

***CLINICAL
PHARMACOKINETICS PHARMACY
SERVICES***



POLICY AND GUIDELINE



**POLICY AND GUIDELINE
OF
CLINICAL PHARMACOKINETICS PHARMACY
2015**

**Clinical Pharmacy Working Committee
(Clinical Pharmacokinetics Subspecialty)
Pharmaceutical Services Division
Ministry of Health Malaysia**

First Edition

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Foreword



Assalamualaikum w.b.t, Salam Sejahtera dan Salam 1 Malaysia

Pharmacy practice was traditionally product centred has now shifted towards patient care. Pharmaceutical care, which is comprehensive and patient focused is vital in ensuring that patients receive rational, safe and effective treatment.

Clinical Pharmacokinetic Service was introduced in 1980's which is also known as Therapeutic Drug Monitoring (TDM) service. Due to the rapidly expanding clinical pharmacokinetics services, it is timely and essential that Pharmaceutical Services Division, Ministry of Health develops and publish this handbook.

This policy and guideline is meant for pharmacist involved in this service. The main objective of this policy and guideline is to ensure the standardisation of clinical pharmacokinetics services to all Ministry of Health (MOH) facilities that offers this service.

The recommendations in this policy and guideline have been made by taking into consideration existing policies in the facilities pertaining to the practice of the clinical pharmacokinetic services. I believe that the contents of this policy and guideline will be able to serve as a standard reference for all hospital pharmacists in practicing and managing the clinical pharmacokinetics services. I am confident that this policy and guideline will also provide useful information in ensuring patients receive rational, safe and effective treatment.

It is my sincere hope that this policy and guideline will serve as a useful reference to all relevant parties. Last but not least, I would like to convey my gratitude to the Clinical Pharmacy Working Committee (Pharmacokinetic Subspecialty) for their hard work to come up with the first edition of 'Policy and Guideline of Clinical Pharmacokinetics Pharmacy 2015'

Thank you.

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1. INTRODUCTION

Clinical Pharmacokinetics is a part of pharmaceutical care involving management of drugs with narrow therapeutic range.

It involves the understanding of pharmacokinetic / pharmacodynamics characteristics of drug in specific disease condition and patient population ⁽¹⁾. Essentially clinical pharmacokinetic service is used to ensure that medications prescribed are within recommended therapeutic range as well as to monitor efficacy, toxicity and compliance. Clinical Pharmacokinetic Services can also be used as a reference to determine optimal therapeutic dosage of drugs based on the patient's clinical condition. The main goal of Clinical Pharmacokinetic Services is utilization of information on the drug concentrations to manage a patient's medication regimen and optimize outcome.

2. OBJECTIVES OF THIS GUIDELINE

- (i) To establish a standardized Clinical Pharmacokinetic approach in management of patients receiving drugs where serum drug concentration are monitored in Ministry of Health (MOH) facilities
- (ii) To assist pharmacists in clinical pharmacokinetic monitoring of the selected drugs
- (iii) To provide general information regarding Clinical Pharmacokinetic Services to other healthcare providers

3. CLINICAL PHARMACOKINETICS ROLE IN PHARMACEUTICAL CARE

Identifying and resolving potential problems related to:

- (i) Inappropriate dose
- (ii) Adverse drug reaction
- (iii) Drug-drug interaction
- (iv) Drug-disease interaction
- (v) Non adherence
- (vi) Suspected toxicity

4. PHARMACISTS' RESPONSIBILITIES IN CLINICAL PHARMACOKINETICS SERVICES⁽²⁾

- (i) Designing patient-specific drug dosage regimens based on pharmacologic characteristics of the drug used, the objectives of drug therapy, concomitant diseases & drug therapy, and other pertinent patient factors.
- (ii) Monitoring & adjusting dosage regimens based on pharmacologic responses and on biological fluid (e.g. plasma, serum, blood) in conjunction with clinical signs and symptoms or other biochemical parameters.
- (iii) Evaluating unusual patient responses to drug therapy for possible pharmacokinetic and pharmacologic explanations.
- (iv) Communicating, verbally and writing, information on patient-specific drug therapy to physicians, nurses, and other clinical practitioners.
- (v) Educating pharmacists, physicians, nurses, and other clinical practitioners on pharmacokinetic principles and/or appropriate indications for clinical pharmacokinetic monitoring.
- (vi) Developing quality assurance programs to document improved patient outcomes and economic benefits resulting from clinical pharmacokinetic monitoring.

5. CLINICAL PHARMACOKINETIC SERVICES POLICIES

5.1 Scope of Work

- (i) To provide 24 hours services 7 days a week for toxicity and urgent cases
- (ii) To assess, interpret, recommend and monitor drug therapy based on patient's pharmacokinetic profile, and clinical condition
- (iii) To assess and reinforce patient compliance
- (iv) To review all results and recommend dosages
- (v) To provide pharmacokinetics information when necessary
- (vi) To communicate and discuss results with prescribers

5.2 Reporting of Therapeutic Drug Monitoring (TDM) Results

All the results should be reported to Pharmacist/Prescriber

5.3 Sample Analysis By Laboratory

- (i) During office hours – Period of time recommended results should be reported not later than 6 hours if the level is sub-therapeutic or with therapeutic range
- (ii) Laboratory turnaround time for toxic level should be less than 2 hours
- (iii) All the results should be informed to the pharmacists first by the lab before it is sent to the wards/units.
- (iv) Lab-based TDM analysis is proposed in the hospitals with newly set up Clinical Pharmacokinetic Service.

5.4 Sample Analysis By Pharmacy

- (i) During office hours – Period of time recommended results should be reported within 4 hours if the level is sub therapeutic or with therapeutic range.
- (ii) All suspected toxicity/supra-therapeutic cases recommendations have to be communicated within 2 hours to the requesting prescribers/units.
- (iii) In future, all samples need to be analyse in pathology laboratory in phases.

6. STANDARD OPERATING PROCEDURES

6.1 Therapeutic Drug Monitoring in Pharmacy based

6.1.1 Ward / Clinic:

- (i) Identify patient that require monitoring of drug therapy
- (ii) Complete the CPS request form (Appendix 1)
- (iii) Withdraw patient's blood sample according to the sampling time
- (iv) Send blood sample and request form to pharmacy

6.1.2 Pharmacy:

- (i) Receive CPS request form and blood samples
- (ii) Screen the CPS request form and blood sample (ensure all the information needed are provided and the correct sample received)
- (iii) Record patient's name and drug required to be analysed.
- (iv) Sample preparation for analysis:
 - a. Centrifuge the blood samples to obtain serum
 - b. For immunosuppressant assay, perform pre-treatment procedure to obtain supernatant
 - c. Transfer serum/supernatant into a sample cup /test tube and run the assay.
- (v) Interpret the result based on patients' clinical status
- (vi) Communicate the results and recommended action to the prescriber
- (vii) Despatch the results and record of recommendations to the respective ward/clinic
- (viii) File the record
- (ix) Follow up on the action taken as per recommendation given and provide guidance on future therapeutic drug monitoring where appropriate

6.2 Therapeutic Drug Monitoring by the laboratory

6.2.1 Ward / Clinic:

- (i) Identify patient that require monitoring of drug therapy
- (ii) Complete the CPS request form (Appendix 1)
- (iii) Withdraw patient's blood sample according to the sampling time
- (iv) Verification of CPS request form
- (v) Send blood sample and request form to laboratory

6.2.2 Laboratory:

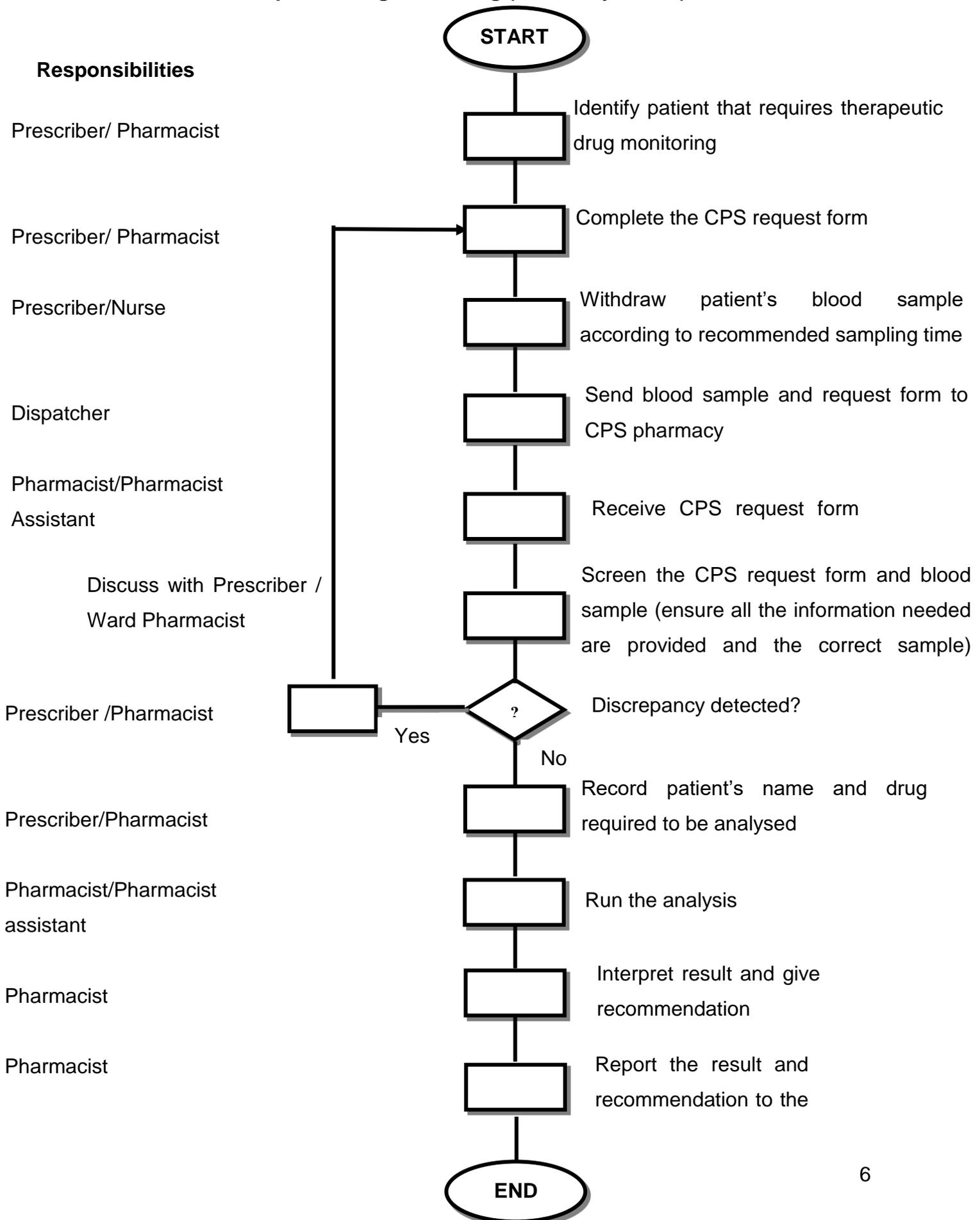
- (i) Receive the copy of CPS request form
- (ii) Screen the CPS request form and blood sample (ensure all the information needed are provided and the correct sample received)
- (iii) Record patient's name and drug required to be analysed.
- (iv) Sample preparation for analysis
- (v) Run the analysis
- (vi) Send result to the pharmacist

6.2.3 Pharmacy:

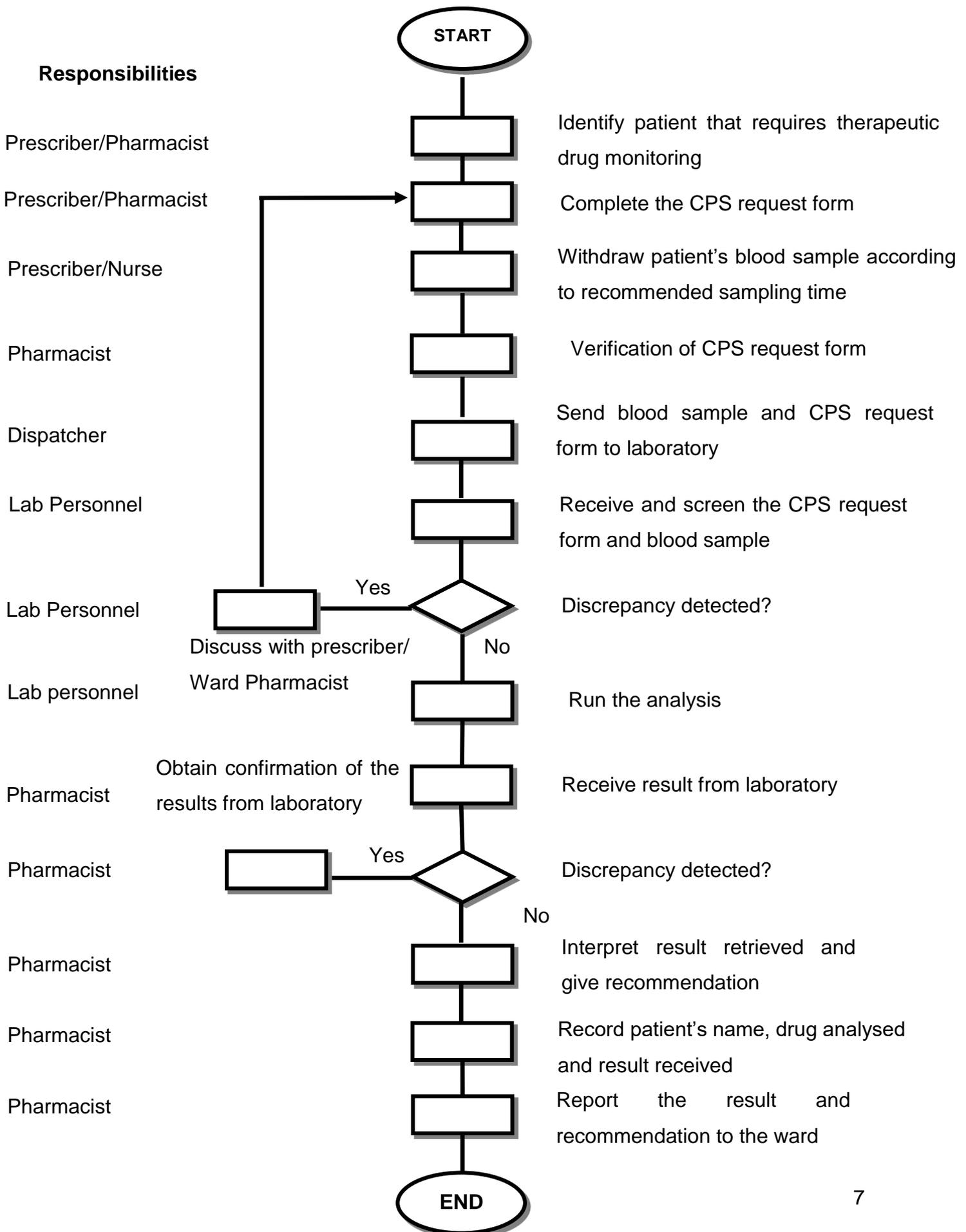
- (i) Receive copy of CPS request form
- (ii) Identify and clerk the patient
- (iii) Interpret the result based on patients' clinical status
- (iv) Communicate the interpretation of results and recommended action to the responsible prescriber
- (v) File the record
- (vi) Monitor the action taken as the recommendation given and provide guidance on future therapeutic drug monitoring where appropriate
- (vii) Record the interventions (if any)

6.3 Flowchart

Therapeutic Drug Monitoring (Pharmacy-based)



Therapeutic Drug monitoring (Lab-based)



6.4 Internal and External Quality Control

- (i) Perform daily internal quality control
- (ii) Perform scheduled maintenance as recommended by manufacturer.
- (iii) Perform calibration when necessary
- (iv) Perform external quality control by following MS ISO 15189 requirements
- (v) Document daily /monthly quality control activities.

6.5 Management and Handling of Stock (Calibrators, Reagents & Controls)

- (i) Store the stocks in storage condition according to product specifications
- (ii) Monitor the refrigerator temperature twice daily
- (iii) Keep buffer stock for at least one month supply

6.6 Handling of Blood Sample

Follow MS ISO 15189 requirements.

6.7 Personnel Safety

- (i) Wear proper personnel protection equipment (PPE) i.e. Face mask, apron and gloves
- (ii) Practice proper hand hygiene

6.8 Maintenance of Work Area

Clean the work area with alcohol 70% before and after procedures

6.9 Waste Management ⁽³⁾

- (i) Discard/dispose all the blood, test tubes, pipette tips, sample cup and other single-used item into the clinical waste bin.
- (ii) Discard all the gloves, masks, and other PPE into clinical waste bin.

- (iii) Maximum used for clinical sharp bin is 7 days or when the container has reached the maximum limit.
- (iv) Discard waste from the machine according to the supplier's recommendation

6.10 Blood Spillage Management

- (i) Wear protective clothing
- (ii) Soak up the excess fluid using disposable paper towels
- (iii) Cover the contaminated area with towels soaked in 10,000ppm (1%) of available chlorine (This is 1 part chlorine to 10 parts water, put water in the container 1st then only add chlorine). Please ventilate room well prior to using chlorine product
- (iv) Leave for at least 2 minutes
- (v) Remove all organic matter and dispose of as clinical waste (infectious waste-blue bag)
- (vi) Clean the area with hot water and detergent
- (vii) Dry the area using disposable paper towels
- (viii) Dispose of protective clothing as above
- (ix) Wash hands

7. DOCUMENTATION

All activities must be well documented with proper filling

8. REFERENCES

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