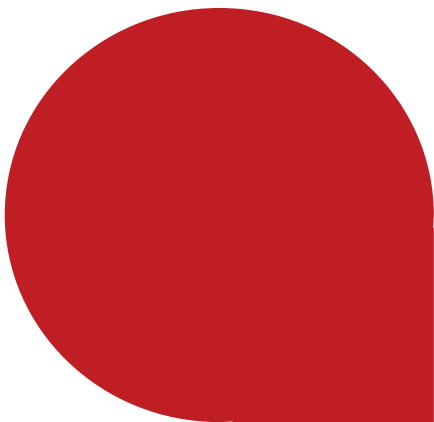




OHSC

Office of Health Standards Compliance
Ensuring quality and safety in health care



Dispensary/ Medicine Cupboard

v1.4

Regulatory Clinic inspection tool

Facility:
Date:

- **Tool Name:** Regulatory Clinic Inspection tool v1.4 - Final
- **HES Type:** Clinics/ PHC
- **Sector:** Public
- **Specialization:** Clinic
- **Created By:** Health Standards Development and Training

3 Dispensary / Medicine Cupboard

Domain 3.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 3.2.1 6 User health records and management

Standard 3.2.1.1 6(1) The health establishment must ensure that health records of health care users are protected, managed and kept confidential in line with section 14, 15 and 17 of the Act.

Criterion 3.2.1.1.1 6(2)(b) The health establishment must ensure confidentiality of health records.

3.2.1.1.1.1 There is a “No unauthorised entry” sign on the door of the Dispensary.

Assessment type: Observation - **Risk rating:** Essential measure

There is a sign that reads “No unauthorised entry” on the Dispensary door. All internal signs must as a minimum be laminated. Text on signs must be typed, no handwritten signs must be accepted. Signs do not need to be framed, but laminating must be in good condition, no turned corners or peeling loose at places. If frames are not used- posters must be neatly fasten to the wall. Any other sign, e.g., “Staff only” will be scored not compliant. Measure should not be assessed if the health establishment does not have a dispensary but only has a medicine storage room (no dispensing is done in medicine storage rooms and user records are therefore not found in medicine rooms). Not applicable: Where the health establishment does not have a dispensary but have medicine cupboard.

Score	Comment

Sub Domain 3.2.2 7 Clinical management

Standard 3.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 3.2.2.1.1 7 The health establishment implements process to ensure environmental cleanliness.

3.2.2.1.1.1 The dispensary or medicine cupboard is observed to be clean.

Assessment type: Observation - **Risk rating:** Vital measure

Inspector to observe general cleanliness in all areas of the dispensary or medicine cupboard. Cleanliness could include but not limited to whether the area is free of dirt and dust.

Not applicable: Never

Score	Comment

Sub Domain 3.2.3 8 Infection prevention and control programmes

Standard 3.2.3.1 8(1) The health establishment must maintain an environment, which minimises the risk of disease outbreaks, the transmission of infection to users, health care personnel and visitors.

Criterion 3.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.

3.2.3.1.1.1 Hand washing facilities are available.

Assessment type: Observation - **Risk rating:** Vital measure

Use the checklist below to check whether hand washing facilities and the items listed below are available. The hand washing facilities can be located within the Dispensary/Medicine Room or immediately outside the Dispensary/Medicine Room, e.g., in a passage or an adjacent room. Score 1 if compliant with the aspect listed below and score 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. Functional hand wash basin (The basin should not be blocked, broken or have cracks)		
2. Taps are functional and not broken.		
3. Plain liquid soap.		
4. Disposable hand paper towels (wall mounted dispenser is optional in Dispensary/Medicine Room)		
5. General waste container. Explanatory note: This could be a wall mounted or a disposable or reusable vessel placed at the point of waste generation for the purpose of receiving waste. It may include but not limited to a bin, bucket, box, etc. The container must be lined with the appropriate colour coded liner or bag.		

3.2.3.1.1.2 Alcohol based hand rub is available.

Assessment type: Observation - **Risk rating:** Vital measure

Observe whether alcohol-based hand rub is available.

Not applicable: Never

Score	Comment

3.2.3.1.1.3 Posters on hand hygiene are displayed.

Assessment type: Observation - **Risk rating:** Essential measure

Observe whether posters on hand hygiene are displayed. This could be a single hand hygiene poster or individual posters for hand washing or correct use of alcohol-based hand rub. Score 1 if available and 0 if not available.

Not applicable: Never

Score	Comment

Sub Domain 3.2.4 9 Waste management

Standard 3.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 3.2.4.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

3.2.4.1.1.1 Appropriate containers for disposal of pharmaceutical waste must be available.

Assessment type: Observation - **Risk rating:** Vital measure

Dark green container marked with the words “Pharmaceutical waste liquid or solid” must be available.

Not applicable: Where the health establishment does not dispose of the medication but packs the medication for removal to a disposing health establishment.

Score	Comment

Criterion 3.2.4.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

3.2.4.1.2.1 Waste is segregated as required by the waste management practices.

Assessment type: Observation - **Risk rating:** Essential measure

Use the checklist below to check if waste is segregated as required by the waste management practices stipulated in the National Environmental Health Norms and Standards. Score 1 if compliant with the aspects below and score 0 if not compliant.

Score	Comment

Aspects	Score	Comment
1. General waste is disposed of separately in a black or beige or white or transparent plastic bag.		
2. Pharmaceutical waste is stored separately in a container or box for removal to the disposing health establishment. (This aspect relates to clinics which transfer their pharmaceutical waste to another health establishment for disposal. Pharmaceutical waste includes obsolete medication and medication returned to the clinic by users).		

Domain 3.3 CLINICAL SUPPORT SERVICES

Sub Domain 3.3.1 10 Medicines and medical supplies

Standard 3.3.1.1 10(1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 3.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

3.3.1.1.1.1 The electronic network system for monitoring the availability of medicines is used effectively.

Assessment type: Observation - **Risk rating:** Essential measure

The electronic network system for monitoring the availability of medicines is used effectively. The electronic systems can include but are not limited to Stock Visibility System (SVS), RX Solutions and JAC. To determine whether the health establishment has reported the availability of medicines as required, visit the website used to view captured medicine availability data, and the Primary Health Care Health Establishment Dashboard associated with it. Score 1 if the aspect is compliant and score 0 if it is not compliant.

Score	Comment

Aspects	Score	Comment
1. The health establishment has a functional electronic network system for monitoring the availability of medicines		
2. The approved list of medicines to be updated is visible in the electronic network system.		
3. The capturing device and accessories are in working order		
4. The capturing device is stored in a lockable unit (only applicable to SVS)		
5. Accessories, which include batteries and a charger, for the device are stored in a lockable unit (only applicable to SVS)		
6. In the last seven working days or more this health establishment has not been marked as non-reporting (at the point of assessment). Explanatory note: The source for the information will be the website used to view the availability of captured medicine data and the associated Primary Health Care health establishment dashboard. (The SVS cell phone will show last reporting date (only applicable to SVS).		

3.3.1.1.1.2 Schedule 5 and 6 medicines in stock correspond with the balance recorded in the register.

Assessment type: Observation - **Risk rating:** Vital measure

Select three medicines from the schedule 5 and 6 medicine cupboard and verify whether the quantity available corresponds with the balance recorded in the register. Score 1 if there is correspondence 0 if not. Score not applicable where schedule 5 and 6 medicines are not held in the health establishment.

Score	Comment	
Aspects	Score	Comment
1. Medicine 1		
2. Medicine 2		
3. Medicine 3		

3.3.1.1.1.3 Re-ordering stock levels (min/max and/or re-order levels) are determined for each item on the district/health establishment formulary.

Assessment type: Observation - **Risk rating:** Vital measure

Randomly sample five items held as stock and verify whether minimum, maximum and/or reorder levels are documented. The levels must be recorded on the bin cards, shelves or any other system used by the health establishment. The system may be manual or electronic. Score 1 if compliant and 0 if not compliant.

Score	Comment

Aspects	Score	Comment
1. Item 1		
2. Item 2		
3. Item 3		
4. Item 4		
5. Item 5		

3.3.1.1.1.4 Stock take of medicine was done in the last 12 months.

Assessment type: Document - **Risk rating:** Vital measure

Documented evidence of a formal stock take will be required, i.e., a report indicating that the stock take has been completed in the last 12 months. Report should detail amongst others-expired medicine and its monetary value.

Not applicable: Never

Score	Comment

3.3.1.1.1.5 The register for schedule 5 and 6 medicines is completed correctly.

Assessment type: Document - **Risk rating:** Vital measure

Accurate, comprehensive recording of administration and dispensing of Schedule 5 and 6 medicines is a legal requirement and must be done in accordance with the applicable legislation. All columns in the registers must be comprehensively completed. Any omitted information noted during the review of the register will result in a non-compliant score. The inspector must confirm that all sections of the register have been completed correctly. If any of the columns have not been completed and balances do not correlate, this measure will be scored 0.

Not applicable: Where schedule 5 and 6 medicines are not held at the health establishment.

Score	Comment

Criterion 3.3.1.1.2 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

3.3.1.1.2.1 Medicines on the current national tracer medicine list is available.

Assessment type: Observation - **Risk rating:** Vital measure

Request the current national tracer medicine list and randomly select 3 items from each category/group of medicine listed below. Check whether the selected items are available and not expired. Score 0 if not all the selected items are available or expired or if there is no tracer medicine list available. Sampled items to be recorded in the comment section. Should medicines be out of stock, substitutions will only be accepted if documented evidence of the recommended substitute from the district pharmacist is available. Alternatively, where tracer medicine list recommends several medicines as equivalent for treatment, substitutions from this list of recommended medicines will be acceptable without a letter from the district pharmacist.

Score	Comment

Aspects	Score	Comment
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Antibiotics

1. Sampled medicine 1		
2. Sampled medicine 2		
3. Sampled medicine 3		

Analgesic

4. Sampled medicine 1		
5. Sampled medicine 2		
6. Sampled medicine 3		

Gastrointestinal

7. Sampled medicine 1		
8. Sampled medicine 2		
9. Sampled medicine 3		

Tuberculosis medicine

10. Sampled medicine 1		
11. Sampled medicine 2		
12. Sampled medicine 3		

Antiretrovirals

13. Sampled medicine 1		
14. Sampled medicine 2		
15. Sampled medicine 3		

Medicine for Non-Communicable Diseases (e.g., Diabetes, Hypertension)

16. Sampled medicine 1		
17. Sampled medicine 2		
18. Sampled medicine 3		

Emergency medicine (e.g., Adrenaline)

19. Sampled medicine 1		
20. Sampled medicine 2		
21. Sampled medicine 3		
Topical treatments		
22. Sampled medicine 1		
23. Sampled medicine 2		
24. Sampled medicine 3		
Contraceptives		
25. Sampled medicine 1		
26. Sampled medicine 2		
27. Sampled medicine 3		
Vaccines		
28. Sampled medicine 1		
29. Sampled medicine 2		
30. Sampled medicine 3		

3.3.1.1.2.2 The scripts in the Dispensary are correlated with the medicines dispensed to ensure that all medicines were received as prescribed.

Assessment type: Patient record audit - **Risk rating:** Vital measure

Select three health care user scripts in the Dispensary and check whether medicines were dispensed against this script. If all medicines as prescribed were dispensed, then score 1. If a user has not received all the medicines as prescribed, score 0. Score not applicable if dispensing is done exclusively in the consulting rooms. Document the unique identifier of the sample users in the comment column.

Score	Comment	
Aspects	Score	Comment
1. User health record 1		
2. User health record 2		
3. User health record 3		

3.3.1.1.2.3 The temperature of the Dispensary/Medicine room is maintained within the safety range.

Assessment type: Observation - **Risk rating:** Vital measure

Use the checklist below to check whether the temperature in the Dispensary/Medicine room is maintained between 15 - 25 degrees Celsius. Score 1 if compliant with the aspect listed below and score 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. There is at least one functional room thermometer		
2. The temperature of the Dispensary/Medicine room is recorded daily (This is to assess if the health establishment consistently monitors the room temperature. Request temperature monitoring sheets from the previous three months.)		
3. The temperature of the Dispensary/Medicine room is maintained between 15 - 25 degrees Celsius		

3.3.1.1.2.4 Procedures to maintain the cold chain for vaccines are implemented.

Assessment type: Observation - **Risk rating:** Vital measure

Use the checklist below to check whether the cold chain for vaccines is maintained. Score 1 if compliant with the aspect below and score 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. The health establishment has a vaccine or medicine refrigerator with a thermometer. Explanatory note: The vaccine or medicine refrigerator can be located in any space in the Clinic, a domestic refrigerator will be scored noncompliant.		
2. The temperature of the refrigerator is recorded twice daily, seven hours apart (check the previous three month's record)		
3. The temperature of the refrigerator is maintained between 2 and 8 degrees Celsius (check the previous three month's records)		
4. There is a cooler box and ice packs available for storage of vaccines if needed.		
5. A functional thermometer is available for use in the cooler box		

Domain 3.5 FACILITIES AND INFRASTRUCTURE

Sub Domain 3.5.1 14 Management of buildings and grounds

Standard 3.5.1.1 14(1) The health establishment and their grounds must meet the requirements of the building regulations.

Criterion 3.5.1.1.1 14(2)(d) The health establishment must as appropriate for the type of buildings and grounds of the establishment have ventilation systems that maintain the inflow of fresh air, temperature, humidity and purity of the air within specified limits set for different service areas such as theatres, kitchen and isolation units.

3.5.1.1.1.1 The Dispensary/Medicine Room has a functional air conditioner.

Assessment type: Observation - **Risk rating:** Vital measure

Observe if the air conditioner switches on and off and provides cold/cool air to the room in accordance with the temperature setting.
Not applicable: Never

Score	Comment



Official Sign-Off

The National Health Act, 2003 (Act No. 61 of 2003) provides for quality requirements and standards in respect of health services provided by health establishments to the public. The main objective is to promote and protect the health and safety of the users of health services and contribute to improved outcomes and improved population health.

To achieve this mandate standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Clinics.

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- National Department of Health for their input and commenting on the inspection tools.

It is hereby certified that the Regulatory Clinic Inspection tools version 1.4 was updated by the Office of Health Standards Compliance.

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