Draft National Clinical Record Audit Guideline for Primary Health Care Facilities

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health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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1. Purpose of the Guideline

This Guideline was developed to conduct clinical record audits in Primary Health Care facilities as set out in the Ideal Clinic Framework, i.e. “Clinical audits are conducted quarterly on priority health conditions”. This guideline is complimentary to the checklist for patient record compliance to Integrated Clinical Services Management in the Ideal Clinic framework.

The purpose of the this guideline to conduct clinical record audits is to enhance the quality of clinical care provided at facility level and promote adherence to the National Guidelines for the management of national priority health conditions.

The template does not replace the in-depth programme reviews that will take place from time to time. The Guideline in no way replaces existing approved provincial guiding documents but is intended to provide guidance to those provinces that do not have existing guidelines to conduct clinical audit on priority health conditions.

2. Introduction

Clinical (or medical) audits form part of the continuous quality improvement process and consist of measuring a clinical outcome or a process, against well-defined standards set on the principles of evidence-based medicine.

The aim of the audit is to highlight the discrepancies between actual practice and standard in order to identify the changes needed to improve the quality of care.

Clinical audit consists of a “quality loop” (Figure1):

- Select an audit topic
- Set measurable criteria and standards
- Evaluate current clinical practice especially in terms of process or outcome
- Develop improvement interventions
- Implement improvement plan
- Cycle can begin again[1].

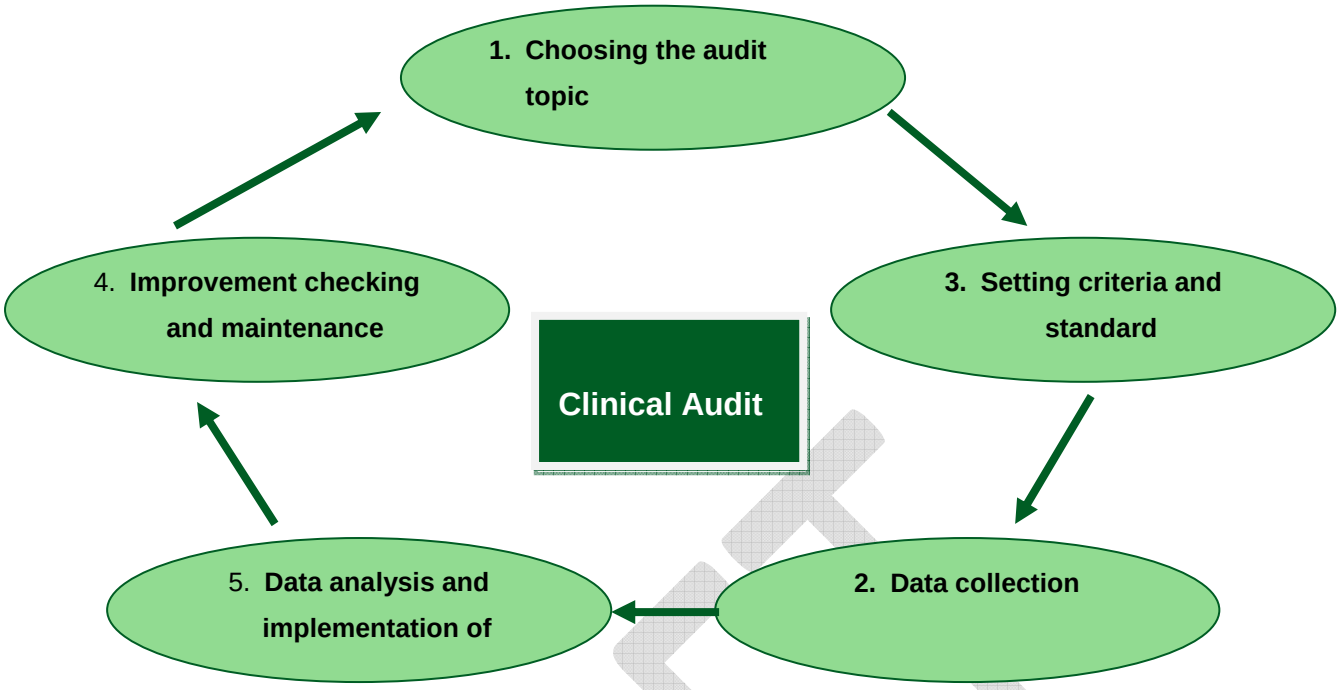

Figure 1: Clinical Audit Cycle

3. Conducting the Clinical Record Audit

3.1 Choosing the Topic

The National Department of Health has defined priority areas based on the disease burden and utilisation of services at primary health care facilities that should be audited on an annual basis:

- Non Communicable Diseases - Hypertension and Diabetes
- Chronic communicable diseases - Human Immune Deficiency Virus (HIV) and Tuberculosis (TB)
- Maternal Health - Antenatal Care (ANC) and Post Natal Care (PNC)
- Children - Well baby and Sick child

3.2 Setting the Standard

The standards against which the audit will be conducted have been designed based on the National Guidelines for each of the priority health condition. For the purposes of the audit the target is that **80%** of all assessed patient records should fulfil the criteria as defined, see page 7 to 22.

3.3 Data Collection

The Adult Primary Care (APC) facility trainer should be the coordinator or audit team leader and assemble an internal audit team (medical practitioner and/or clinical nurse practitioner) if necessary.

An audit will be conducted on the priority areas as per the schedule defined in **Table 1**. Nineteen patient records should be audited annually for each of the priority health conditions listed in table 1[1].

Table 1: Audit Schedule

PRIOTIRY HEALTH CONDITIONS	Month when audit to be conducted
HIV/TB	Apr/May
NCD (diabetes and hypertension)	Jun/Jul
Maternal health (ANC &PNC)	Aug/Sept
Well baby	Oct/Nov
Sick child (IMCI)	Feb/March

An audit will be conducted retrospectively using the patient records as the source document.

The patient records to be audited should be selected as follow:

a. Lot quality assurance sampling will be used for the purposes of the clinical audit.
b. Two weeks prior to the audit - select the patient clinical records for the condition to be audited. Choose patient clinical records that have been active in the past one year.
c. On the date of the audit randomly select the 1st clinical record from the list that you have.
d. Thereafter sample every 3rd patient record until you reach the 19 clinical records required for each of the priority health condition to be audited.
e. Use the checklist (see page 7 to 22) provided for each of the conditions identified and audit the relevant clinical record.

[1] A sample size of 19 provides an acceptable level of error for making management decisions; at least 92% of the time, it identifies whether a coverage benchmark has been reached 19 is the smallest sample size that allows at least 90% sensitivity and specificity for all benchmarks or targets of 10%-95%.

3.4 Data Analysis

Determine the baseline when conducting the initial audit by counting the number of clinical records that comply with 100% of the criteria as per the clinic audit measures checklist (see page 7 to 22). Using the Lot Quality Assurance Sampling **(**LQAS) method, see **Table 2**, determine the percentage compliance for each priority health condition. For example, if 7 records out of the 19 comply with 100% of the criteria in checklist, then the baseline will be 50% as a standard. If 9 clinical records comply with 100% of the criteria, then the baseline will be 60%.

The target set for compliance is 80%; therefore 13 clinical records should meet 100% of the criteria to be compliant.[2] The baseline results should be improved until the target is met.

Table 2: Lot Quality Assurance Sampling (LQAS) table

LQAS Table: Decision Rules for Sample Sizes of 12–30 and Coverage Targets/Average of 10%–95%

Sample Size*	Average Coverage (Baselines)/Annual Coverage Target (Monitoring and Evaluation)																	
	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%	65%	70%	75%	80%	85%	90%	95%
12	N/A	N/A	1	1	2	2	3	4	5	5	6	7	7	8	8	9	10	11
13	N/A	N/A	1	1	2	3	3	4	5	6	6	7	8	8	9	10	11	11
14	N/A	N/A	1	1	2	3	4	4	5	6	7	8	8	9	10	11	11	12
15	N/A	N/A	1	2	2	3	4	5	6	6	7	8	9	10	10	11	12	13
16	N/A	N/A	1	2	2	3	4	5	6	7	8	9	9	10	11	12	13	14
17	N/A	N/A	1	2	2	3	4	5	6	7	8	9	10	11	12	13	14	15
18	N/A	N/A	1	2	2	3	5	6	7	8	9	10	11	11	12	13	14	16
19	N/A	N/A	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
20	N/A	N/A	1	2	3	4	5	6	7	8	9	11	12	13	14	15	16	17
21	N/A	N/A	1	2	3	4	5	6	8	9	10	11	12	13	14	16	17	18
22	N/A	N/A	1	2	3	4	5	7	8	9	10	12	13	14	15	16	18	19
23	N/A	N/A	1	2	3	4	6	7	8	10	11	12	13	14	16	17	18	20
24	N/A	N/A	1	2	3	4	6	7	9	10	11	13	14	15	16	18	19	21
25	N/A	1	2	2	4	5	6	8	9	10	12	13	14	16	17	18	20	21
26	N/A	1	2	3	4	5	6	8	9	11	12	14	15	16	18	19	21	22
27	N/A	1	2	3	4	5	7	8	10	11	13	14	15	17	18	20	21	23
28	N/A	1	2	3	4	5	7	8	10	12	13	15	16	18	19	21	22	24
29	N/A	1	2	3	4	5	7	9	10	12	13	15	17	18	20	21	23	25
30	N/A	1	2	3	4	5	7	9	11	12	14	16	17	19	20	22	24	26

N/A: *Not applicable*, meaning LQAS can not be used in this assessment because the coverage is either too low or too high to assess an SA. This table assumes the lower threshold is 30 percentage points below the upper threshold.

: Lighter shaded cells indicate where *alpha* or *beta* errors are ≥ 10%.

: Darker shaded cells indicate where *alpha* or *beta* errors are > 15%.

[2] The number 13 is determined based on statistical calculation and **is not an arithmetic proportion,** see **Table 2**. If the true percentage of the clinical records meeting 100 % in the facility for that specific condition were **80%,** 13 or more in a sample of 19 records will be compliant more than 90% of the time. (Conversely, one would get less than 13 records being non-compliant less than 10% of the time.)

Record the results of the record audit in **Table 3.** In column A complete the number of records that were 100% compliant and in column B complete the percentage obtained according to the LQAS table.

Table 3: Summary of results of clinical record audit

Priority Health Condition	Column A Number of Clinical Records sampled	Column B Number of clinical records complying with 100% criteria	Column C % Obtained (use the LQAS table to look-up the percentage)
HIV and TB	19	7 (example)	50% (example)
Diabetes and Hypertension	19	9 (example)	60% (example)
Maternal care	19		
Well child	19		
Integrated Management of childhood illness	19		
TOTAL/AVERAGE	**95**		

3.5 Clinical audit meetings

Clinic audit meetings should be conducted once a quarter as set out in the Ideal Clinic Framework. The audit results must be presented and discussed with the rest of the team and relevant facility, sub-district and/or district stakeholders. The potential cause of the problem must be identified, agreed upon and recommendations made for change. Use the template of the Quality Improvement Plan (QIP) as set out in the Ideal Clinic Manual, see Annexure A. Add the QIP under the section for additional areas for improvement and complete the columns for item, activity, by whim, when and results.

3.6 Sustaining improvements and repeating the audit

It is important to sustain improvements and repeat the audit cycle where and if needed. Follow these criteria to ensure sustainability:

- You need to re-audit to check the changes have made the difference you expected?
- Don't re-audit until you have made the changes.
- The re-audit should use the same design as the audit.
- You only need to re-audit standards where changes have been made (unless the changes may have affected other standards)
- If these improvements are sustained, some form of monitoring should replace a full audit. The team should develop structures and systems that integrate, monitor, and sustain the improvements implemented as part of clinical audit. But if performance deteriorates, the full audit should be reactivated.

4. Clinical Record Audit measures for priority health conditions

4.1 Clinical Audit Tool for HIV and TB (score "1" if compliant or "0" if non-compliant)

Facility name	
Audit lead	
Audit topic	**Clinical Record Audit for HIV and TB**
Aim/objective of the audit	Assess the adherence to prescribed standards for treatment of patients with HIV and TB
Exclusion criteria (where applicable)	Patients that no longer follow up at the facility
Period for Audit	

No	Measurement Criteria	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	Total
1	Patient initiated on ART within 1 week or 8 weeks (HIV positive with TB – co infection, Hepatitis B)																				
2	Patient on 1st line regimen of TDF, FTC/3TC, EFZ (Fixed Dose Combination)																				
3	FBC, ALT or fasting cholesterol test done for clients who are on non TDF based ART regimens																				
4	Viral load after 6 and 12 months of ART initiation done and recorded																				
5	Any side effects/adverse incident recorded																				
6	Any switching of regimen done, if Yes, why (see comments section)																				
7	Children < 15 years initiated on ART																				
8	Children who started on Children regimen switched to Adult regimen at >15 years Old																				

9	Children on treatment given correct dosage per weight																				
10	Is there a record of screening for TB symptoms at the last clinical visit?																				
11	If ART was commenced was the initial commencement date after the start of the TB treatment date?																				
12	If HIV-positive, is the dosage, frequency and length of Cotrimoxazole prophylaxis prescribed on a valid script?																				
13	Did smear / GeneXpert positive clients commence treatment within 5 days? (5 days from first positive sputum taken (GeneXpert or smear) to commencement of treatment, including weekends and holidays)																				
14	Are the relevant sputum results filed or results noted?																				
15	Has the correct medication been prescribed on a script that complies with scripting requirements (PACK 2015 pg. 1)?																				
16	Health promotion provided (life style modification)																				
Grand Total																					
Average % (Grand Total/16)																					
Number of records that scored 100%		**(13 of the 19 record must have scored 100% to comply with the target set for 80%)**																			

4.2 Clinical Audit Tool for Diabetes and Hypertension (score "1" if compliant or "0" if non-compliant)

Facility name	
Audit lead	
Audit topic	**Clinical Record Audit for Diabetes and Hypertension**
Aim/objective of the audit	Assess the adherence to prescribed standards for treatment of patients with Diabetes and Hypertension
Exclusion criteria (where applicable)	Patients that no longer follow up at the facility
Period for Audit	

No	Measurement Criteria	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	Total
1	Last BP reading < 140/90																				
2	If the BP>140/90, was there an action taken on the abnormal result?																				
3	Annual BMI or waist circumference:																				
4	Annual urine dipsticks done:																				
5	Annual recording of serum Creatinine:																				
6	Annual Foot Exam:																				
7	Annual Eye Screening																				
8	Annual HbA1C for confirmed diabetics																				
9	If HbA1c above target was action taken?																				
10	Has a Random Total Cholesterol ever been done:																				
11	If a patient qualifies for simvastatin according to policy, did patient receive it?																				

12	Does the patient who qualifies for aspirin for secondary prevention, according to policy receive it?																				
13	Annual Random blood glucose done for hypertension patients																				
14	Has a cardiac risk assessment been done at least one?																				
15	If no record of being HIV+, was the patient offered an HIV test in the last year?																				
16	Health promotion provided (life style modification)																				
Grand Total																					
Average % (Grand Total/16)																					
Number of records that scored 100%		**(13 of the 19 record must have scored 100% to comply with the target set for 80%)**																			

4.3 Clinical Audit Tool for Maternal Health (score "1" if compliant or "0" if non-compliant)

Facility name	
Audit lead	
Audit topic	**Clinical Record Audit for Maternal Health**
Aim/objective of the audit	Assess the adherence to prescribed standards for managing pregnant women
Exclusion criteria (where applicable)	Patients that no longer follow up at the facility
Period for Audit	

NO	Measurement Criteria	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	Total
1	Full History taken (Medical, Past Obstetric)																				
2	Full clinical examination																				
3	Estimated date of delivery calculated																				
4	Blood pressure taken																				
5	Maternal height/weight/MUAC																				
6	Haemoglobin test																				
7	RPR performed																				
8	Urine tested for protein, sugar, nitrites																				
9	Rapid Rh performed																				
10	HIV counselling and testing																				
11	ART for HIV-infected women																				
12	Tetanus toxoid given																				
13	Iron and folate supplementation provided																				
14	Calcium supplementation																				

	provided																				
15	ART given for HIV positive women																				
16	Information for emergencies given																				
17	Antenatal record completed and given to patient																				
18	Asked if fetal movements felt and normal																				
19	Patient screened for TB symptoms																				
20	Clinical examination for anaemia																				
21	Urine tested for protein, glucose																				
22	Uterus measured for growth - twins, IUGR																				
23	Instructions for delivery/transport to institution																				
24	Recommendations for lactation and contraception provided																				
25	Detection of breech presentation and referral																				
26	Remind patient to bring antenatal record in labour																				
27	Doctor or senior midwife to review gestational age at 40 weeks																				
28	Give hospital visit date at 41 weeks for induction																				
Post Natal Care within 1 week																					
27	Patient asked if Feeling unhappy?																				
28	Patients asked about appetite?																				
29	Patients asked about infant																				

	feeding?:																				
30	Cough/ Breathing difficulties noted?																				
31	Lochia if foul smelling?																				
32	Heavy vaginal bleeding?																				
33	Urinary incontinence?																				
General Examination Completed																					
34	Upper Middle Arm Circumference																				
35	Temperature																				
36	Pulse																				
37	Blood Pressure Recorded																				
38	Breast inspected for cracks/inflammation																				
39	Uterine involute or tenderness																				
40	If C/S, is wound infected:																				
42	Sutures removed																				
43	Episiotomy inspected																				
44	Urine dipstick																				
Post Natal Care 6 weeks																					
45	Mother asked if Able to resume normal activities																				
46	Problems with infant feeding?																				
47	Cough/ Breathing difficulties?																				
48	Problems with C/S wound?																				
49	Problems with episiotomy?																				
50	Vaginal discharge?																				

51	Urinary incontinence?																				
52	Upper Middle Arm Circumference																				
53	Temperature																				
54	Pulse																				
55	Blood Pressure Recorded																				
56	Breast inspected for cracks/inflammation																				
57	Urine																				
58	Haemoglobin level																				
59	CD4 taken																				
60	Contraception																				
61	Health promotion provided (life style modification)																				
Grand Total																					
Average % (Grand Total/61)																					
Number of records that scored 100%		**(13 of the 19 record must have scored 100% to comply with the target set for 80%)**																			

4.4 Clinical Audit Tool for Well child (score “1” if compliant or “0” if non-compliant)

Facility name	
Audit lead	
Audit topic	**Clinical Record Audit for Well Children**
Aim/objective of the audit	Assess the adherence to prescribed standards for managing children who are well
Exclusion criteria (where applicable)	Patients that no longer follow up at the facility
Period for Audit	

No	Measurement Criteria	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	Total
1 week assessment																					
1	Type Feeding recorded																				
2	Urine passed?																				
3	Passed stool?																				
4	Temperature recorded																				
5	Assessment of colour																				
6	Jaundice (Y?N)																				
7	Conjunctive examined																				
8	Umbilical cord examined?																				
6 week examination																					
9	Type Feeding recorded																				
10	Sleeping pattern noted?																				
11	Weight recorded																				
12	Head circumference recorded																				
13	Jaundice:																				
14	Pale																				

15	Cyanosis:																				
16	Responds to sound:																				
17	Eyes (white spot)																				
18	Thrush																				
19	Fontanel abnormal (anterior)																				
20	Heart murmur																				
21	Abdominal mass:																				
22	Vaccination provided																				
23	PCR test done																				
24	Bactrim prophylaxis:																				
25	Vitamin A supplementation:																				
10 weeks examination																					
26	10 weeks vaccination recorded																				
27	Weight recorded																				
28	Developmental screening conducted																				
14 weeks examination																					
29	14 weeks vaccination recorded																				
30	Weight recorded																				
31	Developmental screening conducted																				
9 months examination																					
32	9 months weeks vaccination recorded																				
33	Weight recorded																				
34	Developmental screening conducted																				

18 month examination																					
35	18 months weeks vaccination recorded																				
36	Weight recorded																				
37	Developmental screening conducted																				
38	Health promotion provided (life style modification)																				
39	Health promotion provided (life style modification)																				
Grand Total																					
Average % (Grand Total/39)																					
Number of records that scored 100%		**(13 of the 19 record must have scored 100% to comply with the target set for 80%)**																			

4.5 Clinical Audit Tool for Integrated Management of Childhood Illness (score “1” if compliant or “0” if non-compliant)

Facility name	
Audit lead	
Audit topic	**Clinical Record Audit for Integrated Management of Childhood Illness**
Aim/objective of the audit	Assess the adherence to prescribed standards for managing children who are unwell
Exclusion criteria (where applicable)	Patients that no longer follow up at the facility
Period for Audit	

No	Measurement Criteria	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	Total
Infants (Birth to 2 months)																					
1	Has the infant had convulsions?																				
2	Has the infant had any attacks where he stops breathing, or becomes stiff or blue (apnoea)?																				
3	Measure Temperature																				
4	Babies movement noted																				
5	Eyes inspected																				
6	Skin examined																				
7	Palms and soles examined																				
8	History of diarrhoea																				
9	Blood in stools																				
10	Head circumference																				
11	Priority signs for congenital defects noted																				
12	Abnormalities of head and neck noted																				
13	Abnormalities of limbs noted																				
14	HIV status checked and recorded																				

15	Immunisation status checked																				
16	Developmental milestones noted																				
Children between 2 months and 5 years																					
17	Has the child had convulsions?																				
18	Has the child had any attacks where he stops breathing, or becomes stiff or blue (apnoea)?																				
19	Child with cough/difficulty breathing managed according to guidelines																				
20	Child with wheezing managed according to guidelines																				
21	Child with fever managed according to guidelines																				
22	Child with diarrhoea managed according to guidelines																				
23	Child examined for malnutrition and managed according to guidelines																				
24	Child examined for anaemia and managed according to guidelines																				
25	Child with ear infection managed according to guidelines																				
26	Child with skin rash/measles managed according to guidelines																				
27	HIV infection assessed and initiated on ART																				
28	TB risk assessed and classified or initiated on treatment																				

29	Child with sore throat assessed and managed according to guidelines																				
30	Health promotion provided (life style modification)																				
Grand Total																					
Average % (Grand Total/30)																					
Number of records that scored 100%		**(13 of the 19 record must have scored 100% to comply with the target set for 80%)**																			

5. References

1. National Institute for Clinical Excellence. *Principles for Best Practice in Clinical Audit.* Oxon, United Kingdom: Radcliffe Medical Press Ltd, 2002.
2. Davis R. Rapid Health Surveys: Principles and Sampling Design Handbook. California: PB Works, 2012.
3. Robertson SE and Valadez JJ. Global review of health care surveys using lot quality assurance sampling (LQAS), 1984-2004. *Soc Sci Med*. 2006; 63: 1648-60.

Annexure A: Quality Improvement Plan

QUALITY IMPROVEMENT PLAN
Facility Name: _____
Date Generated: _____

Element #	Element	Weigh	Respon-sibility	No	Partial	Comment	Activity	By Whom	When	Results

ADDITIONAL AREAS FOR IMPROVEMENT AS IDENTIFIED TRHOUGH SURVEYS, RISK ASSESSMENTS, COMPLAINTS				
Item	Activity	By Whom	When	Results

Name and Surname of facility manager: _____

Signature: _____

Date: _____