Introduction to Pharmacological Management for SHOs

Newcastle, North Tyneside and Northumberland Mental Health NHS Trust

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Agenda

- NOT the whole of psychopharmacology

- General points (particularly relevant to 3Ns)
- Schizophrenia
- Depression
- Anxiety
- Bipolar disorder
- Night time sedation
- Rapid tranquillisation

Clinical Management

- Identify syndrome – make a diagnosis!!!!!
- Educate patient and others
- Select treatment
- Monitor response and adjust treatment
- Maintenance treatment
- Non-response strategy

Monitoring Patients: CGI severity

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- Simple 7-point scale
- Done considering your total clinical experience of patients with the same condition
- Relate to specific time period

1: Normal not ill
2: Minimally ill
3: Mildly ill
4: Moderately ill
5: Markedly ill
6: Severely ill
7: Very severely ill

Monitoring Patients: CGI Change

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1: Very much improved
2: Much improved
3: Minimally improved
4: No change
5: Minimally worse
6: Much worse
7: Very much worse

PRN prescribing

- Medication should be prescribed at a specific dose and not as a range.
- Give a clear indication for a recognised symptom (beware agitation)
  - Preferred indications are psychotic thoughts and symptoms, disturbed behaviour and violence.
- Drugs should not be prescribed at equal doses written as oral/intramuscular.

PRNs

- Antipsychotic medication:
  - Only one antipsychotic should be prescribed P.R.N
  - Should be the same as any regular antipsychotic
  - P.R.N should be reviewed regularly (at least weekly)
  - If BNF limit of a medication is exceeded then it should be clearly documented in the case notes and an explanation given **and**
    - ECG, FBC, LFT, U&E should be done
    - Consent of patient to high dose clearly recorded
    - Physical examination, pulse, B.P, temperature recorded at least once
    - Consultant endorsement of prescription recorded.
    - Multidisciplinary discussion of medication recorded.
- Benzodiazepine medication:
  - Should not be given daily as regular or P.R.N for longer than 4 weeks.

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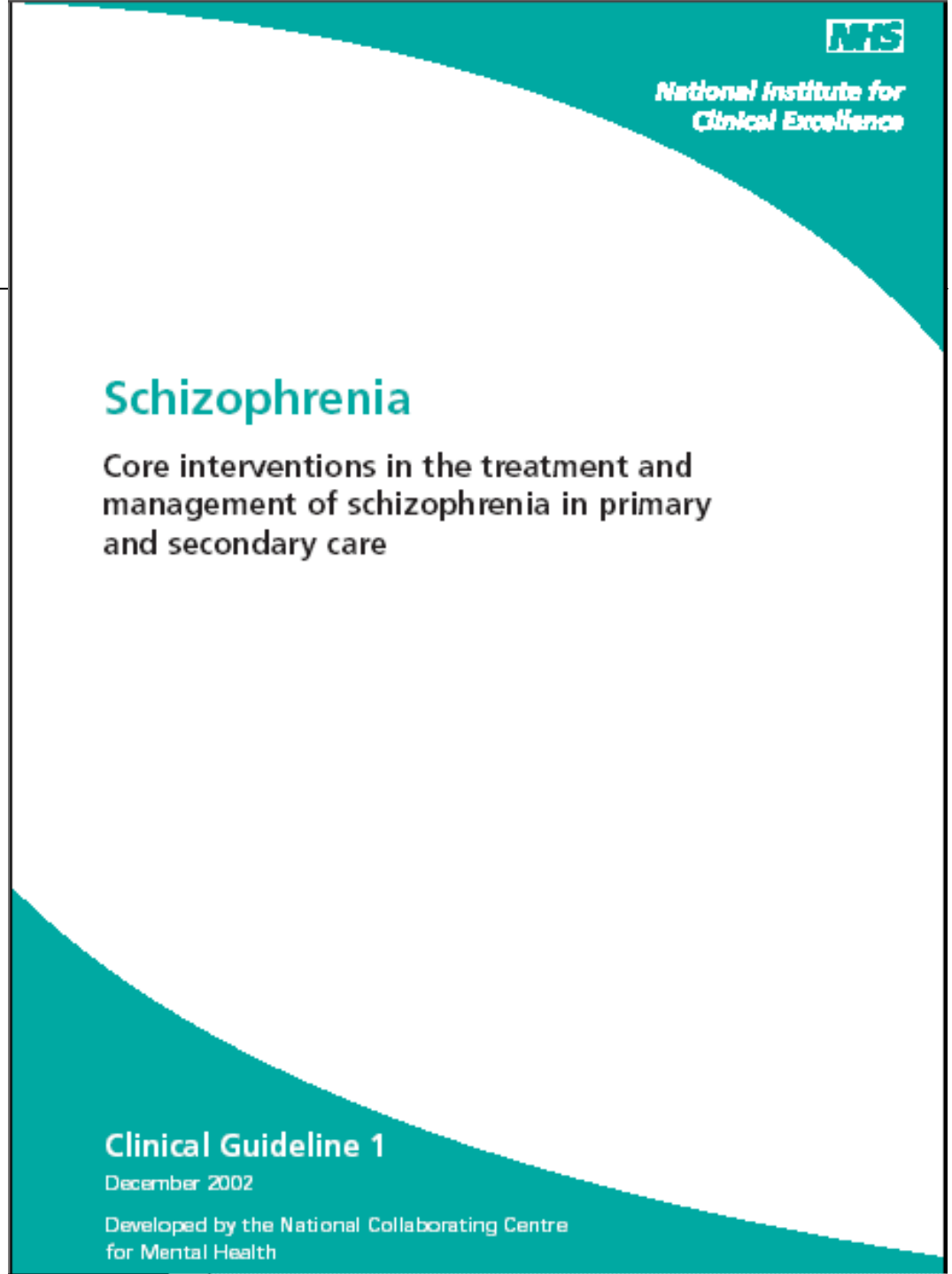
Drug licences, formularies, policies etc

- Avoid using a drug off licence
  - If done, mostly should have consultant agreement
    - (exceptions include valproate for maintenance in bipolar and fluoxetine for OCD)
- Be aware of policies – NICE and 3N's
- If using a non-formulary drug
  - Must be on consultant recommendation
  - Must fill in form fully
- Watch out for monthly D&T newsletters
- D&T website



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Acute Episode

- Informed choice by patient
  - If not able to do this then atypical
- If on typical and SEs are problematic or Sx control is inadequate, then atypical (otherwise remain on conventional)
- Single drug within BNF limits
  - Avoid high doses and loading doses
- Treatment trials should be for periods of 6-8 weeks
- Progress, SEs and user satisfaction should be monitored closely
- Treat for 1-2 years, withdraw slowly and monitor for 2 years after withdrawal

NICE: Treatment resistant schizophrenia

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- Establish that there have been adequate trials of antipsychotics
- If Sx unresponsive to a conventional then use an atypical before consider TRS
- If TRS (min 2 antipsychotics each for 6-8/52, at least one atypical) consider clozapine sooner rather than latter
- Avoid multiple antipsychotics except for pts who have not fully responded to clozapine

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NICE: Relapse prevention

- Oral drugs as per acute episode
- Risk assessment by clinician and MDT regarding concordance and need for depot
- Depots
  - Use if patient chooses this or problems with concordance
  - Use within BNF dose limits
  - Use test doses as set out in BNF
  - Regular review as per orals
  - NB Risperdal consta guidelines exist (consultants only)

Trust antipsychotic policy

Newcastle, North Tyneside and Northumberland Mental Health NHS Trust

- On D&T website
- Detailed information for all indications, first episode, young, elderly, TRS etc
- Note for Schizophrenia recommendation, if all things are equal, to use risperidone (depot – zuclopenthixol)
- Guidance re side effect management and switching antipsychotics, plus monitoring

Antipsychotic monitoring

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Drug	Recommended monitoring		Actions
	Baseline	Continuation	
All	FBG[a]	FBG[a] - at 4/52, 3/12, 6/12 then every 6 months	Consider switch if FBG > 7.0 mmol/l
	U&Es and LFTs	U&Es and LFTs - at 3/12	Repeat/monitor if abnormality detected or clinically indicated
	BMI	Weight (BMI) -4, 8, 12/52 then every 6/12	If ≥5% body weight increase over baseline consider switch to another agent
	Lipids[b]	Lipids[b] - annually	Consider drug treatment if 10 year CHD risk ≥ 15% and total cholesterol ≥ 5mmol/l
		CPK - if suspect NMS	Stop if elevated >3 times baseline
	HbA_{1c}[c]	HbA_{1c}[c] - as needed	Perform OGTT if raised
	ECG[d]	ECG[d] - ..every 3-6/12	Consider switch if QTc > 440 ms in men or > 470 ms in women. Stop if > 500 ms
	BP[e]	BP[e] - at 3/12 then annually	

Antipsychotic monitoring

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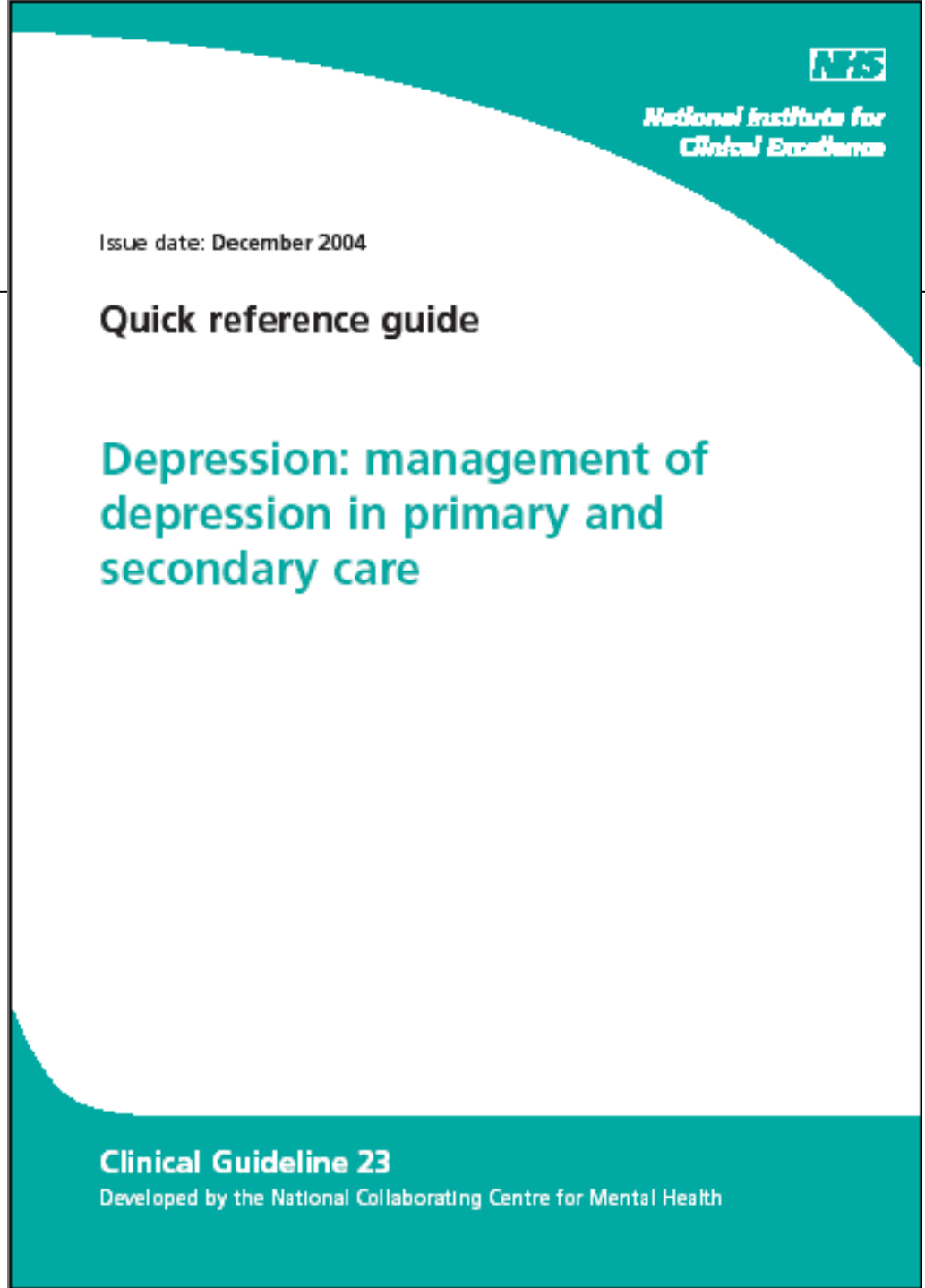
Drug	Recommended monitoring		Actions
	Baseline	Continuation	
Typicals / Amisulpiride / Risperidone / Sulpiride / Zotepine	Prolactin	Prolactin - if symptoms occur	Switch if significant symptoms
Clozapine[f]	BP	BP - 4 hourly during titration, weekly for 18/52 then 2 weekly till 52/52 then every 1/12	
	ECG	ECG - when final dose reached	Consider stopping if important changes or heart failure noted. Refer to cardiologist
		EEG - if myoclonus or seizures	Consider valproate

Risperdal Consta

- Only be initiated by a Consultant Psychiatrist when one of the following apply:
  1. patient intolerant of typical antipsychotic medication (oral or depot) and compliance (or fully-informed patient choice) led to decision to use a depot.
  2. failure to respond to a typical depot.
  3. previous response to an atypical but compliance (or fully-informed patient choice) led to decision to use a depot.
- Prior to starting record reason for Consta and:
  1. current CGI
  2. current side effect burden (on 7 point scale: 7 = very severe burden of side effects, 1 = no side effects evident).
- **At least six monthly,** and preferably at every follow up:
  - CGI, CGI change, side effect burden (as rated above).
- **NEVER** be co-prescribed with a typical depot except during switch
- If 50mg two weekly is insufficient use an alternative
- **ALWAYS** prescribe on a 2-weekly basis



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NICE Guidance

- **Stepped care**
- Step 1: Recognition of depression
- Step 2: Depression in primary care – mild depression
- Step 3: Depression in primary care – moderate to severe
- Step 4: Mental health services – refractory, recurrent, atypical and psychotic depression
- Step 5: Depression requiring inpatient care

Step 2: Mild depression in primary care

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- Antidepressants
  - Not recommended for initial treatment
  - If symptoms persist after other interventions [C]
  - If past history of moderate to severe depression [C]

Step 3: Moderate to severe depression in primary care

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- Antidepressants
  - Should be routinely offered [A]
  - Address common concerns [GPP]
  - Inform about potential side effects [C]
  - Inform about time delay in response [GPP]
  - Review at regular intervals [GPP]
  - Continue for at least 6 months from remission [A]
  - After 6 months review need for medication [GPP]

Step 3

- Choice of antidepressant
  - SSRI in routine care [A]
  - Consider fluoxetine (since generic and long half life, but NB drug interactions) or citalopram (since generic) [C]
  - If SSRI leads to agitation or akathisia then consider switch or benzodiazepine with review in 2/52 [C]
  - If fails to respond to first drug check concordance [GPP]
  - If response inadequate consider increasing dose to BNF limits [C]
  - If not effective switch antidepressant [C]
  - Reasonable alternative to SSRIs = mirtazepine, but consider moclobemide, reboxetine, tricyclics [B]

Step 3

- Choice of antidepressant (cont.)
  - Mirtazepine – warn about sedation and weight gain [A]
  - Moclobemide – ensure previous drug washed out [A]
  - Reboxetine – relative lack of data [B]
  - Tricyclics – poor tolerability, cardiotoxicity and toxicity in OD [B]
    - If used, lofepramine good choice [C]
    - If respond at low dose, maintain this [C]
    - Gradually increase dose, monitoring for SEs, if lack of efficacy [GPP]
  - Venlafaxine

Venlafaxine recommendations (under appeal from Wyeth)

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- Should only be *initiated and managed* under the supervision of specialist mental health medical practitioners (incl. GP's with Special Interest)
  - Also applies to dosulepin, phenelzine, Li augmentation and combined antidepressants
- Avoid in patients with cardiac disease, abnormal electrolytes and hypertension. "Be aware of:"
  - Increased risk of stopping cf SSRIs due to side effects
  - High propensity for discontinuation/withdrawal
  - Toxicity in overdose
- Before prescribing do an ECG and BP
- "Consider monitoring cardiac function". Monitor BP esp. patients on higher doses.
- Recommended for management of TRD by mental health specialists.

Duloxetine

- Duloxetine is approved for third-line antidepressant use by specialists, but only for those who cannot tolerate venlafaxine, or those with hypertension, established CHD or other cardiovascular risk factors which would make the use of venlafaxine undesirable.
- There is no evidence data that doses greater than 60mg/day confer any additional benefits.
- Although not a manufacturer's requirement, a lower starting dose of 30mg/day may be prudent in those who are SSRI/SNRI-naïve"

Step 3: Atypical Depression

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- Atypical Depression
  - Overeating, over-sleeping, interpersonal rejection and over-sensitivity
  - More often female and young onset
  - Comorbid panic, substance misuse and somatisation common
  - Treat with SSRI [C]
  - Refer if don't respond and functionally impaired [GPP]

Step 3

- Monitoring of antidepressants
  - Monitor for akathisia and increased anxiety in early stages of treatment with an SSRI [GPP]
  - If risk of suicide or < 30yrs old review after 1/52, then close monitoring (e.g. by phone)
    - Everyone else review after 2/52 then every 2-4/52 for 3/12

Step 4 - Refractory depression

- Failure to respond to 2 or more ADs
- Consider everything in step 3. [GPP]
- Drugs
  - Lithium augmentation (even after 1 AD) – NB SEs and toxicity [C]
  - Don't augment with BZs [C]
  - ADs plus CBT
  - Venlafaxine up to BNF limits [C]
  - SSRI + mianserin or mirtazepine [C]
    - Monitor carefully for SEs [GPP]
    - Use mianserin with caution esp. in elderly – agranulocytosis [C]
  - Consider phenelzine [C]
  - Carbamazepine, lamotrigine, buspirone, pindolol, valproate, thyroid hormone augmentation not recommended routinely [B]
  - If thinking of other strategies, think of second opinion or tertiary referral – document discussions in notes [C]

Step 4 – recurrent depression

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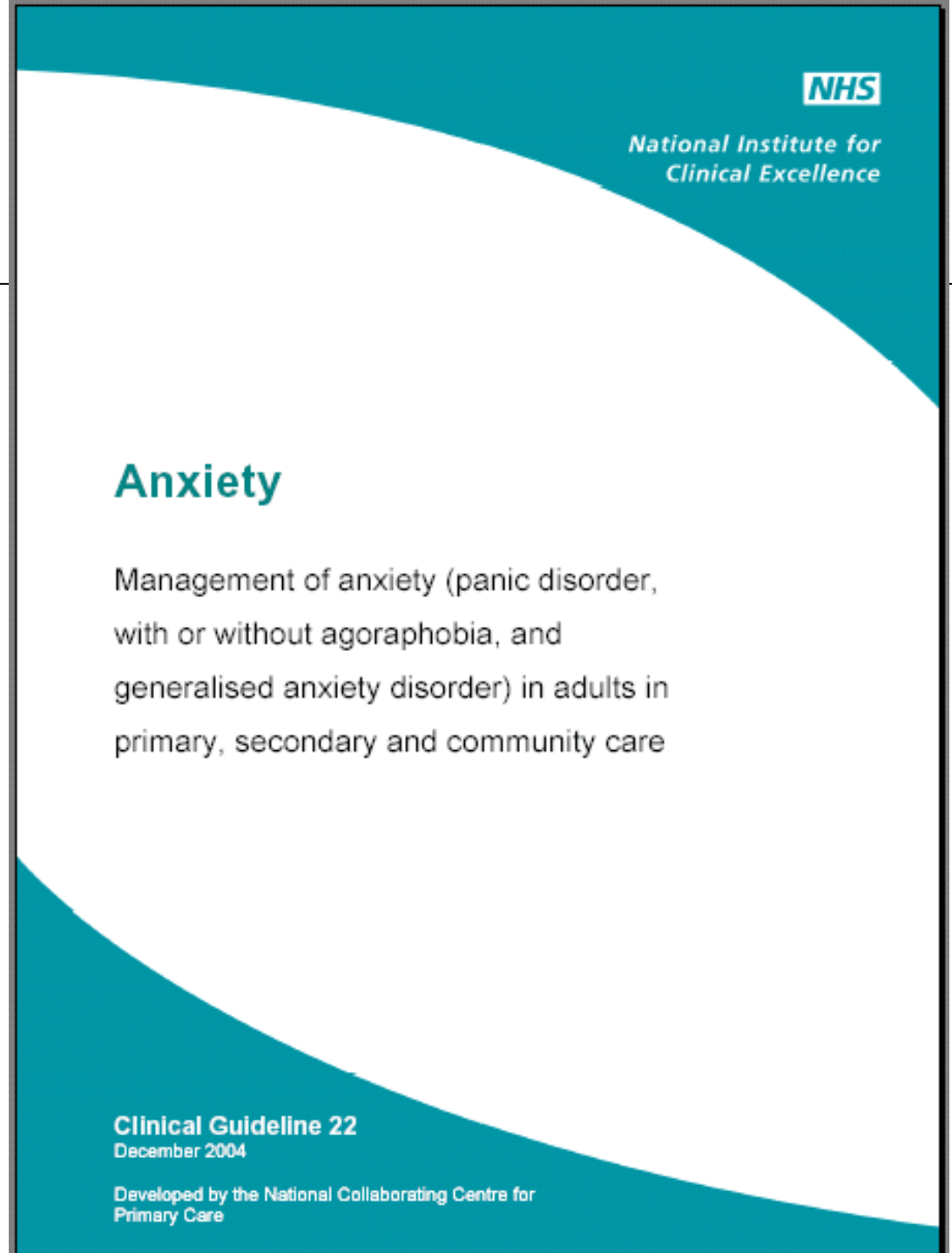
- If 2 or more episodes consider ADs for 2 years [B]
- Re-evaluate risk factors when thinking about going beyond 2 years [GPP]
- Use same dose of AD as for acute treatment [C]
- AD + Li
  - Continue for at least 6/12 [B]
  - If stop one, stop Li [C]
- Li not recommended as sole agent [C]



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NICE Anxiety Guidelines
Panic Disorder
Pharmacotherapy

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- NOT benzodiazepines
- SSRI licensed for panic (citalopram, escitalopram, paroxetine)
- If SSRI not suitable or patient fails 12/52 course consider imipramine or clomipramine
- Long term treatment and doses at the higher end of the dose range may be needed

- In specialist care: “consider a full exploration of pharmaco-therapy

NICE Anxiety Guidelines
GAD
Pharmacotherapy

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- Don’t use benzodiazepines beyond 2-4 weeks
- Offer an SSRI
- If no response after 12 weeks try another SSRI
- Long term treatment and doses at the higher end of the dose range may be needed
- If venlafaxine considered this should only be started by a specialist mental health practitioner

- In specialist care: “consider a full exploration of pharmaco-therapy

NICE Clinical Guideline 26

March 2005

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PTSD (post traumatic stress disorder): The management of PTSD in children and adults in primary and secondary care

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PTSD Pharmacotherapy

- Consider:
  - mirtazepine or paroxetine (general use)
  - amitriptyline or phenelzine (specialist use)
  - N.B. sertraline not recommended
- NOT first line
- Use if:
  - Patient prefers drugs
  - Delay in getting trauma-focused CBT
  - If trauma-focused CBT fails
  - Sleep disturbance (or short term BZ)
- If drug fails, consider increasing the dose or adding adjunctive olanzapine

NICE Clinical Guideline
October 2005

National Institute for Clinical Excellence

Obsessive compulsive disorder: Core interventions in the treatment of obsessive compulsive disorder and body dysmorphic disorder

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NICE OCD guidelines

- First line CBT (brief or group)
- High intensity CBT or SSRI for more severely ill
  - Generic SSRI
  - Increase dose after 4-6/52 if no response
  - Treat for at least 12/12
- If no response after 12/52 then CBT + SSRI
- If no response switch SSRI or use clomipramine (ECG and BP monitoring)
- If no response refer to secondary care
  - More CBT
  - Antipsychotic augmentation (Buspirone for BDD)
  - Clomipramine + citalopram
- If no response refer to tertiary care to consider neurosurgery

BAP Guidelines for the management of Bipolar Disorder

www.bap.org.uk

Outline

- Fundamentals of patient management
  - Diagnosis
  - Access to services and the safety of the patient and others
  - Enhanced care
- Treatment of different phases of bipolar illness
  - Acute Manic or Mixed Episodes
  - Acute Depressive episode
  - Long-term treatment
  - Treatment in special situations

Acute Manic or Mixed Episodes

- Initiate oral administration of an (atypical) antipsychotic or valproate (A)
- For less ill manic patients lithium or carbamazepine may be considered as a short term treatment (A).
- To promote sleep consider adjunctive benzodiazepine (B)
- Antidepressants should be tapered and stopped (B)

Acute Manic or Mixed Episodes

If symptoms uncontrolled and/or mania is very severe

- Add another first-line medicine.
  - Consider the combination of lithium or valproate with an antipsychotic (A).
  - Consider clozapine in more refractory illness (B).
  - ECT may be considered for manic patients who are severely ill and/or whose mania is treatment resistant and patients with severe mania during pregnancy (C).

Outline

- Fundamentals of patient management
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Acute Depression

- Treat with an antidepressant (e.g. SSRI) and an anti-manic drug (e.g. lithium, valproate or an antipsychotic) together (B).
- Antidepressant monotherapy is not recommended for patients with a history of mania (B).
- Consider adding antipsychotic especially if psychotic symptoms present (A)
- Consider ECT for patients with high suicidal risk, psychosis, severe depression during pregnancy or life-threatening inanition (A).

Acute Depression

Choice of antidepressant

- Antidepressants work in bipolar disorder (Ia)
- There is a risk of switch to mania or mood instability during treatment for depression (I).
  - Antidepressants less likely to induce mania when added to lithium, valproate or antipsychotic (IIa).
  - Tricyclic antidepressants more likely (Ia) and not recommended except for treatment resistant patients (C).
  - Consider lamotrigine, esp. if an antidepressant has previously appeared to provoke mood instability (A).

Outline

- Fundamentals of patient management
  - Diagnosis
  - Access to services and the safety of the patient and others
  - Enhanced care
- Treatment of different phases of bipolar illness
  - Acute Manic or Mixed Episodes
  - Acute Depressive episode
  - Long-term treatment
  - Treatment in special situations

Long-term treatment

Choice of long-term treatments

- Consider lithium monotherapy (A)
  - Lithium protects against both mania and depression, but is more effective at preventing mania (Ia)
  - Long term treatment with lithium decreases the risk of suicide (I)
  - If lithium ineffective or poorly tolerated
    - Valproate protects against mania (and depression) (Ia)
    - Olanzapine protects against mania (and depression) (Ia)
    - Carbamazepine is less effective than lithium (Ib) but may be used especially in non-classical illness (B). Oxcarbazepine has fewer pharmacokinetic interactions
    - Lamotrigine protects against depression (and mania) (Ia)
  - Acute response to an agent favours its use long term (B)

Long-term treatment

If the patient fails monotherapy

- Consider long term combination treatment (C).
  - Where the burden is mania, combine predominantly anti-manic agents (e.g. lithium, valproate, an antipsychotic) (D).
  - Where the burden is depressive, lamotrigine or an antidepressant may be more appropriate in combination with an anti-manic long-term agent (D).
- Maintenance ECT if respond acutely and do badly on oral treatments (D)
- Consider clozapine in treatment resistant patients (C).

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Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term management of insomnia

Technology Appraisal 77

April 2004

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NICE and Z drugs

- Hypnotic medication should only be used for the management of severe insomnia interfering with normal daily life
- Use of these drugs should be in strict accordance with their licence (see BNF for details)
- There is a lack of evidence to distinguish between the Z drugs and the older, shorter acting benzodiazepine hypnotics such as Temazepam
- Use the drug with the lowest purchase price
- Switching from one hypnotic to another should only occur if a patient experiences adverse affects to a hypnotic
- Patients who have not responded to one of the hypnotic drugs should not be prescribed any of the others.

Night Time Sedation

- Avoid drugs if possible
  - see www.netdoctor.co.uk depression community
- Use for no more than 2-3 weeks
- Avoid multiple benzodiazepines
- REVIEW p.r.n. and night time sedation frequently and at discharge
- Following NICE D&T recommendations are that the hypnotic of choice is Temazepam and that the Z drugs should not be routinely used.

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Violence

The short-term management of disturbed/violent behaviour in in-patient psychiatric settings and emergency departments

Clinical Guideline 25
February 2005

Developed by the National Collaborating Centre for Nursing and Supportive Care

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Management of the violent incident

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- Safety for all
- Access - unimpeded
- Time - don't rush ("talking down")
- Manner - calm and reassuring
- Staff - multidisciplinary agreement, adequate numbers
- Medical support
- Use non pharmacological means where ever possible
- Resist pressure to make decisions based on inadequate information
- Document the incident clearly and fully afterwards

Guidance on the Management of Acutely Disturbed Adults

Version 2 – February 2005

Newcastle, North Tyneside and Northumberland NHS Mental Health NHS Trust

Pathway 1

Situation escalating and needing pharmacological intervention

Establish rapport with patient and offer oral medication

Patient refuses oral medication

Go to pathway 2

Oral lorazepam 1-2mg#-**OR**
Oral risperidone 2mg#-(tablet/ syrup/ quicklet formulation).
(Consider Olanzapine (tablets or velotabs) but this is more expensive and so consider if patients have had side effect/not responded to other medications).

Improved? Yes → Go to pathway 4

No

Oral lorazepam 1-2mg-#
Oral risperidone 2mg#-**AND/OR**
(tablet/ syrup/ quicklet formulation)

Improved? Yes → Go to pathway 4

No

Continuously increase dose of antipsychotic and lorazepam
NB – this may mean going above the maximum BNF doses

#-No advantage in further administration (in most cases) for at least 45 – 60 mins.

Pathway 2

Urgent situation – patient refusing oral medication

Attempt to establish rapport / persuade patient to accept oral medication. Consider options (nursing staff levels/ placement/ MHA status/ previous history and response to medication/observation level

Patient still refusing oral medication but accepting of IM medication (not life threatening situation)

IM lorazepam 2mg **OR**
IM haloperidol 5mg +/- lorazepam **OR**
IM olanzapine 10mg
(NICE suggests IM anticholinergic is given with haloperidol. NICE does not recommend the use of an atypical in preference to haloperidol in this situation but may be better if history of severe EPSE))

Improved? Yes → Go to pathway 4

No

Accepting oral medication → Go to pathway 1

Not accepting oral medication → **Repeat pathway 2** (If second IM injection is needed reconsider dose/Consider Zuclopenthixol Acuphase 50-100mg.)

Pathway 3

Severe and immediate risk to life and limb

IM lorazepam 2mg **OR**
IM lorazepam 2mg + haloperidol 5mg* **OR**
IM olanzapine 10mg**
*For individual pts lorazepam alone may be appropriate, for severe behavioural disturbance, a combination is likely to be the appropriate response. When using haloperidol NICE suggest IM anticholinergic in addition.
**No clinical trials in this type of patient (may be better for pts with history of severe EPSE.)

Improved? Yes → Go to pathway 4

No

Repeat after an appropriate interval (2 hours recommended for lorazepam).
Max dose of olanzapine – 20mg/24hrs
Max dose of IM haloperidol – 18mg/24hrs
Max dose of IM lorazepam – 16mg/24hrs

Response? Limited → Accepting oral medication

No

Consider Diazepam IV 10mg over 5mins
(Use diazemuls)
Repeat if necessary.

Not accepting oral medication → Consider Zuclopenthixol acuphase 50-100mg
(Sedation in 1-2hours, peak in 36hrs lasts 72hrs)

Pathway 4

Maintenance/ prevention of recurrence.

Regular medication regimen based on 50 – 100% of the antipsychotic dose required in the first 24 hours divided into 6 hourly doses. Use regular lorazepam if this was part of the original regimen (reducing gradually)

Debrief

Ensure availability of:

- **Parenteral procyclidine** (for acute dystonic reactions) 5-10m IM repeat after 20mins **OR** 5-10mg IV repeat after 10mins
- **Flumazenil** (for benzodiazepine induced respiratory depression) 200 micrograms over 15 seconds then 100 micrograms every 60 seconds until desired level of consciousness is obtained..

Read instructions carefully at this point.

- Flumazenil has a short half life and respiratory function once recovered may deteriorate again
- Seizures can occur

Nursing Observations

After emergency sedation:

BP
Pulse
Temperature
Respiration
Level of Consciousness

Must be monitored

Frequency to be decided by the prescribing doctor, in consultation with nursing staff (probably for at least 2-4 hours).

Use of Flumazenil

1. Indications for use: If, after the administration of lorazepam or diazepam, respiratory rate falls below 10/minute.

2. Caution: " Patients with epilepsy who have been receiving long-term benzodiazepines (see point 5 below).

3. Dose and route of administration: 200micrograms **intravenously** over 15 seconds then 100 micrograms "every 60 seconds until "desired level of "consciousness is obtained.

4. "Maximum dose: " 1mg in 24 hours (one initial dose and eight subsequent doses).

5. Side effects and warnings: " Patients may become agitated, anxious or fearful on wakening. Seizures may occur in regular benzodiazepine "users. Flumazenil has a short half-life and respiratory function once recovered may deteriorate again.

6. Management: " Side effects usually subside.

7. "Monitoring: " As per the notes in the box 'Nursing Observations'. If respiratory rate does not return to normal or patient is not alert after initial doses are given then assume sedation to some other cause.

		Time to peak plasma concentration	Approximate plasma half-life	Recommended dosage interval	Single dose	Max BNF dose / 24hours #
Haloperidol	IM	15-60 mins	10-36hours	4-6 hourly	5-18mg	18mg
	ORAL	2-6 hours	20 hours	4-6 hourly	5-20mg	30mg
Lorazepam	IM†	1-3 hours	12 hours	6 hourly	1-4mg	4mg
	ORAL	1-3 hours	12 hours	4 hourly	1-4mg	4mg
Olanzapine	IM*	15-45 mins	32-50 hours	2 hourly	5-10mg	20mg
	ORAL	5-8 hours	32-50 hours	12 hourly	5-20mg	20mg
Risperidone	ORAL	1-2 hours	24 hours	12 hourly	2-4mg	16mg
Diazepam	IV†	8 mins		4 hourly	10mg	20mg
Zuclopenthixol (Acuphase)	IM	36 hours	8-24 hours	24-48 hours	50-150mg	400mg per course of max 4 injections

It can at times be appropriate to exceed BNF maximum 24-hour doses (e.g. with lorazepam but probably not with olanzapine (i.m. + oral combined)). However this should only be done after discussion with the RMO. Extra concern is needed regarding Consent to Treatment, especially in patients detained under the MHA. Document decisions with great care.

* Recommended max of 3 doses in 24 hours for max of 3 consecutive days. Take particular care if administered to patient receiving paenteral benzodiazepines.

† Should not be given within 1 hour of i.m. olanzapine.

NOTE: This document is written for primarily with working age adults in mind. Lower doses may need to be used in the elderly due to the increased risk of side effects. Increased physical observations may also be necessary.

Conclusions

- Psychopharmacology is important and complicated
- We are in a current state of great flux with regard to available drugs and guidelines
- There are no short cuts
- Be familiar with a small number of drugs
- Don’t initiate drugs “off label”