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Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Prescription Auditing

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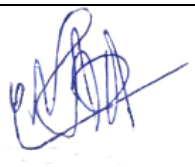
Approved by: **Ms. Aishath Mohamed** **Deputy Director General, Pharmaceuticals** **Maldives Food and Drug Authority**		29.08.2022
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Guideline on Prescription Auditing

1 INTRODUCTION

Irrational prescribing is a global problem. The emerging data reveal that prescribing errors are common and can affect between 4.2 to 82% of the prescriptions. Such errors can result in adverse event, unsafe treatment, additional cost of treatment, inefficient use of resources, and irrational medicine use. Almost 4 in 1000, prescriptions have errors that have the potentials to cause adverse effects.

Prescription errors can result from an individual as well as system-related factors. Prescription errors are typically events that derive from slips, lapses, or mistakes, such as writing a higher or lower dose than the correct one. Factors related to patients can also result in errors and adverse effects, such as history of allergy and non-adherence to instructions. Therefore, detecting such errors is the first crucial step in building safer systems and preventing adverse events. A systemic analysis of prescriptions can detect these errors through the prescription audit. Once opportunities for improvement are identified; set priorities, timelines, and actions to mitigate the occurrence of prescriptions and ordering errors.

2 PURPOSE

- To assess the extent of irrational prescribing.
- Detection of prescribing errors with their reasons.
- To reduce the irrational usage of antibiotics, syrups, injections, etc.
- To identify opportunities for the improvement and developing benchmarks at the facility level, district, state and national.
- To channelize the good practice of writing complete, legible and rational prescriptions by the service providers.

3 SCOPE

This guideline applies to the criteria, frequency and process applied for prescription auditing.

4 RESPONSIBILITY AND ACCOUNTABILITY

1. Pharmaceutical officer
2. Director, Pharmaceuticals
3. Deputy Director General (Medicine Therapeutic Goods Division)
4. Director General (MFDA)

5 Guideline content

5.1 How to Conduct Prescription Audit (A Step-by-Step Methodology)

5.1.1 The auditing process is a cyclical activity of reviewing prescriber's practice of writing prescription order and refining practice to remedy identified deficiencies and measure the outcomes against agreed audit criteria.

5.2 General principles of conducting prescription audit

5.2.1 Outcome under prescription audit need to be measured against predefined prescribing indicators.

5.2.2 Minimum required indicators are given below:

5.2.2.1 Table 1

S.No.	Criteria	Score in percentage (%)
1	OPD Registration Number mentioned?	
2	Complete Name of the patient is written?	
3	Age in years (≥ 5 in years) in case of < 5 years (in months)	
4	Weight in Kg (only patients of paediatric age group)	
5	Date of consultation - day / month / year	
6	Gender of the patient.	
7	Handwriting is Legible in Capital letter	
8	Brief history Written	
9	Allergy status mentioned	
10	Salient features of Clinical Examination recorded	

11	Presumptive / definitive diagnosis written	
12	Medicines are prescribed by generic names	
13	Medicines prescribed are in line with STG.	
14	Medicine Schedule / doses clearly written	
15	Duration of treatment written	
16	Date of next visit (review) written	
17	In case of referral, the relevant clinical details and reason for referral given.	
18	Follow-up advise and precautions (do's and don'ts) are recorded	
19	Prescription duly signed (legibly)	
20	Medicines Prescribed are as per EML/ Formulary	
21	Medicines advised are available in the dispensary	
22	Vitamins, Tonics or Enzymes prescribed?	
23	Antibiotics prescribed?	
24	Antibiotics are prescribed as per facility's Antibiotic Policy	
25	Investigations advised?	
26	Injections prescribed?	
27	Number of Medicines prescribed.	

5.2.3 As the audit system matures, certain other indicators could be added. WHO's 'Core Prescribing Indicators' can be referred to for further information on indicators.

5.2.4 The target sample should be representative of OPD patients to generate meaningful results.

5.2.5 The data are analyzed, and the results reported to maximize the impact of the audit.

5.2.6 An action plan is developed and implemented to take forward any recommendation made.

5.2.7 The prescription audit is a cyclical process that demonstrates that improvement has been achieved and sustained through re-audit.

5.3 Audit Criteria

5.3.1 Describing the definition of prescribing indicators for audit.

5.3.2 Criteria must provide a context for evaluating evidence and understanding the findings, conclusions, and recommendations in the audit report.

5.4 Audit Team and Frequency

5.4.1 Prescription audit should be conducted every 06 months with a team consisting of:

- Deputy Director General of Medicine and Therapeutic Goods Division.
- Director Pharmaceuticals, Enforcement Unit of Medicine and Therapeutic Goods
- Pharmaceutical Officers of Medicine and Therapeutic Goods Division.

5.5 Sample Size Calculation

5.5.1 6.1 Adequate sample size is essential for the audit and meaningful evaluation of prescriptions.

5.5.2 6.2 The sample (prescriptions selected for audit) should be representative of the total OPD attendance. Calculating sample size may be a cumbersome process. For ease of calculation, a sample size calculator is provided below with the Margin of Error (-10%) and Confidence Level (95%).

5.5.3 Facilities having resources may aspire for calculating sample size on -5% margin of error.

5.5.4 The sample (prescriptions selected for audit) should be representative of the total OPD attendance.

5.5.4.1 Table 1: Sample Size Calculator for Prescription Audit

Population (OPD attendance)	Sample Size (No. of Prescriptions to be audited)
	Margin of Error -10%; confidence level 95%
10	9
20	17
50	34
100	50
200	66
300	73
500	81
1000	88
3000	94

5.6 Prescribing Indicators

5.6.1 The Performance of the health care providers related to the appropriate use of drugs, can be accessed by analyzing the different prescribing indicators.

5.6.2 Prescribers can only treat patients in a rational way if they have access to essential medicines as per approved list and such list is based on the current clinical practices and evidences.

5.6.3 World Health Organization (WHO) has established "core prescribing indicators" for analysis of the prescriptions, and promotion of rational use of medicines.

5.6.4 These indicators have been broadly classified into following three categories:

- Prescribing Indicators
- Patient Care Indicators
- Facility Indicators
- Detailed list of core prescribing indicators is given at Annex 1
- Core prescribing indicators do not provide information on recording the patient's demographic details, clinical details, legibility of notes, etc.
- Hence, following indicators are expected to be recorded in undertaking analysis of prescriptions, to cover all dimensions 12 | Prescription Audit Guidelines of prescription-

writing in terms of patient's & prescriber's details and indicators related to the legibility & rationality of prescription.

5.7 Indicators for Completeness of the Prescription

5.7.1 Completeness of the prescription can be assessed, and scores are given for each component of the prescription and its correctness, as given below:

- Patient details- name, age, sex, address,
- Reported allergy, Date of consultation/registration in OPD date.
- Diagnosis or description of the health problem.
- Medicine information- (dosage forms, name of medicines prescribed in full or abbreviation, strength of formulation, dose, advisory (before/after food, at bedtime, etc.) duration of therapy, medicine interactions).
- Non-pharmacological treatment description (Signature and information about the prescriber– doctor's name, qualification, registration no).

5.8 Indicators for Legibility and Rationality of the Prescription

a. Percentage of prescription with legible handwriting.
b. Percentage of prescription where medicines prescribed are in line with STG.
c. Percentage of prescription where allergies are mentioned.
d. Percentage of prescription with brief history written.
e. Percentage of prescription with provisional or Final Diagnosis
f. Percentage of prescription where salient features of clinical examination are recorded.
g. Percentage of prescription where schedule/Dosages are written.
h. Percentage of prescription with Vitamins, Tonics, or Enzymes.
i. Percentage of prescription wherein Antibiotics are prescribed as per Hospital Antibiotic Policy.
j. Percentage of prescription with prescribed injections

5.9 Data Collection

5.9.1 After calculating the sample size, prescriptions should be randomly selected for meaningful analysis.

5.9.2 Simple random sampling techniques may be used.

5.9.3 Half of the sample should be taken from the first two weeks and remaining

5.9.4 Half of the sample is drawn from the subsequent two weeks of a month.

5.9.5 The Pharmacist Officer, Public Health Program Officers shall be collecting the samples

5.9.6 Audit template encompasses following details:

5.9.7 OPD Registration Number mentioned: A Unique Health Identification

5.9.8 Number (UHID) is given to each patient.

5.9.9 Complete Name of the patient is written: It should have first, middle (if have) and last name of the patient written on the prescription.

5.9.10 Age: It should be written in years (≥ 5 in years) in case of < 5 years (in months).

5.9.11 Weight in Kg: Weight of pediatric patients need to be recorded up to two points after the decimal. Weight of low-birth-weight neonates needs to be recorded in grams.

5.9.12 Date of consultation: In the format(day/month/year).

5.9.13 Gender of the patient: Male/Female

5.9.14 Legibility: Prescription should be written in Capital letter for clear understanding of the pharmacist.

5.9.15 Brief history written: For dispensing of correct and proper medication to the patient.

5.9.16 Allergy status mentioned: Mention about a drug that has caused allergy/side effects/unexpected outcome.

5.9.17 Salient features of Clinical Examination recorded: It includes Temperature, Pulse, Blood Pressure, Respiratory rate, etc.

5.9.18 Resumptive/definitive diagnosis written: For dispensing of correct and proper medication to the patient.

5.9.19 Medicines prescribed are in line with STG or as per National/State programme guidelines.

5.9.20 Medicines are prescribed by generic names: Medicines are not prescribed by brand/trade name.

5.9.21 Medicine schedule/doses/duration of treatment clearly written:

5.9.22 Write the quantity of tablets/capsules/liquid & number of times the medicine needs to be taken.

5.9.23 Oral instructions to be followed by the patient are written on the prescription.

5.9.24 Prescription duly signed (legibly): Signed by consulting doctor along with the stamp marked to confirm the authenticity of prescription and to avoid misuse of blank prescription.

5.9.25 Medicines Prescribed are as per EML/Formulary: Medicines advised are available in the dispensary.

5.9.26 Vitamins, Tonics or Enzymes prescribed: Must be in line with the standard treatment guidelines.

5.9.27 Antibiotics prescribed: Antibiotics are prescribed as per facility's Antibiotic Policy.

5.9.28 Investigations advised: Must be in line with the standard treatment guidelines.

5.9.29 Injections prescribed: Exclude immunization injections.

5.9.30 Number of medicines prescribed: To avoid polypharmacy

5.10 STEP 4: Data Analysis

5.10.1 Detailed analysis is required to understand the prescription practices, identification of the bottlenecks and opportunities for improvement.

5.10.2 Once the calculated number of prescriptions have been received, all 26 attributes need to be written in a tabular form.

5.10.3 Afterward, each prescription is evaluated against these attributes in the form of observed response as 'YES' or 'NO'.

5.10.4 The collected information is then transferred into an excel sheet to get a comprehensive view of prescription practices, indicators' calculation, gap identification, and best practices.

5.10.5 Each prescription is evaluated against attributes of the prescription audit tool and has been put in a table.

5.10.6 Following this, two lowest-performing attributes have been identified to prepare an action plan with a defined timeline.

5.10.7 As mentioned in table 2, all 26 attributes can be categorised into positive or negative indicators for further action.

5.10.7.1 Table 2 Data Analysis and Calculation of Indicators

S.No.	Criteria	P1	P2	P3	P4	P5	Indicator
1	OPD Registration Number mentioned?						% of prescription with OPD Registration Number
2	Complete Name of the patient is written?						% of prescription with Complete Name of the patient
3	Age in years (≥ 5 in years) in case of < 5 years (in months)						% of prescription with correct age of the patient.
4	Date of consultation - day/month/year						% of prescription with date
5	Gender of the patient						% of prescription with sex of the patient.

6	Handwriting is Legible in Capital Letters						% of prescription with legible handwriting, preferably in Capital letters.
7	Brief history Written						% of prescription with Brief history Written
8	Allergy status mentioned						% of prescription Allergy status mentioned
9	Salient features of Clinical Examination recorded						% of prescription with Salient features of Clinical Examination
10	Presumptive / definitive diagnosis written						% of prescription with Presumptive / definitive diagnosis
11	Medicines are prescribed by generic names						% of prescription with medicines in Generic names
12	Medicines prescribed are in line with STG						% of prescription with medicines prescribed in line with STG
13	Medicine Schedule/ doses clearly written						% of prescription with clearly written medicine Schedule/ doses
14	Duration of treatment written						% of prescription with duration of treatment.
15	Date of next visit (review) written						% of prescription with date of next visit
16	In case of referral, the relevant clinical details and reason for referral given						% of prescription with details and reasons of referral.
17	Follow-up advise and precautions (do's and don'ts) are recorded						% of prescription with follow-up advise
18	Prescription duly signed (legibly)						% of prescription duly signed.
19	Medicines Prescribed are as per EML/Formulary						% of prescription with medicines prescribed from EML
20	Medicines advised are available in the dispensary						% of prescription with medicines available in dispensary.

21	Vitamins, Tonics or Enzymes prescribed						% of prescription with Vitamins, Tonics or Enzymes.
22	Antibiotics prescribed						% of prescription with antibiotics
23	Antibiotics are prescribed as per facility's Antibiotic Policy						% of prescription with Antibiotics as per Antibiotic Policy
24	Investigations advised						% of prescription with investigations
25	Injections prescribed						% of prescription with injections
26	Number of Medicines prescribed						Average no. of medicines/ prescription

5.10.7.2 Table 3 Formular for analyzing

	Formula	Calculation (Examples)
	No. of prescription with duration of treatment. /No. of prescription audited. X 100	3/5 X 100=**60%**
	No. of prescription with date of next visit/No. of prescription audited. X 100	3/5 X 100=**60%**
	No. of prescription with details and reasons of referral/No. of prescription audited. X 100	2/3 X 100=**33.3%**
	No. of prescription with follow-up advise/No. of prescription audited. X 100	4/5 X 100=**80%**
	No. of prescription duly signed. /No. of prescription audited. X 100	4/5 X 100=**80%**
	No. Prescription with medicines prescribed from EML/ No. of prescription audited. X 100	1/5 X 100=**20%**
	No. of prescription with medicines available in dispensary/No. of prescription audited. X 100	5/5 X 100=**100%**

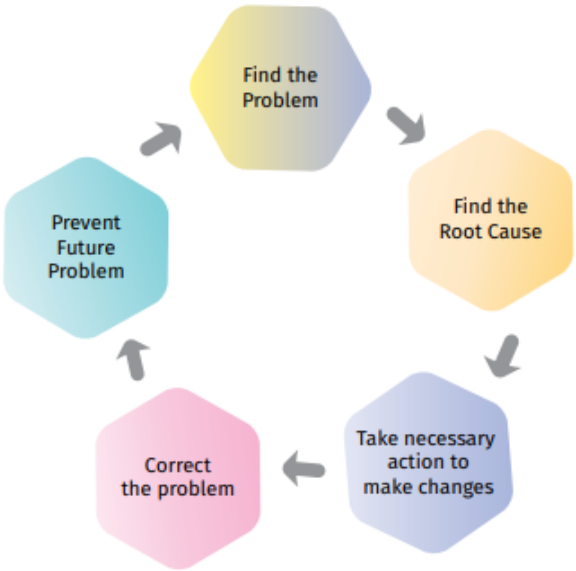
	No. of prescription with Vitamins, Tonics or Enzymes. /No. of prescription audited. X 100	3/5 X 100=**60%**
	No. of prescription with antibiotics/No. of prescription audited. X 100	5/5 X 100=**100%**
	No. of prescription with Antibiotics as per Policy /No. of prescription audited. X 100	3/5 X 100=**60%**
	No. of prescription with investigations/No. of prescription audited. X 100	3/5 X 100=**60%**
	No. of prescription with injections/No. of prescription audited. X 100	5/5 X 100=**100%**
	Total no. of medicines prescribed/Total no. of prescription audited	6+4+10+7+8/5; 35/5=**7**
	No. of prescription with duration of treatment. /No. of prescription audited. X 100	3/5 X 100=**60%**
	No. of prescription with date of next visit/No. of prescription audited. X 100	3/5 X 100=**60%**
	No. of prescription with details and reasons of referral/No. of prescription audited. X 100	2/3 X 100=**33.3%**
	No. of prescription with follow-up advise/No. of prescription audited. X 100	4/5 X 100=**80%**
	No. of prescription duly signed. /No. of prescription audited. X 100	4/5 X 100=**80%**
	No. Prescription with medicines prescribed from EML/ No. of prescription audited. X 100	1/5 X 100=20%
	No. of prescription with medicines available in dispensary/No. of prescription audited. X 100	5/5 X 100=**100%**
	No. of prescription with Vitamins, Tonics or Enzymes. /No. of prescription audited. X 100	3/5 X 100=**60%**
	No. of prescription with antibiotics/No. of prescription audited. X 100	5/5 X 100=**100%**
	No. of prescription with Antibiotics as per Policy /No. of prescription audited. X 100	3/5 X 100=**60%**

	No. of prescription with investigations/No. of prescription audited. X 100	3/5 X 100=**60%**
	No. of prescription with injections/No. of prescription audited. X 100	5/5 X 100=**100%**
	Total no. of medicines prescribed/Total no. of prescription audited	6+4+10+7+8/5; 35/5=**7**

5.11 Overview of Quality Improvement Cycle for Prescription Audit

5.11.1 Aim of the prescription audit is to highlight the discrepancies between actualpractice and standard practice, followed by identification of changes that need toimprove the quality of care. An audit is a cyclical process to identify the problems, tracing the root cause for the occurrence of the problem followed bythe preparation of an action plan to correct the problem. Every time an auditcycle is completed, there should be further improvement in patient care.

5.11.1.1 Figure 1



6 Annexes

- Annex I : WHO Core Prescribing Indicators

7 References:

- Medicine Regulation R-46 (2014)
- Health Service Act

ANNEX I – WHO Core Prescribing Indicators

These drug use indicators were developed to be used as measure of performance in three general areas related to the rational use of drugs

A. Prescribing indicators

- Average number of drugs per encounter
- Percentage of drugs prescribed by generic name
- Percentage of encounters with an antibiotic prescribed
- Percentage of encounters with an injection prescribed
- Percentage of drugs prescribed from essential medical list or formulary

B. Patient care indicators

- Average consultation time
- Average dispensing time
- Percentage of drugs actually dispensed
- Percentage of drugs adequately labelled
- Patients' knowledge of correct dosage

C. Facility indicators

- Availability of copy of essential drugs list or formulary
- Availability of key drugs