caused or prolonged inpatient hospitalisation

Medicine details:

**GGTP** 

LITHIUM CARBONATE (Suspected) Reason : Depression

1 Gram Daily

Batch: Started: Stopped:

LISINOPRIL (Other drug) Reason :

Batch: Started: Stopped:

**Laboratory Investigations:** 

Туре	Range	Date Tested	Result	Details
ALT = SGPT		03/08/2008	51 U/L	
Other data		01/09/2000	0.8 mmol/L	Blood lithium level
Other data		05/02/2008	1.9 mmol/L	Blood lithium level
Other data		09/02/2008	0.8 mmol/L	Blood lithium level
Other data		10/02/2008	0.8 mmol/L	Blood lithium level
Other data		11/07/2008	0.8 mmol/L	Blood lithium level
Other data		03/08/2008	1.1 mmol/L	Blood lithium level
Other data		06/03/2008	1.8 mmol/L	Blood lithium level
Other data		11/03/2008	1.8 mmol/L	Blood lithium level
Other data		18/03/2008	1.8 mmol/L	Blood lithium level
Creatinine		03/09/2008	125 micromol/L	
GGT = SGGT =		03/09/2008	121 U/L	

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Cases Count: 23

**Case Number: 245330** 

Gender: F

**Data Entry Date**: 10/10/2008 **Weight (kg)**: 85

**Hospitalisation**: Required a visit to the doctor Age:

Onset Date : DOB : 14/12/1966

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neuralgia Painful feet, neuropathic Slow lithium withdrawal, pain, burning soles of feet, anti-inflammatories.

pain radiating into legs, including bone, muscular

nerve pain.

Renal impairment

Medicine details:

LITHIUM CARBONATE (Suspected) Reason: Unspecifid affective psychosis

Tablet 750 Milligram Daily Oral

Batch: Started: 10/08/2006 Stopped:

RABEPRAZOLE SODIUM (Other drug) Reason :

20 Milligram Daily Oral

Batch: Started: 21/01/2008 Stopped:

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**Hospitalisation:** 

## **Public Case Detail**

Cases Count: 23

**Case Number : 245402** 

Gender: F

**Data Entry Date**: 14/10/2008 **Weight (kg)**: 0

Age:

**Onset Date**: 15/07/2008 **DOB**: 13/02/1947

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Syncope Caused or prolonged Patient experienced a fall Ceased Clopine

inpatient and fractured her right arm, hospitalisation patient also has a history

of lithium toxicity

Therapeutic agent toxicity Caused or prolonged

inpatient

hospitalisation

Medicine details:

CLOPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 200 Milligram Daily Oral

**Batch**: **Started**: 01/01/2002 **Stopped**: 22/07/2008

LITHIUM CARBONATE (Suspected) Reason : Depression

Tablet 500 Milligram Daily Oral

Batch: Started: Stopped:

DOTHIEPIN HYDROCHLORIDE (Other drug) Reason :

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Serum drug level Lithium blood level: mildly toxic.

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Cases Count: 23

**Case Number : 246499** 

Hospitalisation: Age: 60Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Included in the PI (attached)

The latter incident identified a serious problem, whereby it is likely that the particular assay risks generating spuriously low values when high serum levels of lithium are present-a so-called hook phenomenon, that has been described for some quantitative

immunoassavs.

There was a family history of bipolar disorder in two first-degree relatives.

### Reaction:

Therapeutic agent toxicity

Preferred Term Severity Report Description Treatment

Lithium toxicity, developed mood elevation, stress and depressive symptoms, adverse experienced requiring surgery, mild anaemia, slightly elevated creatinine level at 125 umol/L, drug interaction, slight neutropenia. Patient also experienced agitation

and confusion

Agitation

Anaemia

Blood creatinine increased

Confusional state

Depressed mood

Drug interaction

Elevated mood

Hepatic enzyme increased

Memory impairment

Neutropenia

### Medicine details:

LISINOPRIL (Interaction) Reason: Essential benign hypertension

Tablet 20 Milligram Daily Oral

Batch: Started: Stopped:

LITHIUM CARBONATE (Interaction) Reason : Unspecifid affective psychosis

Tablet 1 Gram Daily Oral

Batch: Started: Stopped:

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**Laboratory Investigations:** 

Type Range Date Tested Result Details

Electroencephalograph Showed a pattern consistent with lithium

toxicity.

Creatinine (40-120)19/03/2008 125

Liver function tests Elevation of some liver enzymes.

ALT = SGPT Level of 51 U/L exceeding the upper

limit of 45 U/L, level of 121 U/L

exceeding the upper limit of 121 U/L.

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**Cases Count: 23** 

**Case Number: 246886** 

Gender: F

**Data Entry Date**: 08/12/2008 **Weight (kg)**: 0

**Hospitalisation**: Admitted to hospital **Age**: 31Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

**Information:** History of bipolar affective disorder, obesity and psoriatic arthropathy.

Reaction: **Preferred Term** Severity **Report Description Treatment** Pyrexia Caused or prolonged Patient experienced fever, Treatment with Lithium and inpatient tremor, lethargy, Olanzapine were discontinued. hospitalisation leukocytosis, platelets elevated, decreased haemoglobin levels and possible encephalopathic syndrome. Haemoglobin decreased Caused or prolonged inpatient hospitalisation Caused or prolonged Lethargy inpatient hospitalisation Caused or prolonged Leukocytosis inpatient hospitalisation Plateletcrit increased Caused or prolonged inpatient hospitalisation Tremor Caused or prolonged inpatient hospitalisation

Medicine details :				
LITHIUM CARBONATE (Suspected)		Reas	son :	
	900	) Milligram	Daily	
Batch :	Started :			Stopped:
SODIUM VALPROATE (Suspected)		Reas	son :	
Batch :	Started :			Stopped :
ENOXAPARIN (Other drug)		Reas	son :	
Batch :	Started :			Stopped :
OLANZAPINE (Other drug)		Reas	son :	
Batch :	Started :			Stopped :

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**Laboratory Investigations:** 

Type Range Date Tested Result Details

White blood cells WBC = > 25

Platelets elevated > 1000

Haemoglobin decreased = < 90

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**Onset Date:** 

# **Public Case Detail**

Cases Count: 23

**Case Number: 247860** 

Gender: F

Age:

**Data Entry Date**: 21/01/2009 **Weight (kg)**: 89

Hospitalisation: Required a visit to the doctor

**DOB**: 10/02/1962

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Renal impairment Progressive renal Lithium ceased

impairment

Medicine details:

LITHIUM CARBONATE (Suspected) Reason: Unspecifid affective psychosis

1.2 Gram Daily

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details
Creatinine 0.20
Glomerular filtration 23
rate

Selection Parameters: Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: CAMCOLIT, LITHICARB, LITHIUM CARBONATE, PRIADEL, QUILONUM SR, TIMONIL, Lithicarb SR

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