SOUTH AFRICAN PRIMARY HEALTHCARE LEVEL ESSENTIAL MEDICINES LIST
CHAPTER 16: MENTAL HEALTH CONDITIONS
NEMLC RECOMMENDATIONS FOR MEDICINE AMENDMENTS (2020 -2023 REVIEW CYCLE)

The Primary Health Care (PHC) Mental Health Conditions Chapter underwent detailed clinical editing resulting in editorial changes for clarity and alignment with the Adult Hospital (AHL) Mental Health Conditions and Substance Misuse Chapter.

Medicine amendment recommendations, with supporting evidence and rationale are listed below.
Kindly review the medicine amendments in the context of the respective standard treatment guideline (STG) and supporting medicine reviews.

A: PROPOSED AMENDMENTS

SECTION	MEDICINE/MANAGEMENT	ADDED/DELETED/AMENDED/ NOT ADDED/ RETAINED
16.1.2 AGGRESSIVE DISRUPTIVE BEHAVIOUR IN ADULTS	Benzodiazepines (e.g., Midazolam buccal & IM and Diazepam oral)	Retained with addition of note regarding onset and duration of action
	If alcohol use is suspected: Thiamine, Oral	Retained
	Haloperidol, IM	Deleted
	Olanzapine, IM & oro-dispersable	Added
16.1.3 AGGRESSIVE DISRUPTIVE BEHAVIOUR IN CHILDREN AND ADOLESCENTS	Benzodiazepines (e.g., Midazolam, IM)	Retained
	Haloperidol, IM	Deleted with cross reference to Paediatric Hospital Level STG for management, if unresponsive to benzodiazepines
	Olanzapine, IM	Not added
	Olanzapine, oro-dispersable	Not added
16.5.2 SCHIZOPHRENIA SPECTRUM DISORDERS (SCHIZOPHRENIA)	Haloperidol, Oral	Retained with amendment in dosage range
	If good response/ tolerability to haloperidol, or patients' preference: Flupenthixol decanoate, IM & Zuclopenthixol decanoate, IM	Retained, but moved up in the algorithm (with change in level of prescriber)
	If good response but extrapyramidal side effects: Anticholinergic, e.g Orphenadrine, Oral	Added to align with Adult Hospital Level STG
	If poor response: Risperidone, oral	Retained
	Patients already stabilised on chlorpromazine: Chlorpromazine, Oral	Retained
	For breakthrough episodes, short-term therapy of: Risperidone, Oral	Retained
16.9.1 SUBSTANCE USE DISORDERS	**For severe anxiety, irritability, and insomnia:** Diazepam, Oral	Retained (duration of treatment lowered and aligned with Adult Hospital Level STGs)

The Primary Health Care (PHC) Mental Health Conditions Chapter, was updated to include "Doctor prescribed" for all schedule 5 medicines as PHC nurses with section 56(6) permit are prohibited to prescribe schedule 5 medicines.[1]

In the introduction of the chapter an editorial change was made replacing "mentally ill" with "people with mental illness". A recommendation to consider the addition of registered counsellors as mental health practitioners was accepted as this service is gradually rolling out in the public sector. The link to training material for the South African

[1] Minutes of the NEMLC meeting of 20 July 2023.

Police Service (SAPS) has been deleted because the training manuals are no longer available, as confirmed by the national mental health directorate, and as raised by an external commentator the interactive links in the chapter are no longer valid. The reason is that civilians cannot provide training to the SAPS. Relevant mental health training is to be incorporated into standard SAPS training.

The STG was amended as follows:

Nurses with authorisation as provided by Section 56(6) of the Nursing Act 33 of 2005 may initiate and/or maintain treatment with medicines as per the STGs and in accordance with their scope of practice. Precepts of the Mental Health Care Act (MHCA) No. 17 of 2002 include: » All people with mental~~ly~~ illness and/or intellectual disability~~ed~~ must be managed under the Act and its regulations as either Voluntary, Assisted or Involuntary Mental Health Care Users. » All registered medical practitioners, professional nurses, psychologists, occupational therapists (OTs), ~~and~~ social workers, and registered counsellors whose training includes mental health are designated Mental Health Care Practitioners. » At the PHC level, familiarity with MHCA Forms 01, 02, 04, 05, 07, 11, 13A, 22 and 48. An understanding of the related processes is required by all mental health practitioners. » Specific obligations of the South African Police Service (SAPS) to protect, apprehend, and assist with transfer, people with mental illness.

An external comment was received, for all conditions, to include the psychoeducation of the patient's family regarding the condition, management (importance of adherence to medication and psychotherapy/counselling), as well as red flags to look out for when patient is relapsing. It was motivated that by this intervention the potential for stigma will be reduced and conflict in families might be reduced offering the patient more. Furthermore, it was motivated that by promoting better supervision and adherence, risk to the patient and others, as well as relapse frequency can be reduced significantly potentially improving quality of life for the patient and family and preserving the patient's functionality and ability to contribute to society.

The committee supported adding a note regarding either counselling or psychoeducation of the family to all conditions, with a slight variation in phrasing depending on the condition. Furthermore, the meaning of the selected terminology of psychoeducation[2] was added to the introduction of the chapter to ensure that the definition is understood throughout the chapter and to promote investment in time in ensuring that the patient's family and friends have a clear understanding of the patient's condition.

The following was added to the STG

Meaning of selected terminology used in this chapter: » Psychoeducation (psychological education) involves informing a patient and their family or support system about their illness and providing problem solving, communication, and assertiveness skills training. The goals are to enable understanding, self-care, crisis management, suicide prevention, and relapse prevention. Information on aetiological factors, signs and symptoms, early signs of relapse, treatment options, need for adherence to treatment, and long-term course and outcome should be provided with consideration of the individual and their family's culture, beliefs, and coping mechanisms. Myths and misconceptions regarding the illness and its treatment are identified and managed in a person-centred manner. Advice on managing difficult behaviour and emergency situations is provided, and stigma should be dispelled. Psychoeducation may require several individual, family, or group sessions, depending on the complexity of the illness and the understanding of the problem by the individual and their family/ support system. Involvement of a registered counsellor, occupational therapist, and/or social worker is advised.

Level of Evidence: IVb: Guidelines

A description of risk assessment was also provided citing and adapting Australian Guidance[3] as there are currently no South African standardised guidance tools available for risk assessment.

The following was added to the STG:

[2] Definition (Psychoeducation): Sarkhel S, Singh OP, Arora M. Clinical Practice Guidelines for Psychoeducation in Psychiatric Disorders General Principles of Psychoeducation. Indian J Psychiatry. 2020 Jan;62(Suppl 2):S319-S323. doi: 10.4103/psychiatry.IndianJPsychiatry_780_19. Epub 2020 Jan 17. PMID: 32055073; PMCID: PMC7001357

[3] Definition (Risk Assessment): New South Wales Government. SESLHDGL/082 Clinical Risk Assessment and Management. 2022/04 Version 7.2

» **Risk assessment** refers to a clinical judgement of the patient's potential for:
- suicide or self-harm
- aggression or violence towards others
- being assaulted by others
- high risk impulsive or addictive behaviour for e.g. high-risk sexual intercourse
- severe self-neglect
- being exploited
- reputational damage
- non-adherence to treatment
- causing damage to property
- poor physical health

A risk assessment is performed by collecting information from the patient and relevant stakeholders, which may include the person's family/ support system, healthcare providers, (including community health workers or social workers who have knowledge of the person's home), as well as past clinical and forensic history.

Close attention must be given to women in the perinatal period, people who care for others (e.g., parents, grandparents, teachers, and health and social care providers), and those with previous high-risk behaviour.

While the clinical judgement may not always be accurate it should be justified by the available information. The clinical judgement serves to inform precautionary interventions, e.g., close clinical follow-up after hospital discharge with increased attention by the Ward-Based Outreach Team (WBOT), referral to social welfare / statutory services, advice regarding a protection order, and/or further psychoeducation.

A useful clinical guideline on how to conduct a risk assessment is available at:
https://www.seslhd.health.nsw.gov.au/sites/default/files/documents/SESLHDGL%20082%20-%20%20Clinical%20Risk%20Assessment%20and%20Management%20-%20Mental%20Health2.pdf

Level of Evidence: IVb: Guidelines

A comment to mention palliative care in the PHC Mental Health Conditions Chapter was not accepted; as the chapter covers mental health conditions in all patient populations (e.g., general medical, emergencies, obstetrics & gynecology, surgical, palliative care and poisoning). The committee recommended, as is current practice in the STGs, that other chapters where appropriate are cross-referenced to mental health conditions so that mental health conditions are integrated into the general healthcare process.

An external commentator raised that Dementia is not covered in sufficient detail in the mental health conditions chapter. Dementia is covered in PHC Chapter 15 Central Nervous System (CNS).

16.1.2 AGGRESSIVE DISRUPTIVE BEHAVIOUR IN ADULTS

General Measures

The STG was updated to include the importance of listening to the patient.

An external comment was received suggesting that a section on manual restraints be included in line with National Policy Guidelines, in line with the adult hospital level mental health conditions and substance misuse chapter, to inform and educate the family of aggressive patients restrained regarding the reasons for the restraints. It was motivated that this could assist with processing the traumatic nature of restraints by the patient and family, as well

as serve to reduce complaints received from the family. A section on manual restraint was added to the STG in line with National Policy[4] and the adult hospital level mental health conditions and substance misuse chapter[5].

Level of Evidence:IVb: Guidelines

An external comment was received and accepted that any injuries or death that occurred associated with restraining a patient must be reported in writing to the Mental Health Review Board under the Mental Health Care Act (MHCA). Additionally, a note for reporting to the health facility quality assurance was also added in line with standard reporting mechanisms.

For mechanical restraints, as prescribed by a doctor was added to the STG.

The STG was updated to include guidance for restraint for aggressive disruptive behavior in pregnant women including sparing restraint in a supported semi-seated position (not supine or prone), with care, and instruction never to leave pregnant women unattended.

For "aggressive disruptive behaviors", an external commentator reiterated the need for including psychoeducation of family as often times the patient is accompanied by a family member who waits in the waiting room; and it would be helpful to explain procedures to the family so even if the patient is not fit to understand the treatment plan, the family understands and can offer further support and reassurance once the patient has been stabilised. An added motivation for including counselling of family was that it may prevent redress cases. A section on “Counsel the family/ friend/ patient escort” has now been added.

The STG was updated as follows:

[4] National Department of Health. Policy Guidelines on Seclusion and Restraint of Mental Health Care Users 2012. https://www.knowledgehub.org.za/elibrary/policy-guidelines-seclusion-and-restraint-mental-health-care-users-2012.

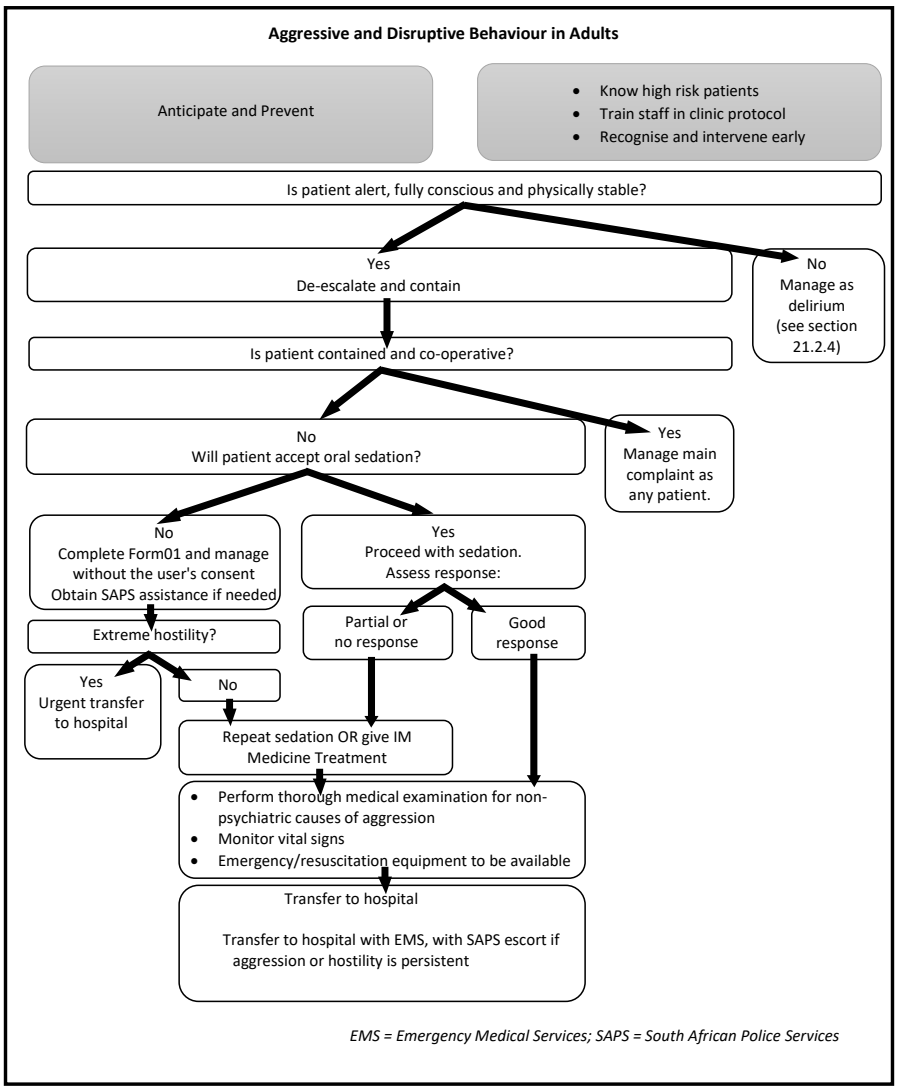
[5] National Department of Health: Essential Drugs Programme. Adult Hospital level STGs and EML. https://www.knowledgehub.org.za/content/standard-treatment-guidelines-and-essential-medicines-list

GENERAL MEASURES

» Be prepared:
  - Be aware of high-risk patients e.g. those known with previous violence, substance misuse, State patients.
  - Have a step-wise protocol available to ensure safety of the patient and all in the clinic.
  - Establish clear roles for all staff members.
  - Have a triage plan for early signs of aggression.
  - Have available backup – security, SAPS, and Emergency Medical Service (EMS).
  - Prepare a designated calming area – suitable for regular monitoring.
» De-escalate and contain:
  - Be calm, confident, kind and reassuring. Listen to the patient.
  - Maintain a submissive posture with open hands; do NOT turn your back.
  - Do NOT argue, confront delusions, or attempt to touch the patient.
» Be vigilant for delirium, medical, and other causes while calming the patient.
» Manual restraint:
  - Manual restraint refers to interventions done with hands or bodies without the use of any device, to limit a user's movement of body or limb. It is sometimes called "holding".
  - May be necessary to administer medication – must be respectful, controlled, kept to a minimum, and should preferably be applied by personnel of the same sex as the patient.
  - Report any injuries or death associated with the restraint to the Mental Health Review Board and health facility quality assurance department.
» Mechanical restraint:
  Only use when absolutely necessary to protect the patient and others in an acute setting for as short a period of time as possible and as prescribed by a doctor. See national policy guidelines: https://www.knowledgehub.org.za/elibrary/policy-guidelines-seclusion-and-restraint-mental-health-care-users-2012
  - Record type, sites, and duration of any restraints used, with 15-minute monitoring of vital signs, mental state, restraint sites, and reasons for use.
  - For people managed under the MHCA, complete and submit MHCA Form 48, along with reports of any injuries or death incurred, to the Mental Health Review Board and health facility quality assurance department.
» Pregnant women:
  - Never leave unattended.
  - Use restraint sparingly and with care, with mother in a supported, semi-seated position (not supine or prone).
» Counsel the family/friend/patient escort regarding:
  - Possible causes for the behaviour.
  - Reasons for restraints if used.
  - Importance of their continued support of the patient after hospital discharge.

The algorithm for aggressive disruptive behavior in adults was amended, including South African Police Service (SAPS) assistance only if needed i.e., if aggression or hostility is persistent.

The amended algorithm is as follows:



Benzodiazepines (e.g., Midazolam buccal & IM and Diazepam oral): *Retained with addition of note regarding onset and duration of action*

The following note regarding the onset and duration of action for the various benzodiazepines was added to the STG to align to the Adult Hospital Level STGs and EML.

Note:
» To avoid inappropriate repeat dosing allow at least 30 minutes for the oral/IM medication to take effect.
»
» Do not administer IM olanzapine and IM benzodiazepines together
» Midazolam IM has a rapid onset of action (10–20 minutes) and very short duration of sedation (approximately 1hr20 minutes).

If alcohol use is suspected:
Thiamine, Oral: *Retained*

Haloperidol, IM: *Deleted*
Haloperidol injection was not available in the South African market. However, haloperidol IM is included in the therapeutic interchange database for aggressive disruptive behaviour. Additionally, Clotiapine 40mg/l injection is listed in the therapeutic interchange database.

Olanzapine IM: *Added*
Olanzapine, oro-dispersable: *Added*

Refer to the medicine review - Olanzapine for aggression in adults, 14 March 2024, below:



Olanzapine for agression_PHC-Adults

Recommendation: Considering that parenteral haloperidol supply has been erratic in South Africa, the PHC/Adult Hospital Level Committee suggest using olanzapine, oral, oro-dispersible or parenteral formulations.
Rationale: The very low certainty evidence suggests olanzapine may be superior to lorazepam and to the combination of haloperidol and promethazine in reduction of agitated or aggressive behaviour. There appears to be no difference in achieving sedation.
Level of Evidence: Very low certainty evidence
Review indicator: New evidence of benefit or harm

The STG was amended as follows:

MEDICINE TREATMENT
Oral treatment:
Benzodiazepines, e.g.: (Doctor prescribed)
Diazepam, oral, 5 mg, immediately.
OR
Midazolam, buccal, 7.5–15 mg, immediately, using the parenteral formulation.
~~If alcohol use is suspected:~~
~~**ADD**~~
~~Thiamine, oral, 300 mg immediately and daily for 14 days.~~
~~If oral treatment fails after 30–60 minutes,~~

~~Inadequate~~ If response to oral benzodiazepine (after 30–60 minutes) or oral treatment refused, administer parenteral or orodispersible olanzapine:

- Olanzapine, orodispersible tablet or IM, 5–10 mg immediately (Doctor prescribed)
    - Repeat after 30–60 minutes if needed.

Note:
» Use lower doses of olanzapine (2.5–5mg) in elderly, frail, or medically unwell patients.
» Repeated doses may result in excessive sedation.

If previous intolerability to olanzapine (e.g., previous neuro-malignant syndrome) administer parenteral benzodiazepine:
Short-acting benzodiazepines, e.g.: (Doctor prescribed)
Midazolam, IM, 7.5–15 mg immediately.
Repeat after 30–60 minutes if needed.

Note:
» To avoid inappropriate repeat dosing allow at least 30 minutes for the oral/IM medication to take effect.
» Do not administer IM olanzapine and IM benzodiazepines at the same time.
» Midazolam IM has a rapid onset of action (10–20 minutes) and very short duration of sedation (approximately 1 hour and 20 minutes).

Note: Long acting injectable antipsychotics e.g., flupenthixol decanoate and zuclopenthixol decanoate have NO role in rapid tranquillisation.

The following note was added to the STG before a caution box regarding rapid tranquillisation and thiamine dosing if alcohol use is suspected.

Note: Long-acting injectable antipsychotics e.g., flupenthixol decanoate and zuclopenthixol decanoate have no role in rapid tranquillisation.

CAUTION

» Rapid tranquillisation may cause cardiovascular collapse, respiratory depression, neuroleptic malignant syndrome, and acute dystonic reactions.
» The elderly, children, intellectually disabled and those with comorbid medical conditions and substance users are at highest risk.
» **An emergency trolley, airway, bag, oxygen, and intravenous line equipment must be available**.

If alcohol use is suspected:
ADD

- Thiamine, oral, 300 mg immediately and daily for 14 days.

16.1.3 AGGRESSIVE DISRUPTIVE BEHAVIOUR IN CHILDREN AND ADOLESCENTS

Benzodiazepines (e.g., Midazolam, IM): *Retained*
Haloperidol, IM: *Deleted with cross reference to Paediatric Hospital Level STG for management, if unresponsive to benzodiazepines*
Olanzapine, IM: *Not added*
Olanzapine, oro-dispersable: *Not added*

Haloperidol injection was not available in the South African market, with limited irregular supply through Section 21 Approval. The Paediatric Hospital STG has retained haloperidol IM for the indication of sedation of an acutely disturbed child or adolescent until supply diminishes completely. Thereafter, a circular will be formulated for managing alternative recommendations to Haloperidol and a formal review for alternatives conducted in the next paediatric review cycle; if Haloperidol continues to be a problem.[6]

The STG was expanded to include additional nonpharmacological measures including notes on de-escalation, calming and containing methods; excluding and managing abuse or psychological trauma and involving a social worker. Consideration was also given to autism spectrum disorder and intellectual disability with a cross reference to Section 16.8.1: intellectual disability.

For Aggressive disruptive behaviour in children and adolescents under mechanical restraints an external comment to add that MHCA 48 would only be completed and sent to Mental Health Review Board if the restrained patient is in fact a Mental Health Care User under the Mental Health Care Act was accepted and added.

The STG was updated as follows:

AGGRESSIVE DISRUPTIVE BEHAVIOUR IN CHILDREN AND ADOLESCENTS
R45.1/R45.4-6

As with adults, agitation among children and adolescents may escalate to overt aggression and violence. However, aggression may also occur suddenly, without warning signs, particularly in children with neurodevelopmental conditions such as intellectual disability and autism spectrum disorder. All children and adolescents should be treated respectfully and calmly, especially if seen in a busy, noisy clinic environment.
Possible causes for aggressive, disruptive behaviour include:

» **Physical:** epilepsy (pre-, intra-, and post-ictal), acute medical (e.g. encephalopathy, infection, metabolic disease, medication adverse effects) ~~e.g. encephalopathy or other intracranial pathology, infection, seizures, metabolic disease, medication adverse effects and intoxication.)~~or surgical conditions, injuries (including traumatic brain injury).
» **Neuropsychiatric:** severe anxiety, distress, and/or acute or chronic traumatic stress, especially in children with neurodevelopmental disorders (which may be mild and missed clinically; see Section 16.8.1 ~~Special considerations~~: Intellectual disability), severe anxiety.

[6] Minutes of the NEMLC meeting of 31 March 2022.

» **Substance use:** alcohol, cannabis, methaqualone (mandrax) intoxication or withdrawal, stimulant (cocaine, methamphetamine [tik], methcaninone [cat]) intoxication or withdrawal.
» **Psychological factors:** high levels of impulsivity and antagonism, hypersensitivity to rejection or insult, and poor frustration tolerance may contribute to aggression and rage.

CAUTION

» **An unsafe home/ school/ community environment must always be considered**
» Children who have been abused, and /or have a neurodevelopmental or other psychiatric condition may also have medical conditions, trauma and substance misuse. **Do not assume aggressive behaviour is due to abuse, mental illness or psychological factors**

GENERAL MEASURES

» Be prepared – have in place:
  - a step-wise protocol to ensure safety and protection of the child or adolescent aligned with the Childrens Act No. 38 of 2005 and the nationa Policy Guidelines on Child and Adolescent Mental Health (available from https://www.gov.za/documents/policy-guidelines-child-and-adolescent-mental-health).
  - clear roles for all staff members.
  - a triage plan for children and adolescents at high risk of aggression.
  - a designated calming area – suitable for regular monitoring.
» De-escalate and contain:
  - Be calm, confident, kind and reassuring.
  - Maintain a submissive posture with open hands; do NOT turn your back.
  - Limit the number of the people attending the child, limit noise levels.
  - Do NOT attempt to touch the patient unnecessarily
  - Do NOT confront, argue, or smother with kindness.
  - Try and discern the child's/adolescent's wishes and attend to them immediately.
» Examine for delirium, medical, and other causes while calming the patient.
» Mechanical restraint:
  - Only use when absolutely necessary to protect the patient and others in an acute setting for as short a period of time as possible.
  - Beware of using excessive force, especially if the child/ adolescent fights back.
  - Type, sites, and duration of any restraints used must be documented, with 15-minute monitoring of vital signs, the mental state, restraint sites and reasons for use.
  - ~~Ccomplete MHCA Form 48 and submit to Mental Health Review Board if mechanical restraint was used.~~ For people managed under the MHCA, complete and submit MHCA Form 48, along with reports of any injuries or death incurred, to the Mental Health Review Board and health facility quality assurance department.

~~Exclude medical causes, e.g. encephalopathy or other intracranial pathology, infection, seizures, metabolic disease, medication adverse effects and intoxication.~~

MEDICINE TREATMENT

For children < 6 years of age:
Sedation with psychotropic agents should only be considered in extreme cases and only after consultation with a specialist.

For children ≥6 years of age and adolescents:

- Benzodiazepines, e.g.: (Doctor prescribed)
- Midazolam, IM, 0.1–0.15 mg/kg/dose immediately as a single dose ~~(Doctor initiated).~~
  - Onset of action: within 5 minutes.

~~**CAUTION**~~

~~» Rapid tranquillisation may cause cardiovascular collapse, respiratory depression, neuroleptic malignant syndrome (see Section 16.2.2: Neuroleptic malignant syndrome) and acute dystonic reactions (see Section: 16.2.1: Extra-pyramidal side effects).~~
~~» The elderly, children, intellectually disabled and those with comorbid medical conditions and substance users are at highest risk.~~

~~**An emergency trolley, airway, bag, oxygen and intravenous line must be available**~~.

If sedation with benzodiazepines is inadequate: See Hospital Paediatric STGs Chapter 14.1 SEDATION OF AN ACUTELY DISTURBED CHILD OR ADOLESCENT, for further medicine management.

~~- Haloperidol, IM, 0.025–0.05 mg/kg/day in 2–3 divided doses (Doctor initiated).~~
  ~~- Maximum daily dose: 0.15 mg/kg/day.~~

~~**For management of acute dystonic reaction: See Section 16.2.1: Extra-pyramidal side effects.**~~

CAUTION

Always consult with a doctor, preferably a psychiatrist where possible, when prescribing antipsychotic medication to children and adolescents.

» Rapid tranquillisation may cause cardiovascular collapse, respiratory depression, neuroleptic malignant syndrome (see Section 16.2.2: Neuroleptic malignant syndrome), and acute dystonic reactions (see Section: 16.2.1: Extra-pyramidal side effects).

» The elderly, children, intellectually disabled, and those with comorbid medical conditions and substance use~~rs~~ are at highest risk.

» **An emergency trolley, airway, bag, oxygen and intravenous line equipment must be available.**

16.3 ANXIETY DISORDERS

General Measures

An external commentator indicated that referral for counselling services when addressing psychosocial stressors can also include registered counsellors employed by the Department of Health and not only non-governmental organisation counsellors. The term registered counsellor was added.

It was recommended, by an external commentor, to include for anxiety disorders reassurance and support of the patient and family; and if the crisis is ongoing and current, provide emotional containment and counselling on how to manage the crisis. The commentor elaborated that this may include referral to access police, social work and/or legal services; and that if the crisis is very recent, provision of emotional containment, as well as normalization of and psycho-education on symptoms and their management, e.g., advise on the importance of engaging with thought and feelings towards making sense and feeling safer again. Psychotherapy, usually of a supportive/cognitive-behavioural nature was raised as an important inclusion; trauma debriefing was mentioned as not routinely recommended. Therefore, 'educate' patient and family was modified to 'psychoeducate', which would include psychological aspects of the education process. The type of psychotherapy (under medicine treatment) is not specified as is not within the scope of essential medicines list (EML), but retained as an alternative to medicine treatment for those parts of South Africa where a psychologist is available (type of therapy would be determined by the psychologist).

The STG was amended as follows

GENERAL MEASURES

» Assess severity of the condition.

» Maintain an empathic and concerned attitude.

» ~~Educate the patient and family regarding the nature of the anxiety.~~

» Exclude underlying medical conditions and optimise treatment for comorbid medical conditions (e.g. heart disease, hypertension, COPD, asthma, GORD, inflammatory bowel disease, thyroid disease, epilepsy).

» Screen for, and manage, underlying or co-morbid substance use, e.g. nicotine, alcohol, over the counter analgesics, benzodiazepines.

» Psychoeducate the patient and their family regarding the nature of anxiety, importance of managing the condition, and early signs of recurrence.

» Explore and address psychosocial ~~stressors~~factors:

- Stress management/coping skills – refer to ~~social worker~~ registered counsellor or non-governmental organization (NGO) counselling services, e.g. SA Depression and Anxiety Group (https://www.sadag.org/)
- Social support systems, relationship, and family issues – refer to social worker, registered counsellor, or NGO counselling, e.g., Family and Marriage Society of South Africa (https://famsa.org.za)
- Abuse – refer to a social worker, social welfare, and/or People Opposing Women Abuse (https://www.powa.co.za/POWA/).

16.4.1 DEPRESSIVE DISORDERS

General Measures

Psychoeducation was included under general measures.

The STG was amended as follows:

GENERAL MEASURES

» Assess severity of the condition.
» Maintain an empathic and concerned attitude.
» Exclude underlying medical conditions and optimise treatment for comorbid conditions (e.g. hypothyroidism, anaemia, HIV/AIDS, TB, cancers, diabetes).
» Screen for, and manage, underlying or co-morbid substance use, e.g. nicotine, alcohol, over the counter analgesics, benzodiazepines.
» Psychoeducate the patient and their family regarding the nature of depression, importance of managing the condition, and early signs of recurrence.
» Explore and address psychosocial stressors:
  - Stress management / coping skills – refer to social worker or NGO counselling services, e.g. SA Depression and Anxiety Group (https://www.sadag.org/)
  - Social support systems, relationship and family issues – refer to social worker or NGO counselling, e.g., Family and Marriage Society of South Africa (https://famsa.org.za/)
  - Abuse - refer to a social worker, social welfare, and/or People Opposing Women Abuse (https://www.powa.co.za/POWA/).

16.4.2 BIPOLAR DISORDER

Description

An editorial change was affected under the description section of the bipolar disorder STG where cross reference to Section 16.6: Psychiatric patients - general monitoring and care was moved to the end of the STG.

The STG was amended as follows:

DESCRIPTION

A lifelong illness which may have an episodic, variable course with the presenting episode being manic, hypomanic, mixed, or depressive (according to accepted diagnostic criteria). An episode of mania is typically characterised by an elevated mood where a patient may experience extreme happiness, lasting days to weeks, which might also be associated with an underlying irritability. Such mood is associated with increased energy/activity, talkativeness and a reduction in the need for sleep, and features may be accompanied by grandiose and/or religious delusions.

The diagnosis of bipolar disorder should be confirmed by a specialist. It may present with any mood state, e.g. with treatment resistant depression. The diagnosis requires either a current or previous episode of mania (bipolar I disorder) or hypomania (bipolar II disorder), but this history is not always clear, in which case a trial of treatment may be indicated. ~~In stable patients with good insight and support, PHC may continue treatment and management of comorbid medical conditions - See Section 16.6: Psychiatric patients - general monitoring and care.~~

Comorbid substance use is common. It may confuse the clinical presentation and may cause poor adherence to medication. The 'dual diagnosis' of bipolar disorder and an addiction requires referral to a specialist and ongoing monitoring after discharge

GENERAL MEASURES

» Provide ~~R~~reassurance and support of the patient and family.
» Psychoeducate regarding the nature of bipolar disorder, the importance of treatment adherence, and early signs of recurrent episodes.

MEDICINE TREATMENT

For manic, agitated and acutely disturbed patients:
Stop antidepressants if prescribed.
Manage as for the aggressive or disruptive patient. See Sections 16.1.2: Aggressive disruptive behaviour in adults and 16.1.3 Aggressive disruptive behaviour in children and adolescents.

For stable patients:

Support treatment adherence and manage comorbid medical conditions - See Section 16.6: Psychiatric patients - general monitoring and care.

REFERRAL

All patients

16.5 PSYCHOSIS

The STG was aligned to the Adult Hospital Level STG on psychotic disorders as follows:

DESCRIPTION

Psychosis is characterised by a loss of contact with reality, and may present with:

» Delusions: Fixed, unshakeable, false beliefs which are not in keeping with a person's society, culture, or religion. Beliefs may be ~~along~~ persecutory, referential, grandiose, religiose, erotic, or bizarre in nature.
» Hallucinations: Perceptual disturbances, e.g. auditory hallucinations, which are heard as voices distinct from the patient's~~'~~ thoughts.
» Disorganised thinking: Manifests as disordered flow of speech, such that the person does not make sense.
» Grossly disorganised or abnormal motor behaviour (including catatonia).
» Negative symptoms: reduced emotional expression, apathy, avolition, lack of speech, lack of social interaction.

Psychosis occurs in psychotic disorders (which may be acute, transient, or chronic), other psychiatric conditions such as bipolar disorder or depression, medical conditions (e.g. certain types of epilepsy), or substance use (intoxication or withdrawal).

Psychosis is often accompanied by a lack of insight into the symptoms and poor judgement. The risk to self and others must always be assessed. It may be necessary to treat as an Assisted or Involuntary User under the MHCA.

~~The patient may experience perceptual disturbances, e.g. hallucinations that are generally auditory, as well as disturbances of thought content, i.e. delusional thought process. Patients generally have no insight into their symptoms and may be resistant to intervention. The presentation may be acute (acute psychosis) or chronic (schizophrenia).~~

16.5.1 ACUTE AND TRANSIENT PSYCHOTIC DISORDERS

Description

The STG was aligned to Adult Hospital Level STG and the description and management revised from aggressive/ disruptive behaviour to that of acute and transient psychotic disorders

General Measures
Psychoeducation for the patient and their family regarding the condition and red flags to watch for if the psychosis worsens or recurs was added.

The STG was updated as follows:

ACUTE AND TRANSIENT PSYCHOTIC DISORDERS
F23.0-F23.9/F24/F28/F29 + (F10.0-F19.9/R45.0-8/Z65.0-5/Z65.8-9/Z81.0-4/Z81.8)
~~F23.0-3/F23.8-9 + (F10.0-F19.9/R45.0-8/Z65.0-5/Z65.8-9/Z81.0-4/ Z81.8)~~

DESCRIPTION
Sudden onset of ≥ 1 psychotic symptoms (usually delusions, hallucinations or disorganised thinking) which resolves spontaneously, usually within 1 month, with a full return to premorbid social or occupational functioning. Stressful events may precede the psychotic episode. Within 3 years, 40-50% will have a recurrent episode or develop schizophrenia or bipolar disorder.
~~Acute psychosis is a clinical state characterised by recent onset of psychotic symptoms such as: hallucinations, delusions, disorganised or illogical speech, agitation or bizarre behaviour and extreme and labile emotional states.~~
~~These symptoms may be preceded by a period of deteriorating social, occupational and academic functioning.~~

GENERAL MEASURES
» Refer all new onset psychosis to hospital for a medical, substance use, and mental health evaluation (see Adult Hospital STG Section 15.5.1: : Acute and transient psychotic disorders).
» For agitated and acutely disturbed patients, manage as for the aggressive or disruptive patient. See Section 16.1.2: Aggressive disruptive behaviour in adults and 16.1.3 Aggressive disruptive behaviour in children and adolescents.

» Ensure the safety of the patient and those caring for them.
» Minimise stress and stimulation.
» Do not challenge what appear to be false statements or delusions.

After hospital discharge/ on return to PHC:
» Provide active follow-up with 6-monthly visits for three years with mental health and substance use screening and general health promotion.
» Psychoeducate the patient and their family regarding the condition and red flags to watch for if the psychosis worsens or recurs.
» Address psycho-social stressors – refer to social worker, counselling services.

Women of childbearing potential:
» Ensure family planning
» If the patient is a parent/guardian – refer to social worker to assess home functioning and childcare.

MEDICINE TREATMENT
» ~~For agitated and acutely disturbed patients, manage as for the aggressive or disruptive patient.~~ See Sections 16.1.2: Aggressive disruptive behaviour in adults and 16.1.3 Aggressive disruptive behaviour in children and adolescents.

REFERRAL
All patients with active psychosis

16.5.2 SCHIZOPHRENIA SPECTRUM DISORDERS (SCHIZOPHRENIA)

Haloperidol, Oral: *Retained with amendment in dosage range*

The STG was aligned to the Adult Hospital Level STG. As the oral haloperidol formulation available is a 1.5mg scored tablet; the lower end of the dosage range for oral haloperidol was amended for ease of dosing.

If good response/ tolerability to haloperidol, or patients' preference
Flupenthixol decanoate, IM: Retained, with change in level of prescriber and *initial dose aligned with maintenance dose.*

Zuclopenthixol decanoate, IM: Retained, with change in level of prescriber and adjustment of dosing range to align with Adult Hospital level dosing

Long-acting injectable antipsychotics (*Flupenthixol decanoate* or *Zuclopenthixol decanoate* were added in line with adult hospital level algorithm, to facilitate adherence and relapse prevention, for prescribing by medical officer at PHC level.

If good response but extrapyramidal side effects, add:
Anticholinergic, e.g Orphenadrine, Oral[7]: *Added to align with Adult Hospital Level STG*

If poor response switch to risperidone:
Risperidone, oral: *Retained*

Patients already stabilised on chlorpromazine:
Chlorpromazine, Oral: *Retained*

For breakthrough episodes, short-term therapy of:
Risperidone, Oral: *Retained*

Psychoeducation of the patient and their family regarding the nature of schizophrenia, the importance of treatment adherence, and early signs of recurrent episodes was added.

The STG was updated as follows:

SCHIZOPHRENIA SPECTRUM DISORDERS (SCHIZOPHRENIA)
F20-F20.9/F21/F22.0-22.9; F25.0-25.9 + (F10.0-F19.9/R45.0-8/Z65.0-5/Z65.8-9/Z81.0-4/ Z81.8)
~~F20.0-6/F20.8-9 + (F10.0-F19.9/R45.0-8/Z65.0-5/Z65.8-9/Z81.0-4/Z81.8)~~

DESCRIPTION
Schizophrenia is the most common, chronic psychotic disorder and is characterised by recurrent, severe, psychotic episodes which are accompanied by a marked deterioration in personal, social, and occupational functioning.
Onset is usually in ~~youth~~ adolescence or young adulthood. Prognosis is worsened with delay in initial treatment, repeated episodes, and comorbid substance use. Comorbid substance use and medical conditions (e.g., metabolic syndrome) are common.
~~a loss of contact with reality. It is further characterised by:~~

- ~~positive symptoms, delusions, hallucinations and thought process disorder~~
- ~~negative symptoms, blunting of affect, social withdrawal~~
- ~~mood symptoms such as depression may be present~~

~~Clinical features include:~~

- ~~delusions: fixed, unshakeable false beliefs (not shared by society)~~
- ~~hallucinations: perceptions without adequate corresponding external stimuli, e.g. hearing voices~~
- ~~disorganised thoughts and speech: e.g. derailment or incoherence~~
- ~~grossly disorganised or catatonic behaviour~~
- ~~negative symptoms: affective flattening, social withdrawal~~
- ~~social and/or occupational dysfunction~~

The diagnosis of schizophrenia should be confirmed by a specialist. In stable patients with good insight and support, primary care facilities may continue treatment and social support. ~~See Section 16.6: Psychiatric patients - general monitoring and care.~~

GENERAL MEASURES

- See Section 16.6: Psychiatric patients - general monitoring and care.
- Supportive intervention includes:
  - Psychoeducation of the patient and their family regarding the nature of schizophrenia, the importance of treatment adherence, and early signs of recurrent episodes.
  - Supportive group therapy for patients with schizophrenia.
- Rehabilitation may be enhanced by:
  - Assertive community programs.
  - Occupational therapy.
  - Work assessment, and bridging programmes.

[7] South African Medicines Formulary, 14th Edition. Division of Clinical Pharmacology. University of Cape Town, 2022.

- Appropriate placement and supported employment.

» Assessment of risk to self and others, and early signs of relapse should be performed at every review.

MEDICINE TREATMENT

~~Schizophrenia where a less sedating agent is required:~~

Adults

» Haloperidol, oral. (Doctor prescribed)
» Initial dose: 1.5 mg daily, increasing to 5 mg daily, if initial treatment tolerated and according to clinical response.
» Once stabilised, administer as a single dose at bedtime.

Elderly

» Haloperidol, oral. (Doctor prescribed)
» Initial dose: 0.75 mg twice daily.
» Increase dose more gradually until symptoms are controlled or until a maximum of 5 mg daily, if tolerated, is reached.
» Once stabilised, administer as a single dose at bedtime.

See Section 16.8.2: Special considerations: Older patients (≥ 45 years).

If there is a good response/ tolerability to haloperidol, or patient's preference: ~~Long-term depot therapy where adherence problem, or patient preference:~~

» Flupenthixol decanoate, IM, ~~20-80~~ 10–40 mg every 4 weeks. (Doctor prescribed)
» Initial dose: 10mg.

OR

» Zuclopenthixol decanoate, IM, ~~2~~100–~~6~~400 mg every 4 weeks. (Doctor prescribed)
» Initial dose: 100 mg.

Note:

» Patients, patients should initially be stabilised on an oral antipsychotic agent before changing to a depot preparation.
» Administer an initial test dose of the depot antipsychotic and observe the patient for 1 week before administering higher doses.
» Reduce the oral antipsychotic formulation, stopping once patient is stabilised on the long-term depot therapy.
» Long-acting injectable antipsychotics are particularly useful in patients unable to adhere to their oral medication regimens, but need to be accompanied by a track and trace programme to be effective for adherence
» Long-term therapy should always be in consultation with a doctor or, if available, with a psychiatrist. Patients should be re-assessed every 6 months.

For breakthrough episodes, on an injectable antipsychotic, consider additional short-term therapy of:

» Risperidone, oral 2 mg daily (Doctor prescribed).

If good response to IM antipsychotic but patient has, extrapyramidal side effects (EPSEs), add:

» Anticholinergic, e.g.:
» Orphenadrine, oral, 50 mg 8 hourly, and refer for review of medication.

Note:

» Anticholinergic medicines (e.g. orphenadrine) should not be used routinely as prophylaxis to prevent EPSEs to antipsychotic medication.
» **For management of extra-pyramidal adverse drug reactions and acute dystonic reactions: See Section 16.2.1: Extra-pyramidal side effects.**

If poor response, to IM antipsychotic or poor EPSE response to anticholinergic switch to risperidone: ~~rather than adding an anticholinergic medicine:~~

» Risperidone, oral, 2 mg daily (Doctor prescribed).
» ~~Initial dose: 2 mg daily.~~
» Increase to 4 mg daily if there is a poor response after 4 weeks.

If patient is already stabilised on chlorpromazine:

» Chlorpromazine, oral (Doctor ~~initiated~~ prescribed).
» Maintenance dose: 75–300 mg at night, but may be as high as 800 mg.

~~Only for health care workers with advanced psychiatric training:~~

~~**Long-term depot therapy where adherence problem, or patient preference:**~~

- ~~» Flupenthixol decanoate, IM, 20–80 mg every 4 weeks.~~
- ~~» Initial dose: 20 mg.~~

~~**OR**~~

- ~~» Zuclopenthixol decanoate, IM, 200–600 mg every 4 weeks.~~
- ~~» Initial dose: 100 mg.~~

~~**Note:** Initially, patients should be stabilised on an oral antipsychotic agent before changing to a depot preparation. Administer an initial test dose and observe the patient for 1 week before administering higher doses. Reduce the oral antipsychotic formulation, stopping once patient is stabilised on the long-term depot therapy.~~

~~For breakthrough episodes, consider short-term therapy of:~~

- ~~» Risperidone, oral 2 mg daily (Doctor prescribed).~~
- ~~» Long-acting antipsychotics are particularly useful in patients unable to adhere to their oral medication regimens but need to be accompanied by a track and trace programme to be effective for adherence~~
- ~~» Long-term therapy should always be in consultation with a doctor or, if available, with a psychiatrist. Patients should be re-assessed every 6 months.~~

16.6 PSYCHIATRIC PATIENTS - GENERAL MONITORING AND CARE

The following editorial adjustment was made to the STG

From:

» In women: family planning and pregnancy counselling

To:

» Women: family planning, pregnancy counselling, supportive home visits in childcare

Lithium monitoring added to the PHC Essential Laboratory List and the STG updated as follows.

» Lithium:
- The therapeutic range is 0.8–1.0 mmol/L in acute mania, 0.6–0.8 mmol/l for prevention of mania and 0.4–0.8 mmol/l for prevention of depressive relapse.
- Monitor lithium concentration and eGFR every 6 months (3-monthly in elderly or those with medical comorbidity);
- Monitor TSH and calcium concentrations annually.
- Women of childbearing potential must be on family planning; refer all pregnant women on lithium immediately (See caution on lithium in Adult Hospital Level STGs, "Chapter 15: Mental Health Conditions and Substance Misuse - Section 15.3.2 BIPOLAR AND RELATED DISORDERS").

16.7 SUICIDE RISK ASSESSMENT

General Measures

An external comment was received that patients should not selectively be screened for suicide risk, but that each patient visiting the clinic should receive a Mental State Examination (MSE) (to identify any psychiatric symptoms, not just depression), as well as be screened for substance use.[8] The Committee agreed that the list under general measures represents findings after conducting a history and examination and therefore the phrasing was amended accordingly.

The STG was amended as follows:

[8] National Department of Health. Adult https://knowledgehub.health.gov.za/elibrary/adult-primary-care-apc-guide-20192020-updated

GENERAL MEASURES

Any of ~~Screen for self-harm/suicide risk if any of the following present~~ the following factors may indicate a high risk of suicide:

Extreme hopelessness and despair
Current thoughts/plan/act of self-harm/suicide
History of self-harm/suicide
Mental health condition: depression, ~~mood~~bipolar disorder, substance use disorders, psychoses, dementia
Chronic condition: chronic pain, disability
Extreme emotional distress
Key population groups (LGBTQIA+) and adolescents

Monitoring and follow-up:

Regarding monitoring and follow-up an external comment was received that it would be important to provide the patient with resources for family to also receive support i.e., counsellors, social workers, police. The comment was substantiated with the following rationale: Often times the patient's family might also experience the same psychosocial stressors as patient and may also require assistance. By offering these resources it may assist the patient to feel reassured that the family has been taken care off. The section was rephrased to emphasise the role and need for support of family/ carers.

The STG was amended as follows:

3. **Monitoring and follow-up:**

For all cases of medically serious acts of self-harm/suicide or where there is an imminent risk of self-harm/suicide:

~~Do not leave person alone. Place in a secure, supportive environment in health facility while awaiting referral.~~

- ~~Remove access to means of self-harm/suicide (bleach, pesticides, firearms, medications) known to be toxic in overdose including paracetamol, amitriptyline, theophylline).~~

» Remove access to means of self-harm/suicide (bleach, pesticides, firearms, medications) and medicines known to be toxic in overdose, including paracetamol, amitriptyline, theophylline

» Maintain regular contact if possible – suggested weekly contact for the first 2 months. Follow-up for as long as the risk of self-harm/suicide persists. At every contact, re-assess for suicidal thoughts and plans.

Educate patient and family:

- To seek help from a trusted family member, friend, or health worker if they have any thoughts of self-harm/suicide.
- That family/ carers may also need psychosocial support – provide patient with resources (e.g., brochures if available, SA Depression and Anxiety Group details https://www.sadag.org/)
-

Educate family/friend/carer: ~~carer:~~

~~» If one has thoughts of self-harm/suicide, seek help from a trusted family member, friend or health worker.~~

- Talking about suicide does not trigger the act of suicide, and may lower the risk of following through on suicidal ideation.
- Where they may get support for their own mental health and to better support the patient.

Refer to social worker, registered counsellor, mental health services if available, or to community resources such as NGO or faith-based organisation ~~religious centres,~~ crisis centres or support groups.

~~Try to locate family/friends to care for and support patient during this phase. Encourage carers to find support for themselves as well.~~

16.8.4 MATERNAL MENTAL HEALTH

An external comment to specifically label the cross-reference to the PHC STGs maternal mental health section in the Obstetrics & gynaecology was accepted; in addition to an external comment to include a cross reference to the adult hospital level mental health conditions and substance misuse chapter for managing depression and anxiety which are mostly primary care conditions.

An external comment to link to the NDOH Maternal Perinatal and Neonatal Care Guidelines was not accepted as the 2016 guidelines are currently under review and the updated content not yet finalised. The NDOH program and NEMLC are in consultation regarding alignment of the STGs and guidelines.

The STG was finalised as follows

~~See~~ Details regarding maternal mental healthcare are provided in:

- Primary Health Care STGs Chapter 6: Obstetrics, Section 6.9: Maternal mental health.
- Adult Hospital STGs Chapter 15: Mental health conditions and substance misuse.

16.9.1 SUBSTANCE USE DISORDERS

For severe anxiety, irritability, and insomnia:

Diazepam: *Retained* (duration of treatment lower and aligned with Adult Hospital Level STGs)

Histoically, in the PHC STGs, diazepam was indicated for severe anxiety, irritability, and insomnia for a duration of 5 to 7 days. Number of days of treatment has been revised to 3 to 5 days in alignment with the adult hospital level STGs.

The STG was finalised as follows

MEDICINE TREATMENT

For severe anxiety, irritability, and insomnia:

- Benzodiazepine, e.g.: (Doctor prescribed)

Diazepam, oral, 5–10 mg as a single dose or 12 hourly for 5–7 days