Adverse effects of antipsychotic medication

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Plan

- Types of ADRs – a reminder
- Antipsychotics
  - EPS
  - Weight gain/metabolic/diabetes
  - Hyperprolactinaemia
  - QT prolongation
  - Clozapine and gastro-intestinal motility

- Medicines information for patients
- Useful resources and links to other medicines related info for prescribers
Types of adverse reactions

ADRs have traditionally been categorized as Type A and Type B:

- **Type A reactions** (pharmacological/augmented) result from an exaggeration of a drug’s normal pharmacological actions when given at the usual therapeutic dose. They are *dose dependent* and are therefore readily reversible on reducing the dose of (or withdrawing treatment with) the drug.

- **Type B reactions** are *idiosyncratic*/bizarre reactions which cannot be predicted from the known pharmacology of the drug.

Type A adverse reactions are more common than Type B reactions and account for more than 80% of all reactions.

(Additional classifications include characteristics: C, D, E [continuing/chronic, delayed (difficult to diagnose), end of use])
Examples

Type A:
- Dry mouth, blurred vision, constipation etc = anticholinergic ADRs with TCAs
- Hypotension with quetiapine (and other Aps) = alpha1 blockade
- Hyperprolactinaemia with FGAs (and some SGAs) = production of PRL from lactotroph cells primarily controlled by DA

Type B:
- clozapine induced neutropenia,
- SJS with lamotrigine
Standardised definitions of incidence

- Very common = >1 in 10
- Common = 1 in 10 to 1 in 100
- Uncommon = 1 in 100 to 1 in 1000
- Rare = 1 in 1000 to 1 in 10,000
- Very rare = <1 in 10,000

Used by manufacturers in their product licences
Dopamine pathways

- **a) Nigrostriatal Dopamine Pathway**
  - responsible for motor control

- **b) Mesolimbic Dopamine Pathway**
  - thought to be involved in behaviours such as pleasurable sensations, powerful euphoria of drug abuse, delusions and hallucinations of psychosis

- **c) Mesocortical Dopamine Pathway**
  - role in mediating +ve and –ve symptoms of schizophrenia or cognitive side effects of schizophrenia
EPSE

- EPSE are complex side effects, related to dopamine blockade in the nigrostriatal pathway, *but not exclusively so.*
- Dose related effect.
- Greatest risk = high dose, high potency FGAs
- Lowest risk = clozapine, olanzapine, quetiapine, aripiprazole
- Once present, may be persistent, but can improve
- Patients with one type of EPS may be more vulnerable to develop others
- Some evidence that vulnerability may be genetically determined
EPSE: “Atypical” – 5HT antagonism
(Serotonin Dopamine Antagonists)

- Serotonin stimulation of 5HT2a post-synaptic receptors on dopamine neuron = inhibits dopamine release
- 5HT2a antagonist = increases dopamine release
- This increased dopamine counteracts the D2 antagonist effect in
  - The nigrostriatal pathways = fewer EPSE
  - The mesocortical pathway = ? improved negative symptoms via 5HT2A mediated DA release
  - The tuberofundibular pathway = reduced prolactin release (theoretical and not the same for all SDAs)
- However 5HT2a antagonism does not exert enough of an influence to cancel out the antipsychotic effect of these drugs.
Affects about 20% of chronically treated patients
Mimics Parkinson’s Disease; stiffness, tremor, pill-rolling and cogwheel movements, akinesia, drooling, mask-like face.
Elderly females are most at risk
Usually appears in the days/weeks of treatment.

**Treatment:**
- Type A, dose related side effect – reduce antipsychotic dose
- Switch to lower risk AP if appropriate
- Prescribe anti-cholinergic – procyclidine 2.5 -5mg PO up to TDS (not ON)
- May resolve – review 3 monthly; review dose/ discontinue if no longer required.

**Caution:** long term use → increases risk of TD, cognitive impairment.
EPSE – Acute dystonic reactions

- Affects approx. 10% of people given a first generation antipsychotic
- More commonly seen with high potency D2 blocking antipsychotics (eg haloperidol)
- Muscle spasms of head and neck twisting sideways (torticollis) or upwards (opisthotonus), sometimes accompanied by oculogyric crisis or laryngeal spasm
- Approx. 50% of acute dystonic reactions will occur within the first 48 hours of therapy and 90% develop within 5 days.
- Younger men or those who are neuroleptic naïve are particularly susceptible
- Treatment needs to be prompt as swallowing reflex may be lost
**EPSE – Acute dystonic reactions**

**Treatment**
- Prescribe procyclidine – may need IM
- IM procyclidine peaks in 10-20 mins
- Oral procyclidine slower to absorb – DO NOT use for acute dystonia.

**Prevention**
- Choice of antipsychotic – lower risk - SGA with less potent D2 blockade
- Dose related side effect - start low and go slowly, especially with IM.
Approx. 25% develop akathisia – incidence varies between antipsychotics.

Generally a lower risk with SGAs vs FGAs

- aripiprazole > lurasidone > risperidone > olanzapine > quetiapine > clozapine.

Syndrome of restlessness which may manifest as:

- Inability to remain seated or stand still
- Pacing, rocking back and forth
- Other repetitive purposeless actions
- Subjective feeling of inner restlessness

May be associated with higher risk of suicide / aggression.

Occurs within hours to weeks of treatment.

DOES NOT respond to anticholinergic treatment.
Akathisia - treatment

- Reduce the antipsychotic dose
- Change to an antipsychotic with a lower risk
  - E.g. quetiapine, olanzapine (lowest dose possible)
- Pharmacological treatment options (evidence is generally poor):
  - Propranolol 30-80mg/day – takes up to 3 months
  - Benzodiazepines – e.g. low dose clonazepam 0.5-3mg/day
  - Mirtazapine 15-45mg/day* - systematic review/meta-analysis +ve
  - Cyproheptadine 16mg/day*
  - Trazodone 100mg/day*

*all are 5HT2 antagonists
EPSE: Tardive Dyskinesia

- 5% of patients per year of exposure to FGA
- Can occur in untreated schizophrenia
- Usually takes months to years to develop
- Abnormal movements of the mouth and tongue, lip smacking, puckering, sucking, facial grimacing.
- Approx. 50% is irreversible
- Treatment:
  - Stop anticholinergic – can make it worse
  - Reduce dose of antipsychotic and / or consider switch
  - Antipsychotics of choice: SGAs: especially clozapine or quetiapine
  - Tetrabenazine (DA depleting agent)?…ADRs
  - Clonazepam, Ginkgo biloba,…
  - [American Academy of Neurologists TD guideline](#)
EPSE: Time course

Severity of symptoms

- akathisia
- dystonic
- drug-induced Parkinsonian tremors
- tardive dyskinesia

Weeks of treatment

Bezchlibnyk-Butler KZ & Jeffries JJ. Clinical Handbook of Psychotropic Drugs 8e, 1998. Canada
Weight gain

- Important adverse effect of nearly all antipsychotics with obvious consequences for health, self-image and adherence

- Risk factors
  - Younger age and female
  - Low baseline body weight
  - Family or personal history of obesity
  - Prone to overeating under stress

- Suggested mechanisms include
  - Sedation – decreased activity
  - Thirst – anticholinergic side effects
  - Increased appetite – via blockade of H1, 5HT2A, 5HT2C receptors
  - Increased serum leptin and/or prolactin
  - Others….
Managing antipsychotic induced weight gain

**BAP guidelines 2016:**
First line – Lifestyle interventions

**Pharmacological options:**
- No clear relationship with dose
- Switch antipsychotic to aripiprazole, lurasidone, amisulpride, (haloperidol, asenapine)
- Adjunctive aripiprazole
  - trial evidence available with clozapine or olanzapine only
  - Loss of 2kg vs placebo
- Adjunctive metformin (biguanide) – good evidence.
  - Reduced hepatic glucose production
  - Increases insulin sensitivity in muscle
  - Loss of 3kg vs placebo.
  - Could use early to attenuate weight gain (....quality of evidence?).
  - Normal doses as for diabetes required.

Diabetes

- High incidence of diabetes in schizophrenia –2-fold (predates use of SGAs)
- Many SGAs associated with increased risk of diabetes, diabetic ketoacidosis and glucose intolerance
- FGAs are not without risk
- These changes can occur with or without weight gain.
- Mechanism unclear
- Risk highest with clozapine and olanzapine
  - Up to 1/3 of clozapine patients develop diabetes in 5 years.
  - Many within first 6 months
- Risk lowest with aripiprazole, amisulpride, asenapine, lurasidone
- Appears greatest in younger age (<24) (prevalence in general population v low)
Lipids

- Increased LDL and decreased HDL
- Increases in TGs
- Phenothiazine (poorly quantified); haloperidol minimal effects

**SGAs**
- Olanzapine (incr TG by 40% over short (12 wk) and medium (16 mo) term)
  - Levels can rise for up to 1 yr
  - 2/3 have raised TG
  - 10% severely raised (can occur independently of weight gain)
- Clozapine (mean TG doubles after 5 yr)
- Moderate effects: risperidone, quetiapine
- Low risk: aripiprazole, lurasidone
Hyperprolactinaemia

- Dopamine inhibits prolactin release - D2 stimulation
- D2 antagonism at pituitary causes prolactin elevation
- Often asymptomatic.
- Can present with gynaecomastia, galactorrhoea, sexual dysfunction
- Long term risk due to secondary hypogonadism
  - Reductions in Bone Mineral Density → osteoporosis
Causes of elevated prolactin

<table>
<thead>
<tr>
<th>Physiological causes:</th>
<th>Pharmacological causes</th>
<th>Pathological causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pregnancy</td>
<td>• Antipsychotics</td>
<td>• Prolactinoma</td>
</tr>
<tr>
<td>• Lactation</td>
<td>• Antidepressants</td>
<td>• Other pituitary or hypothalamic tumours or lesions</td>
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<tr>
<td>• Stress (PRL levels of up to about 700 mU/L in men and 900 mU/L in women)</td>
<td>• Opiates</td>
<td>• Hypothyroidism</td>
</tr>
<tr>
<td>• Circadian variation (levels are highest in morning)</td>
<td>• Peripheral dopamine receptor blockers e.g. metoclopramide, domperidone</td>
<td>• Polycystic ovary syndrome</td>
</tr>
<tr>
<td>• Macroprolactin (large molecular aggregates lacking biological activity but leading to falsely elevated PRL result. Screening for macroprolactin is routinely conducted by the lab if PRL is found to be raised.)</td>
<td>• Antihypertensives e.g. calcium channel blockers, methyldopa</td>
<td>• Severe renal or liver disease</td>
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<tr>
<td></td>
<td>• H2 antagonists e.g. cimetidine</td>
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<td></td>
<td>• Proton pump inhibitors e.g. omeprazole</td>
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<td></td>
<td>• Oestrogens</td>
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</table>
Managing hyperprolactinaemia

- Consult your local trust’s AP induced hyperprolactinaemia guideline
  - (Oxford Health: http://www.oxfordhealthformulary.nhs.uk)
- Measure at baseline for prolactin raising APs – prior to antipsychotic use
  - Prolactin can elevate within day(s) of antipsychotic use
- Enquire about symptoms at 3 months on stable dose and repeat level if symptomatic
- Only treat if symptomatic or confirmed hypogonadism (menstrual Hx females; low testosterone males)

<table>
<thead>
<tr>
<th>Low risk antipsychotics</th>
<th>High risk antipsychotics</th>
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</thead>
<tbody>
<tr>
<td>Aripiprazole, Quetiapine, Lurasidone, Clozapine</td>
<td>Amisulpride, Risperidone, Paliperidone, Sulpiride, Typical antipsychotics.</td>
</tr>
</tbody>
</table>

Treatment:

1. Consider dose reduction or switch to prolactin sparing antipsychotic
2. If unsuitable, consider addition of low dose (5mg) aripiprazole (not with amisulpride)
3. Amenorrhoeic women – use of COC/ HRT preparations (with advice from specialist)
4. Avoid dopaminergic drugs (cabergoline) which may increase risk of psychosis.
QT prolongation

- SMI – reduced life expectancy (suicide and cardiovascular disease)

- ALL antipsychotics contribute to prolongation of ventricular repolarisation.

- Many have class 1A anti-arrhythmic-like effects – presenting as QT interval lengthening.

- Class 1A agents act by blocking (open) voltage dependent Na+ channels. Essentially cardiac depressants, and act on the atrial and ventricular muscle cells, the Purkinje fibres and the AV node. They 1) decrease the automaticity of the heart by slowing phase 4 of the cardiac action potential and by raising the threshold of phase 0; and 2) slow phase 0 and lengthen the refractory period – e.g. – disopyramide, quinidine, procainamide
Possible with all antipsychotics – risk varies

QTc – corrected for heart rate (increasing HR shortens interval)
  - Imprecise indicator of risk of TdP/ increased cardiac mortality
  - Normal = up to 440msec (men), up to 470msec (women)
  - Controversy over exact association between QTc and arrhythmia risk
  - No absolute cut off; values > 500msec – considered a definite increase in risk
  - Effect most prominent at peak drug levels
  - Interpretation dependent on various factors
    - Time of day, age, gender, electrolytes, underlying condition, medication etc

Torsades de Point; Ventricular Fibrillation; sudden death (2x population) – QTc effect may not necessarily equate directly to risk

Class warning in product licence of all antipsychotics – sudden cardiac death – absolute risk low (but higher than e.g. fatal agranulocytosis with clozapine)
### Effects of antipsychotics on QTc

(table from: Maudsley Prescribing guideline 13th edition)

<table>
<thead>
<tr>
<th>No effect</th>
<th>Low effect (&lt;10ms or &gt; following OD)</th>
<th>Moderate (&gt;10ms at therapeutic dose)</th>
<th>High effect (&gt;20ms at therapeutic dose)</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cariprazine</td>
<td>Aripiprazole</td>
<td>Amisulpride</td>
<td>Sertindole</td>
<td>Pipothiazine</td>
</tr>
<tr>
<td>Lurasidone</td>
<td>Asenapine</td>
<td>Chlorpromazine</td>
<td>Pimozide</td>
<td>Trifluoperazine</td>
</tr>
<tr>
<td>Clozapine</td>
<td></td>
<td>Quetiapine</td>
<td>High dose APs</td>
<td>zuclopenthixol</td>
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<tr>
<td>Flupentixol</td>
<td></td>
<td>Ziprasidone</td>
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<tr>
<td>Fluphenazine</td>
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<td>Haloperidol</td>
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<td>Perphenazine</td>
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<td>Prochlorperazine</td>
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<td>Olanzapine</td>
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<td>Paliperidone</td>
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<tr>
<td>Risperidone</td>
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<tr>
<td>Sulpiride</td>
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</tbody>
</table>
## Management of QT prolongation

*(table from: Maudsley Prescribing guideline 13th edition)*

<table>
<thead>
<tr>
<th>QTc</th>
<th>Action</th>
<th>Refer to cardiologist</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;440ms</td>
<td>None unless abnormal T waves</td>
<td>Consider if in doubt</td>
</tr>
<tr>
<td>&gt;440ms (men) or &gt;470ms (women) but &lt;500ms</td>
<td>Consider reducing the dose or switching to drug of lower effect; repeat ECG</td>
<td>Consider</td>
</tr>
<tr>
<td>&gt;500ms</td>
<td>Repeat ECG; stop suspected causative agent and switch to drug of lower effect</td>
<td>Immediately</td>
</tr>
<tr>
<td>Abnormal T wave morphology</td>
<td>Review treatment. Consider reducing dose or switching to drug of lower effect</td>
<td>Immediately</td>
</tr>
</tbody>
</table>
**Clozapine – significant adverse effects**

<table>
<thead>
<tr>
<th>Sedation</th>
<th>Neutropenia</th>
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<tbody>
<tr>
<td>Hypersalivation</td>
<td>Agranulocytosis</td>
</tr>
<tr>
<td>Constipation</td>
<td>Myocarditis</td>
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<tr>
<td>Hypotension</td>
<td>Cardiomyopathy</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>Seizures</td>
</tr>
<tr>
<td>Weight gain</td>
<td>Nocturnal enuresis</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Toxicity</td>
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<tr>
<td>Dyslipidaemia</td>
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CLOZAPINE and the GI Tract

- Affects whole GIT – from swallowing difficulties to rectal bleeding
- Clozapine – minimal D2 antagonism but...
- Potent peripheral anticholinergic effects:
  - Delay colonic transit
  - Relax intestinal smooth muscle
- Antagonism at serotonin receptors:
  - Compounds the inhibiting effects on smooth muscle contraction
- Constipation = very common, up to 60%, usually benign
- Compounded by poor lifestyle – diet, fluid, exercise etc.
Clozapine-induced gastrointestinal hypomotility (CIGH)

- Unrecognised CIGH → rare but potentially fatal consequences
- Many reports of death associated with:
  - Aspiration of vomit secondary to bowel obstruction
  - Toxic megacolon
  - Necrotising colitis
  - Colonic perforation
  - Abdominal compartment syndrome
  - Bowel infarction
- Other life-threatening illness where hypomotility found to be a likely cause:
  - Sepsis, organ failure, pneumonia, cardiac abnormalities
- Prevalence of life-threatening CIGH = 3 per 1000
Under-recognised....

- ***CIGH is significantly more of a risk than blood dyscrasias***

Up to 2013:
- 5061 reports of GI ADRs – 82 = fatal
- 5 blood disorder fatalities during same time frame

Risk factors include
- High dose
- Stopping smoking
- Age
- Co-prescribing with other constipating drugs*
Clozapine: reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus

If constipation occurs during treatment with clozapine (Clozaril, Denzapine, Zaponex), it is vital that it is recognised and actively treated.

Published 26 October 2017  
From: Medicines and Healthcare products Regulatory Agency
Clozapine - other uncommon/unusual ADRs

- Colitis: a few reports, causal link not clear, refer
- Delirium: rarely seen if slowly titrated & plasma levels monitored
- Eosinophilia: fairly common
- Heat stroke: may interfere with thermoregulation (& other APs)
- Hepatic failure: rare (benign changes common)
- Interstitial nephritis: handful of reports
- Pancreatitis: rare, sometimes associated with eosinophilia
- Pneumonia: aspiration of saliva (v rare); infection rate higher
- Important to note that respiratory infections = raised clozapine levels
- Thromboembolism: known risk with APs – possibly highest with clozapine. Threshold for prophylactic antithrombotics (immobility, surgery etc) should be low
Other antipsychotic adverse effects

- Anticholinergic effects
- Sedation
- Sexual dysfunction
- Thromboembolism
- Other cardiovascular effects
- Neuroleptic Malignant Syndrome
- Etc…
Guidelines - choice

http://www.oxfordhealthformulary.nhs.uk/docs/Guideline%20for%20the%20use%20of%20antipsychotics%20to%20treat%20schizophrenia%20and%20psychosis%20FINAL%20for%20Chiltern%20and%20AV%20CCG%20March%202018.pdf?UNLID=504260122019513173548
### Physical health monitoring requirements for antipsychotic medication

<table>
<thead>
<tr>
<th>Test</th>
<th>Agreed monitoring</th>
<th>Secondary care monitoring</th>
<th>Primary care monitoring</th>
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<tbody>
<tr>
<td>ECO</td>
<td>Baseline and then weekly for 4 weeks in all moderate (cholinergic, anticholinergic, pimozide, quetiapine, risperidone, clozapine) and high risk (cholinergic, anticholinergic, and clozapine) antipsychotics, then every 2-4 weeks until weight and height have returned to normal and annually. Observations: Baseline and then those recorded as above before the patient to weight themselves and report weight gain.</td>
<td>Baseline and as described within the first year. As part of annual review if weight increases at annual review and patient to review antipsychotic therapy. Weight management should be encouraged rather than change medication. Patients should be referred to local mental health services if there is a particular concern.</td>
<td>Non-specific items should be initialed.</td>
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<td>Pulse</td>
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<td>Blood Pressure</td>
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<td>Lipid profile</td>
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<td>Full Blood Count</td>
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[Guidelines – monitoring: physical health](http://www.bucksformulary.nhs.uk/docs/Guideline_262FM.pdf)
Guidelines – high dose monitoring

http://www.oxfordhealthformulary.nhs.uk/docs/High%20Dose%20Antipsychotic%20Therapy%20Guideline%20v3%20with%20updated%20ready%20reconciler%20v7%20August%202018_1.pdf?UNID=504260122019513173548
Patient information – “Choice and Medication”

- Medicine leaflets
- Translations
- Picture leaflets for LD/ young people
- Comparison charts
- Handy fact sheets eg serotonin syndrome, EPS, NMS, hypersalivation
- Mental health condition information
- How medicines work booklet
- Medicines in pregnancy leaflets

https://www.choiceandmedication.org/oxfordhealth/
Some bedtime reading...

- Psychotropic Drug Directory 2018 (Bazire, S.)
- Life threatening effects of antipsychotic drugs (Manu, P., Flanagan R.J., & Ronaldson, K.J., Elsevier 2016)
- BAP guidelines (https://www.bap.org.uk/guidelines)

For further advice, don’t forget your CCG advice line and your local mental health Medicines Advice Service.... 😊