LEADERSHIP AND ADMINISTRATION

1- A Drug Information Center had established in the hospital or under Medical Affair and headed by a qualified DIC personal with appropriate experiences.
   1.1 The DIC has a clear organization structure.
   1.2 DIC head holds minimum Pharm.D. or Master with Board Certificate or Residency.
   1.3 DIC head has signed an updated job description.
   1.4 Evidence of valid Saudi Council of Health Specialties license to practice in Saudi Arabia.
   1.5 The DIC head has updated curriculum vitae.
   1.6 Evidence of work experience in hospital and DIC setting.

2- The DIC has a clear mission, vision, and values
   2.1 Mission is clearly written, posted, and verbalized by DIC staff.
   2.2 Vision is clearly written, posted, and verbalized by DIC staff.
   2.3 Values are clearly written, posted, and verbalized by DIC staff.

3- The DIC space is adequate. Hours of operation are determined, announced, and followed.
   3.1 The space provided for DIC services allows the principal functions to be carried out in efficient and effective manner.
   3.2 Hours of operation of each DIC section are clearly defined in the policy and procedure, announced within the hospital and posted at the DIC entrance.
   3.3 Monthly work schedule is written and announced.
**Administrative Policies and Procedures for MOH hospitals /PHC Centers**

<table>
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<th>POLICY NUMBER :</th>
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<tr>
<td>TITLE: MINIMUM STANDARD OF DRUG INFORMATION CENTERS AT KSA</td>
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<td>REVISION DATE :</td>
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4. The DIC has qualified and licensed staffing.
4.1 All DIC staff has valid licenses from Saudi commission for Health Specialties to practice in Saudi Arabia.
4.2 All staff has a current job description.
4.3 Each staff signed his/her job description.
4.4 40% of DIC staff must be Clinical Pharmacist with minimum Pharm.D. or MSc Degree with Board Certificate and Special Training Program

5. The DIC Supervisor reports workload statistics to the appropriate and leadership number of FTE (Full Time Equivalent) staff and actual workload are published.
5.1 Standard time for each function/task is determined.
5.2 Answering question depends on the priority of the question.
5.3 Monthly workload is reported for Drug Information Center.
5.4 Monthly workload is reported for Clinical Pharmacokinetics Center.
5.5 Monthly workload is reported for Research and Clinical Trial Center.
5.6 Monthly workload is reported for Patient and Family Education
5.7 Monthly workload is reported for Documentation and Quality of Informatics.
5.8 Monthly workload is reported for activities (e.g. meetings, in-services, education lecture, etc.).
5.9 Workload statistics are reported monthly to the Pharmacy Director then to National Drug Information center at General Pharmaceutical Care Department through regional DI.
5.10 The DIC has the necessary manpower to operate the available service as evidenced by the workload statistics.
5.11 The DIC has the Documentation System of its activity.
6- The DIC shows evidence of Quality Improvement by:

6.1 Having standards for all the DIC care process.
6.2 Subjecting current standards to evaluation.
6.3 Developing and maintaining a plan and documented performance and improvement of program.
6.4 Continually determining areas for improvement.
6.5 Immediately reporting life threatening issues to the Pharmacy Director and hospital TQM department (e.g. morbidity, mortality, and teratogenicity), any new ADR or toxic events of new drugs.
6.6 Reporting any questionable drug quality to Pharmacy director.

7- RESOURCE AND ACTIVITY
Drug Information Service includes:

7.1 Written policies and procedures.
7.2 A good collection of up-to-date information resources: Micromedex, IOWA drug information system, local and external therapeutics journals, pharmacy textbooks and manuals, online formularies and other specialty references as needed.
7.3 Being equipped with: an office with its computer, scanner, printer, reading table with chairs, storage shelves and cabinets, telephone line with internet connection, quiet and well illuminated reading area.
7.4 All questions being logged in with date and time of arrival. All answers are documented and filed in order, either manual or electronically.
7.5 Giving priority to poisoning and critical care patients.
7.6 Posting and making available telephone number for the poison control center and poison antidote information.
PATTERN NUMBER:

TITLE: MINIMUM STANDARD OF DRUG INFORMATION CENTER IN KSA

8- If Drug Information service is not available, on call DIC pharmacists should have adequate drug information resources and includes but is not limited to:

• Micromedex
• Lexicomp
• Online formularies
• Uptodate

9- The DIC has administrative rules regarding availability of answering call for 24 hours a day.

9.1 The DIC is open 24 hours/day.
9.2 If the DIC is not open 24 hours/day, on call service is announced to all hospital service areas for use after working hours.

10- The DIC has a system for answering calls.

10.1 Written multidisciplinary Internal Policies and Procedures (IPP) for accepting and transcribing telephone calls by medical staff.
10.2 IPP clearly defines urgency situation for telephone calls and time frame for questions.
10.3 IPP clearly defines staff who may accept a telephone call.
10.4 IPP defines proper procedure for receiving and documenting telephone calls.
10.5 DIC Staff clearly understands how to handle telephone calls.

11- The Hospital has an updated formulary system.

11.1 The Hospital formulary is established by DIC in collaboration with the Pharmacy and Therapeutics Committee. (DIC pharmacist is a member in P&T committee)
11.2 The Hospital formulary is updated at least once in 2 years.
11.3 The Hospital formulary is available to all healthcare team.
Ministry of Health
General Pharmaceutical Care Department
Total Quality Management

Policy Number:

Title: Minimum Standard of Drug Information Center in KSA

Version No.:

No. of Pages:

Original Date:

Originator:

Revision Date:

12- The Hospital formulary is very well structured.

12.1 The Hospital formulary should have the following information; generic name, dosage form, strength, therapeutic classification, and prescribing information.

12.2 The Hospital formulary is properly indexed using alphabetical indexing for generic named drugs.

12.3 An approved abbreviation list for prescribing is included in a separate section.

12.4 The hospital formally has Policy and Procedure for Prescribing, Dispensing, and Administration Regular Medication.

12.5 The hospital formulary has Policy and Procedure for Prescribing, Dispensing, and Administration of Narcotics.

12.6 The Hospital formulary provides guidance to medication use:

12.6.1 Medication utilization guidelines and / or restriction are included in a separate section.

12.6.2 Evidence of implementation by prescribers of the medication utilization guidelines.

12.6.3 Medication dispensing as per medication hospital policy (dosing, duration, restriction, etc.).

13- DIC has system for Drug Evaluation Process which includes:

13.1 Drug request form that includes but not limited to:

13.1.1 Generic Name, Proprietary Name, Manufacturer, Dosage Form, Pharmacological Classification, and Therapeutic Use.

13.1.2 Drug compared to the existing current formulary drugs in terms of: Indications, Therapeutic Efficacy, Adverse Effects, and Cost.

13.1.3 The drug currently in the formulary may be replaced.

13.1.4 The drug to be restricted to use by certain specialty of the medical staff.

13.1.5 The anticipated annual use rate if this drug is added to the drug formulary.

13.1.6 Other information useful in supporting the addition of this drug.
13.2 Drug Evaluation Form that includes the following but not limited to: Pharmacological Approved Country, Pharmacologic Drug Therapeutic classification, Toxic Doses, and the following things:

- 13.2.1 Evidence base studies of Indication.
- 13.2.2 Evidence base studies of Safety.
- 13.2.3 Evidence base studies of PharmacoEconomic and Cost.
- 13.2.4 Biostatistical Analysis comparison with the available Medication, Indication, Safety, and Cost.

14- DIC has a process for PharmacoEconomic System that's include:

- 14.1 Written policy and procedure for PharmacoEconomic
- 14.2 Definition types of PharmacoEconomic Analysis.
- 14.4 Intensive analysis is performed for all significant potential cost of the medications.
- 14.5 Evidence for using reported PharmacoEconomic data to improve medication use process and reduce cost rate.
- 14.7 Process for improving PharmacoEconomic Analysis.
- 14.8 Evidence of reporting PharmacoEconomic Analysis.

15- The DIC has a system for handling non-formulary drug requests.

- 15.1 Written multidisciplinary IPP for handling non-formulary drugs including clearly defined time frame for drug procurement.
- 15.2 Non-formulary drug request form is available.
- 15.3 Clear evidence of proper handling of non-formulary drug request is available.
16- The DIC has system for using formulary drugs for unapproved indications.
   16.1 Written multidisciplinary IPP for using a formulary drugs for an unapproved indication and / or investigation.
   16.2 Request form for using formulary drug for an unapproved Indication is available.
   16.3 Clear evidence of proper adherence to the IPP for using formulary drugs for an unapproved indication.

17- DIC has a process for monitoring, detecting, and reporting adverse drug reaction (ADRs) and includes:
   17.1 Written policy and procedure for ADR.
   17.2 Definition of significant or serious ADR and timeframe for reporting.
   17.3 ADR reporting forms are available.
   17.4 Intensive analysis is performed for all significant or serious ADRs.
   17.5 Notification of treating physician.
   17.6 There is evidence that the patient receives appropriate care for ADR.
   17.7 There is evidence that the medical record has been flagged for known allergies.
   17.8 Process for improving ADR reporting.
   17.9 Evidence of reporting any serious or unexpected ADR to NDIC the MOH.

18- DIC has a process for monitoring, identifying, and reporting significant medication errors (ME) and includes:
   18.1 Written policy and procedure for medication error reporting
   18.2 Definition of a significant medication error, timeframe for reporting, and reporting format.
   18.3 Evidence of active reporting exists.
   18.4 Intensive root-cause analysis is performed for all significant medication errors.
   18.5 Evidence for using reported data to improve medication use process and reduce error rate.
   18.6 Mechanism to prevent serious medication errors (e.g. removal of concentrated intravenous potassium, magnesium, hypertonic saline, other high risk stocks from nursing units).
19- DIC has a process for Clinical Pharmacokinetic Monitoring and includes:

19.1 Designing patient-specific drug dosage regimens based on the: pharmacokinetic and pharmacologic characteristics of the drug product-used, the objectives of drug therapy, concurrent diseases and drug therapy, and other pertinent patient factors (e.g., demographics, laboratory data) that improve the safety and effectiveness of drug therapy and promote positive patient outcomes.

19.2 Recommending or scheduling measurements of drug concentrations in biological fluids (e.g., plasma, serum, blood, cerebrospinal fluid) or tissues in order to facilitate the evaluation of dosage regimens.

19.3 Monitoring and adjusting dosage regimens on the basis of pharmacologic responses and biological fluid and tissue drug concentrations in conjunction with clinical signs and symptoms or other biochemical variables.

19.4 Evaluating unusual patient responses to drug therapy for possible pharmacokinetic and pharmacologic explanations.

19.5 Communicating patient-specific drug therapy information to physicians, nurses, and other clinical practitioners and to patients orally and in writing, and including documentation of this in the patient’s health record.

19.6 Educating pharmacists, physicians, nurses, and other clinical practitioners about pharmacokinetic principles and appropriate indications for clinical pharmacokinetic monitoring including the cost-effective use of drug concentration measurements.

19.7 Developing quality assurance programs for documenting improved patient outcomes and economic benefits resulting from clinical pharmacokinetic monitoring.
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19.8 Promoting collaborative relationship with other individuals and departments involved in drug therapy monitoring to encourage development and appropriate use of pharmacokinetic principles in pharmaceutical care.

19.9 The opportunity to assume the following additional responsibility: designing and conducting research to expand clinical pharmacokinetic knowledge and its relationship to pharmacologic responses, exploring concentration response relationship for specific drug, and contributing to the evaluation and expansion of clinical pharmacokinetic monitoring as an integral part of pharmaceutical care.

19.10 Developing and applying computer programs and point-of-care information systems to enhance the accuracy and sophistication of pharmacokinetic modeling and applications to pharmaceutical care.
20- DIC has process for Medication-Use Evaluation and includes:

20.1 Established organizational authority for the MUE process and identify responsible individuals and groups.

20.2 Developed screening mechanism (indicators) for comprehensive surveillance of the medications-use system.

20.3 Set priorities for in-depth analysis of important aspects of medications-use.

20.4 Inform health-care professionals (and other as necessary) in the practice settings about the objectives and expected benefits of the MUE process.

20.5 Establish criteria, guidelines, treatments protocols, and standards of care for specific medications and medications-use processes. These should be based on sound scientific evidence from the medical and pharmaceutical literature.

20.6 Educate health-care professionals to promote the use of criteria, guidelines, treatment protocols, and standards of care.

20.7 Establish mechanisms for timely communication among health-care professionals.

20.8 Initiate the use of MUE criteria, guidelines, treatments protocols, and standards of care in the medication-use process

20.9 Collect data and evaluate care.

20.10 Develop and implement plans for improvement of the medications-use process based on MUE findings (if indicated). Assess the effectiveness of action taken, and document improvements.

20.11 Incorporate improvements into criteria, guidelines, treatments protocols, and standards of care when indicated.
20.12 Repeat the cycle of planning, evaluating, and taking action for ongoing improvements in medications-use processes.

20.13 Regularly assess the effectiveness of the MUE process itself and make needed improvements.

21- The DIC has a system for handling pharmaceutical representative’s medical samples.
   21.1 Written multidisciplinary IPP to outline the relationship of pharmaceutical representatives with DIC staff and health care professionals.

22- The DIC actively participates in all relevant hospital committees as evidenced by meeting minutes.
   22.1 The DIC actively participates in the Pharmacy and Therapeutics Committee.
   22.2 The DIC actively participates in the Antibiotic Committee.
   22.3 The DIC actively participates in the Mortality and Morbidity Committee.
   22.4 The DIC actively participates in the Research and Ethical Committee.

23- The DIC shows evidence of continuing education and staff training by:
   23.1 Written policy and well defined DIC orientation and continuing education program.
   23.2 Evidence of completion of DIC orientation by all newly hired DIC staff.
   23.3 Evidence of continuing education activities (provision or attendance of lectures, in-services, conferences and symposia, or distant learning e.g., internet or CE articles).
   23.4 Each DIC section has the following reference manuals and/or policies. (DI manual, P&T manual, PharmacoEconomic manual, Medication safety manual)
24- The DIC has a system developed for patient and family education and counseling before going home which include:

24.1 Patient and families are offered education for dispensed medication.

24.2 Written drug counseling materials are available in easy understandable language (Arabic and English), lexicomp*

24.3 The medication’s trade name, generic name, common synonym, or other descriptive names and, when appropriate, its therapeutic class and efficacy.

24.4 The medication’s use and expected benefits and action. This may include whether the medication is intended to cure a disease, eliminate or reduce symptoms, arrest or slow the disease process, or prevent the disease or a symptom.

24.5 The medications expected onset of action and what to do if the action does not occur.

24.6 The medication’s route, dosage form, dosage, and administration schedule (including duration of therapy).

24.7 Directions for preparing and using or administering the medication. This may include the adaptation to fit patient’s lifestyles or work environments.

24.8 Action to be taken in case of a missed dose.

24.9 Precautions to be observed during the medication’s potential risks in relation to benefits.
24.10 Potential common and severe adverse effects that may occur, actions to prevent or minimize their occurrence, and actions to take if they occur, including notifying the prescriber, pharmacist, or other health care provider.


24.12 Potential drug-drug (including nonprescription), drug-food, and drug-disease interactions or contraindications.

24.13 The medication’s relationships to radiological and laboratory procedures (e.g., timing of doses and potential interferences with interpretation of results).

24.14 Prescription refill authorizations and the process for obtaining refills.

24.15 Instructions are for 24-hour access to a pharmacist.

24.16 Proper storage of the medication.

24.17 Proper disposal of contaminated or discontinued medications and used administration devices.

References: