

26 - 9. ADR Databases

9. ADR Databases

© SPMM Course 9. ADR Databases It is vital that adverse drug reactions (ADRs) that are hitherto unreported are detected rapidly and recorded to reduce the hazards of medical prescribing. Such reports will also trigger regulatory action to ensure further patient safety. MHRA encourages reporting adverse reaction through Yellow Card system even if it is not certain that the drug has caused it, or if the reaction is well recognised, if an overdose has been taken or if other drugs have been given at the same time. Prescribers, patients, carers and pharmacists can all use the yellow card scheme. The black triangle symbol is used to inform that a preparation is newly licensed and requires additional monitoring by the European Medicines Agency. For medicines with the black triangle symbol, the MHRA requires that all suspected reactions (including those that are not serious) be reported. For all other drugs, the yellow cards can be used to report side effects that are serious, medically significant, or result in harm. Adverse drug reactions that result from a medication error are also reportable using Yellow cards. Term used to describe frequency Rates observed Very common Greater than 1 in 10 Common 1 in 100 to 1 in 10 Uncommon or 'less commonly' in BNF 1 in 1000 to 1 in 100 Rare 1 in 10 000 to 1 in 1000 Very rare Less than 1 in 10 000

WHO established an international system for monitoring adverse reactions to drugs (ADRs) in 1971. This is located at WHO Collaborating Centre for International Drug Monitoring, Uppsala Monitoring Centre, (UMC), in Sweden. The ADRs database held by WHO contains over three million reports of suspected ADRs. Similar reporting systems exist in many other developed nations. The Canada Vigilance Adverse Reaction Online Database and the European Medicines Agency ADR Reporting systems are some examples of other well-developed national/international ADR databases.

Worsening of glaucoma: paroxetine, quetiapine, TCAs Retinal pigmn: Thioridazine Corneal deposits: CPZ Visual field defects: vigabatrin Osteoporosis: hyperprolataemic antipsychotics WBC suppression: ^zapines(olanz, mirtaz, cloz, carbama), mianserin Haemolytic anaemia: nomifensine Myocarditis / Pul Embolism: clozapine QT prolong: all antipsychotics esp .Thioridazine, Pimozide, droperidol Arrhythmias: high dose TCAs High BP: VFX, TCAs Hypersalivation: clozapine Bruxism: stimulants Hypothyroidism: Li Fine tremors: therapeutic dose of lithium, TCAs Coarse tremors: antipsychotic Parkinsonism, Wt gain: all antipsychotics (less for APZ, ZPD), TCAs, Li, VPA, CBZ Wt loss: Topiramate, Bupropion Guillian Barre: Zimeldine Pedal oedema: MAOIs Cramps: AchEs Orthostatic hypotension: all TCAs, all antipsychotics Priapism: Trazodone, risperidone PCOD: Valproate Erectile dysfunction: all TCAs, antipsychotics Delayed ejacln or anorgasmia: SSRIs Hepatic damage: nefazodone, VPA, tacrine Enz induction: CBZ, phenytoin, barbiturates Ac. Pancreatitis: VPA P.ileus: clozapine GI bleed: SSRIs, AchEs Renal damage: Lithium Nephrolithiasis:

topiramate EPSEs: all neuroleptics (less for Anticholinergic neuroleptics e.g. CPZ), higher dose atypicals Delirium: Anticholinergic TCAs, Anticholinergic antipsychotics Seizures: bupropion, clozapine Tics: stimulants Amnesia: BDZ Rashes, SJS: CBZ, Lamotrigine Thrombocytopenia: Valproate Sweating: all SSRIs, TCAs, esp. VFX Acne, psoriasis: Li Psychotropics Adverse Effects Chart © SPMM Course AchEs: Anticholinesterases, BDZ: Benzodiazepines, CBZ: carbamazepine, CPZ: Chlorpromazine VFX: Venlafaxine VPA: Valproate, SJS: Steven Johnson Syndrome,

© SPMM Course Notes prepared using excerpts from: Ashton, H & Young, A. SSRIs, drug withdrawal and abuse: Problem or treatment? Selective Serotonin Reuptake Inhibitors (SSRIs): Past, Present and Future, Chapter 5, 1999. <http://www.benzo.org.uk/ssri.htm> Bolland, W., & Simon, C. (2008). Controlled drugs: regulations and prescribing. *InnovAiT: The RCGP Journal for Associates in Training*, 1(2), 163-171. Brown E & Chanlder S. Mood and Cognitive Changes During Systemic Corticosteroid Therapy. *Prim Care Companion J Clin Psychiatry*. 2001 Feb; 3(1): 17-21. Di Lorenzo, R & Brogli, A. *Neuropsychiatr Dis Treat*. 2010; 6: 573-581. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis and management. *Lancet* 2000; 356:1255-9. <http://www.evidence.nhs.uk/formulary/bnf/current/yellow-card-scheme> Jones, O. Managing a suspected adverse drug reaction. *Student BMJ* 2001; 09:261-304 Kaplan & Sadock's *Synopsis of Psychiatry: Behavioral Sciences/Clinical Psychiatry*, 10th Edition. Lippincott Williams & Wilkins 2007. Pg 982. Kasper, S. (2002) Managing reboxetine-associated urinary hesitancy in a patient with major depressive disorder: a case study. *Psychopharmacology*, 159, 445-446. Lewis S & Lieberman, J. *The British Journal of Psychiatry* Mar 2008, 192 (3) 161-163 Paton C, Ferrier IN. SSRIs and gastrointestinal bleeding *BMJ* 2005; 331 :529 Seeman P, Tallerico, P. *Mol Psychiatry*. 1998 Mar;3(2):123-34. Shiloh, R., Nutt, D. & Weizman, A. (2000). *Atlas of psychiatric pharmacotherapy*. Martin Dunitz, London. Page 18 Sidhu KS & Balon R (2008). Watch for nonpsychotropics causing psychiatric side effects. *Current Psychiatry*; 7(4); 61 Swann, A. Major system toxicities and side effects of anticonvulsants. *J Clin Psych* 2001; 62 [16-21] Szabadi, E. (1998) Doxazosin for reboxetine-induced urinary hesitancy. *The British Journal of Psychiatry*, 173, 441b-442. Thakore, JH. *The British Journal of Psychiatry* Jun 2005, 186 (6) 455-456; UK Home Office <http://drugs.homeoffice.gov.uk/drugs-laws/misuse-of-drugs-act/>

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Revision #1

Created 2026-01-04 20:04:41 UTC by Omar Ayman

Updated 2026-01-04 20:04:41 UTC by Omar Ayman