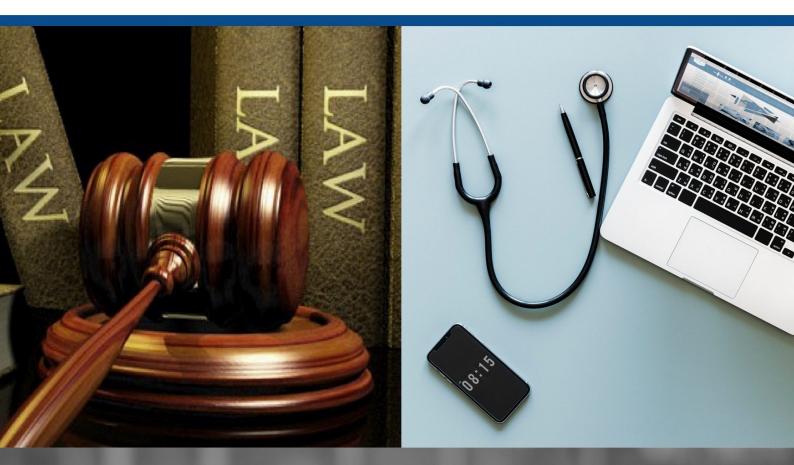


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GUIDELINE ON THE MANAGEMENT OF MEDICO LEGAL COMPLAINTS IN THE MINISTRY OF HEALTH

2nd Edition - 2019



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Medico Legal Section Medical Practice Division

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MESSAGE FROM THE DIRECTOR GENERAL OF HEALTH



Healthcare providers are facing a new challenge in this era of information technology. Questionable medical facts are easily obtained from the internet and sensational news can get viral in a matter of hours. Dissatisfaction on healthcare services can arise due to misinformation and when this frustration is channeled through social media, it can lead to significant pressure to the healthcare providers and affect the Ministry of Health's (MOH) reputation.

This guideline is an update to the 2007 edition of 'Guidelines on the Management of Complaints and Medico Legal Cases' which had been used as a reference by MOH administrators and healthcare providers in managing medico legal complaints. In this guideline, the MOH has been focusing on the latest medico legal issues to develop a more comprehensive guide that is in keeping with today's challenges.

I would like to take this opportunity to congratulate the Medico Legal Section of the Medical Practice Division in publishing this guideline. It is hoped that this new guideline will establish a systematic and efficient management of medico legal complaints while maintaining transparency and integrity.

Datuk Dr. Noor Hisham bin Abdullah

Director General of Health Ministry of Health Malaysia

MESSAGE FROM THE DEPUTY DIRECTOR GENERAL OF HEALTH (MEDICAL)



Today, the Malaysian public has high expectations of MOH healthcare services as a result of increasing level of awareness and education. Inadvertently, this has led to a higher number of medico legal complaints against MOH healthcare facilities.

This guideline will provide a much needed improvement in the current system of managing medico legal complaints. With the addition of surveillance and audit activities, healthcare providers will be able to enhance the quality of services which in turn will help reduce the number of complaints.

Lastly, I would like to express my gratitude to the Medico Legal Section of the Medical Practice Division along with the other contributors in their effort to publish this guideline.

Dato' Dr. Azman bin Hj. Abu Bakar

Deputy Director General of Health (Medical) Ministry of Health Malaysia

MESSAGE FROM THE DIRECTOR OF MEDICAL PRACTICE DIVISION



Healthcare administrators and healthcare providers faces the daunting task of managing various complaints from the public; be it long waiting time for consultation, attitudes of the personnel, uncomfortable ward condition and so on. However, complaints of medico legal nature are particularly difficult to handle especially for those who are inexperienced.

This guideline will provide MOH healthcare administrators and healthcare providers a step by step guide on how to manage medico legal complaints with the intention to resolve the issue amicably. The ultimate aims of managing these complaints are to reduce its numbers and to prevent similar reoccurrence in the future.

I hope that this guideline will be adopted as a useful tool by all MOH healthcare administrators and healthcare providers for the continuous improvement of healthcare delivery provided by the ministry.

Dr. Ahmad Razid bin Salleh

Director of Medical Practice Division Ministry of Health Malaysia

PREFACE

Medico Legal Section was established in the year 2004 as part of the Medical Practice Division, Ministry of Health. The function of this Section is to manage medico legal cases by coordinating the investigation towards any medico legal complaint. Medico Legal Section also oversees all medical negligence litigation cases against Ministry of Health facilities.

Since 2006, a no fault compensation scheme or now known as ex gratia was initiated as a settlement for medico legal cases. This scheme is created to reduce the number of litigation cases against MOH and also to reduce the amount of pay-out.

In addition, this Section collects and analyses the data and trends of all medico legal cases in MOH. This information is used to improve the services in MOH facilities and to prevent similar incident.

Medico Legal Section also provides training and courses to MOH staff on medico legal related matter. This Section aims to raise awareness among MOH staff especially doctors and paramedics on how to avoid and manage medico legal cases.

PART 1: MANAGEMENT OF MEDICO LEGAL COMPLAINTS

1.1 INTRODUCTION

This guideline is only applicable for medico legal complaints involving Ministry of Health (MOH) healthcare facilities. Complaints made against non-MOH healthcare facilities or private healthcare facilities are excluded from this guideline.

1.1.1 Medico legal complaint

- a. Defined as complaints of alleged medical negligence while receiving services and treatment at MOH healthcare facilities; and
- b. Complaints can be from any source(s) provided that the facility and the patient can be identified.

1.1.2 Role of Medico Legal Section

- a. To coordinate the management of medico legal complaints against MOH healthcare facilities;
- b. To analyze medico legal complaints or investigation reports;
- c. To recommend the formation of Independent Inquiry Committee; and
- d. To analyze the Independent Inquiry Report.

1.2 INTERNAL INQUIRY COMMITTEE

1.2.1 Objectives

- a. To identify and analyze the issues brought up by the complainant;
- b. To ensure all existing standards, procedures or guidelines were adhered to;
- c. To identify contributing factors and personnel involved in the complaint; and
- d. To provide recommendations to prevent similar incident in the future.

1.2.2 Terms of Reference

- a. To investigate the validity of the complaint;
- b. To identify the relevant event(s) and personnel involved;
- c. To conduct Grievance Mechanism; and
- d. To suggest for corrective actions and recommendations.

1.2.3 Initiation of Internal Inquiry Committee

All medico legal complaints must be reported to the Director of the facility involved and the following actions should be taken:

- a. Evaluate the complaint to determine whether it is a medico legal complaint and if so, proceed with Internal Inquiry;
- b. Retrieve the patient's medical records and/or any other available document related to the case;
- c. Prepare a case summary including chronology of events and identify personnel involved; and
- d. Ensure the Internal Inquiry is conducted within <u>30 working days</u> from the date of complaint.

1.2.4 Internal Inquiry Committee Members

- a. The Internal Inquiry Committee comprises of the following members:
 - Chairperson : Hospital Director/District Health Officer/District Dental Officer
 - Secretary : To be appointed by Chairperson
 - Members : i. Head of Department of discipline(s) concerned
 - ii. Others as deemed necessary

*Healthcare personnel directly involved in the clinical management of the case should be excluded from the committee.

1.2.5 Preparation of Documents

The following essential documents shall be obtained:

- a. The evidence of complaint;
- b. Patient's medical records and other relevant documents;
- c. Written reports on events relating to the complaint by persons involved (if available); and
- d. Reports of previous/preliminary inquiry/incident report (if available).
- * Sufficient copies should be made for the committee members.

1.2.6 Preparation of Healthcare Personnel Involved

- a. Healthcare personnel involved in the case should be given sufficient notice of the date and time of the inquiry. They should be briefed by the Secretariat before the inquiry on what is expected during the inquiry.
- b. Role:
 - i. To verify documented facts; and
 - ii. To provide additional information in relation to the case.

c. The secretariat is responsible to ensure the attendance of the healthcare personnel involved. The refusal to attend the inquiry will be considered as an act of insubordination and further action can be taken in accordance with the General Order (*Peraturan-Peraturan Pegawai Awam (Kelakuan dan Tatatertib)* 1993 (*Pindaan*) 2002 Peraturan 38).

1.2.7 Conduct of Inquiry

The committee should be able to address issues raised up by the complainant and consider the management of the patient as a whole. The committee shall ascertain and establish the facts that are related to the complaint by:

- a. Interviewing patient and/or complainant to clarify the complaints;
- b. Interviewing healthcare personnel involved;
- c. Reviewing the medical record of the related patient;
- d. Reviewing reports of previous/preliminary inquiry/incident report;
- e. Referring to documented policies and procedures of the facilities and other relevant guideline and regulations or any evidence based literatures; and
- f. Reviewing the written reports of person involved in the management of the patient (if available).

*Presence of legal counsel/ third party is **NOT** allowed during the process.

1.2.8 Analysis of the Facts and Deriving Conclusions

- a. Analysis of the Facts
 - i. To discuss and respond to each issues raised in the complaint.
 - ii. To obtain a consensus of opinion.
 - iii. If there is any differing opinion regarding the issues, it should be recorded.
- b. Deriving Conclusion

Conclusion must be made based on the facts and findings available or established during the inquiry. Conclusion should include:

- i. Whether the complaint is valid or otherwise; and
- ii. Whether there is any shortfall in management of the patient.
- c. Recommendations

The committee shall make recommendations as below:

- i. To notify relevant authorities to initiate appropriate actions.
- ii. To suggest necessary action against identified personnel.
- iii. To improve healthcare delivery services.

- iv. To prevent recurrences of similar incidents and complaints.
- d. Grievance Mechanism

The Chairman shall inform the complainant regarding the findings and conclusion of inquiry. To clarify if complainant:

- i. Satisfied with explanation.
- ii. If not satisfied, to enquire requests/expectations by the patient and/or complainant.
- e. Preparation of Report
 - i. The secretary of the committee shall draft the report according to facts and findings of the investigation by the committee.
 - ii. The draft of the report should be circulated to all the committee members for corrections and comments.
 - iii. The report signed by all the committee members shall be considered as the final report.
 - iv. Report format Refer to appendix.

1.2.9 Submission and Retention of Report

a. The Director of the healthcare facility shall submit the final report to the State Health Director within **seven** working days from the internal inquiry.

- b. The State Health Director shall submit the final report to Medico Legal Section, Medical Practice Division within **seven** working days.
- c. Copies of the report shall be retained in relevant files at the:
 - i. Healthcare facility involved
 - ii. State Health Department
 - iii. Medico Legal Section, Medical Practice Division

* The report should be made confidential as stipulated in the Official Secret Act 1972.

1.3 INDEPENDENT INQUIRY COMMITTEE

1.3.1 Objectives

- a. To ensure transparency and fairness during the conduct of an investigation;
- b. To ascertain facts and analyze issues pertaining to complaint;
- c. To ensure that certain criteria, standards, guidelines and management protocols are adhered by healthcare personnel;
- d. To identify factors leading to the complaint and recommend appropriate action to be taken;
- e. To identify steps for improvement in order to avoid occurrence of similar incidents and complaints in the future; and

f. The committee shall inform the complainant regarding the findings after the meeting.

1.3.2 Terms of Reference

The inquiry committee will limit its task to:

- a. Fact finding;
- b. Identify healthcare personnel involved;
- c. Identify problems or weaknesses in the case management; and
- d. Identify corrective and preventive measures.

1.3.3 Initiation of Independent Inquiry Committee

The Director of Medical Practice Division will instruct the formation of an Independent Inquiry Committee based on the following criteria:

- a. Patient/complainant not satisfied with the Internal Inquiry Committee findings; and/or
- b. Patient/complainant requested for compensation.

1.3.4 Independent Inquiry Committee Members

The prerogative and duty of forming the Independent Inquiry Committee lies with the State Health Director. He is duty bound to form the committee as instructed by the Director of Medical Practice Division or Director General of Health. The possibility of conflict of interest and undue influence shall also be considered when appointing members.

Committee Member	Role
i. Chairperson	Ensure the inquiry is unbiased and
Senior consultant	transparent.
clinician from the	
same discipline but	Conduct the inquiry as follows:
from a different	i. Define objectives;
state (JUSA C and	ii. Brief the members on the objectives of
above).	the inquiry and the procedures to be followed;
 ii. Clinician from the same or related discipline but from different hospital and not involved in patient's care. 	iii. Brief every witness regarding the purpose of the interview;iv. Gather and analyze facts and findings;v. Derive conclusion and opinion;
iii. A senior nursing or paramedic from different hospital.	3 1
iv. Co-opted members as necessary.	

v. Representative from Medical	To facilitate the committee pertaining in handling the inquiry.
Practice Division. vi. Representative from State Health Director.	To explain regarding the management of the case at the ministry level to the patient and/or next of kin.
	To address the demands of the patient and/or next of kin.
	To monitor and ensure that the duties of the secretariat are carried out.
vii. Hospital Visiting Board or Health Advisory Panel	To ensure that the patients' rights are upheld during investigations by the Independent Inquiry Committee.
	Ensure transparency and fairness during the conduct of the investigation into the complaint.
	Any offer of help by the Community Representative to the complainant with regard to non-technical matters of the complaint must be recorded.
	The presence of the Hospital Visiting Board Member will provide support and confidence to the complainant or next of kin or patient to voice out their problems.

	*To maintain the confidentiality of the information obtained during the Independent Inquiry meeting.
 viii. Secretary The Director of the healthcare facility involved. If more than one facility is involved, the Secretary will be appointed by the Medical Practice Division. 	 i. A copy of the complaint. ii. The patient's medical record including the case note, charts, images, and investigation results. iii. Reports of previous/ preliminary inquiries. iv. These documents should be

Preparation of inquiry session i. To arrange all logistic requirement (venue, equipment, parking and transport).
To ensure the attendance of patient and/or complainant.
To prepare and submit the inquiry report.
*Secretariat are discouraged to interview patient, complainant and witnesses during the inquiry.

1.3.5 Conduct of Inquiry

a. Refer to 1.2.7

*Presence of legal counsel/third party is **NOT** allowed during the process.

1.3.6 Analysis of the Facts and Deriving Conclusions

a. Refer to **1.2.8**.

1.3.7 Submission and retention of Report

a. The secretary shall submit the report to the State Health Director within **14** working days upon completion of the Inquiry.

- b. The State Health Director should review the report before submitting to Medico Legal Section, Medical Practice Division within **seven** working days.
- c. Copies of the report shall be retained in relevant files at:
 - Healthcare facility involved
 - State Health Department
 - Medico Legal Section, Medical Practice Division

* The report should be made confidential as stipulated in the Official Secret Act 1972.

PART 2: EX GRATIA

2.1 INTRODUCTION

The term "ex gratia" originates from a Latin phrase defined as a favor where no legal obligation exists. Ex gratia payment is an initiative by MOH which offers compensation for resolution of certain medico legal complaints.

Medical Practice Division has produced a separate 'Guideline on Ex Gratia for Medico Legal Complaints (1st Edition, October 2018)'. The guideline is to be used as reference for all MOH healthcare administrators and healthcare providers in managing medico legal complaint within MOH healthcare facilities.

2.2 OBJECTIVES

The objectives of ex gratia payment are:

- a. To offer alternative resolution of medico legal claims against MOH healthcare facilities and healthcare providers.
- b. To reduce the number of litigation against MOH healthcare facilities.

2.3 SCOPE AND APPLICATION

The scope and the application of ex gratia payment covers medico legal complaints, namely;

a. If there is claim for compensation;

- b. Occurring in MOH healthcare facilities;
- c. Involving clinical services provided by MOH; and
- d. Cases which have not been filed in court.

Medico legal complaints involving non-MOH staff(s) working in MOH healthcare facilities, are subjected to the terms as stated in the Memorandum of Understanding (MoU) or Memorandum of Agreement (MoA) between MOH and the agencies concerned.

2.4 EX GRATIA MEETING AND COMMITTEE MEMBERS

Medico legal complaints with request for compensation will be presented in the Ex Gratia Meeting. The Committee consists of following members:

- a. Director of Medical Practice Division (Chairperson);
- b. Federal Counsel from Attorney's General Chamber;
- c. Federal Counsel from MOH Legal Advisor Office;
- d. Deputy Director of Medico Legal Section, MOH; and
- e. Officers from Medico Legal Section, MOH.

2.5 EX GRATIA OFFER

a. Meeting with the recipient for ex gratia offer will be organized either by MOH, State Health Department or healthcare facility representatives.

- b. Ex gratia offer shall be conducted at either:
 - i. Healthcare facility involved
 - ii. District Health Office
 - iii. State Health Department
 - iv. Medico Legal Section, MOH
- c. Any forms of recording are prohibited.
- d. Presence of legal counsel is **NOT** allowed during the process.
- e. Documents involved in ex gratia offer include:
 - i. Attendance sheet
 - ii. Ex gratia offer letter
 - iii. Acceptance Form, Refusal Form and Extension of Time Form.
 (*Recipient is expected to submit one of the forms during the meeting*)

2.6 EX GRATIA RECIPIENT ELIGIBILITY

- a. Patient age eighteen (18) and above;
- b. Next of kin for:
 - Minor patient (less than 18 years old) according to Child Act 2001;
 - ii. Mentally disabled patient, according to Mental Health Act 2001;
 - iii. Deceased patient, according to Civil Law Act 1956;

- c. Care-giver for the patient. (Statutory Declaration is required); or
- d. Estate Administrator person appointed by the court to manage and take charge of the assets and liabilities of the deceased in accordance to the law.

2.7 EX GRATIA PROCEDURE:

Refer flow chart.

PART 3: POST PAYMENT INVESTIGATION

3.1 INTRODUCTION

Mechanism of compensation/settlement for medico legal cases are done through ex gratia or court orders.

An inquiry is mandated by the Ministry of Finance Malaysia (MOF) following each payment to investigate and determine any factors contributing to the incident.

3.2 TERMS OF REFERENCE

- a. To identify if the healthcare personnel involved are negligent while conducting his/her duty or contributed by other factors.
- b. To recommend disciplinary action towards the healthcare personnel if necessary.
- c. To identify corrective and preventive measures taken to avoid recurrence of similar incident.

3.3 COMMITTEE MEMBERS

- a. Chairperson : Director of State Health Department/ Health Institute
 - Alternative: DeputyDirector(Management)orDeputyChairpersonDirector (Medical), State Health Department

- b. Committee : i. Deputy Director (Public Health / Oral members
 Health Division / Pharmaceutical Services) from the State Health Department/ Health Institute involved
 - ii. State Clinical Advisor / Head of Department / Consultant in the respective discipline involved
 - iii. Co-opted members as necessary
- c. Secretariat : Appointed from Deputy Director's (Management) Office

3.4 CONDUCT OF INQUIRY

The Inquiry Committee report has to be prepared and submitted to the Medical Practice Division as stipulated in the *Surat Pekeliling Ketua Setiausaha Kementerian Kesihatan Malaysia bil.* 12 (1 November 2017).

PART 4: SURVEILLANCE AND AUDIT

4.1 INTRODUCTION

- a. Surveillance
 - i. Surveillance is a process that involves collating data, continuous data analysis and systematic data interpretation.
 - ii. The datas are collected from medico legal cases in MOH healthcare facilities.
 - iii. The information derived from the data will be used to enhance the quality of services in MOH healthcare facilities.
- b. Surveillance Audit
 - i. Medico legal surveillance audit is performed periodically by a team of an external auditor from Medical Practice Division and conducted at State Health Departments or healthcare facilities.

4.2 OBJECTIVES

- a. To achieve optimum standard quality of services in MOH healthcare facilities by providing adequate training and ensuring adherence to policy and procedure;
- b. To prevent recurrence of similar incidences through recommendations and sharing of best practices; and

c. To create awareness among healthcare practitioners regarding the medico legal issues and its prevalence in MOH healthcare facilities.

4.3 SURVEILLANCE ACTIVITIES

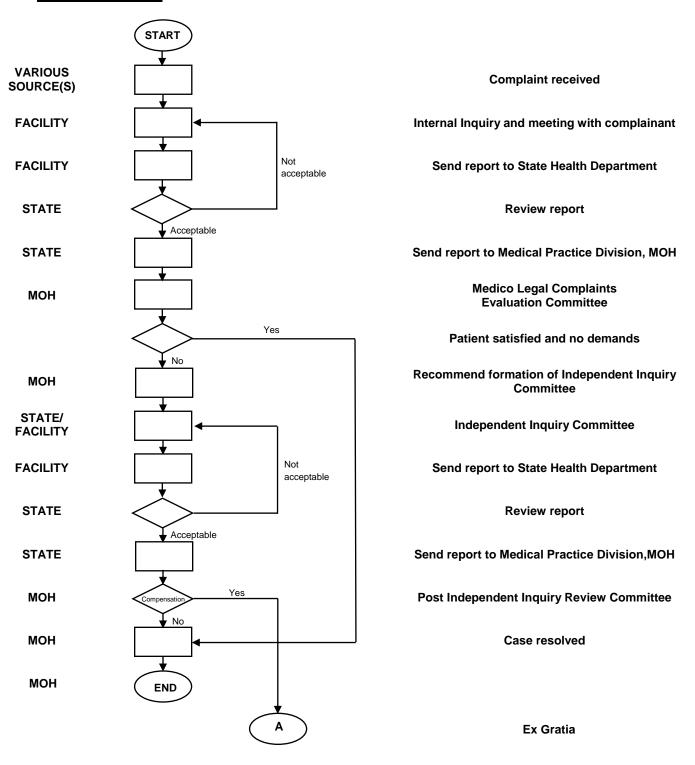
- a. Data collection and analysis of medico legal cases.
- b. Generate reports upon completion of data analysis and systematic data interpretations.
- c. Review and analyze the corrective and preventive measures recommended by the Inquiry Committees.
 - i. Appropriate preventive and corrective measures should be carried out by the stakeholders at state and facility levels in accordance with the recommendations made by the Inquiry Committees.
 - ii. The report should be submitted to Medical Practice Division within **3 months** after the inquiries.

4.4 MEDICO LEGAL CASE AUDIT AND SURVEILLANCE MEETING

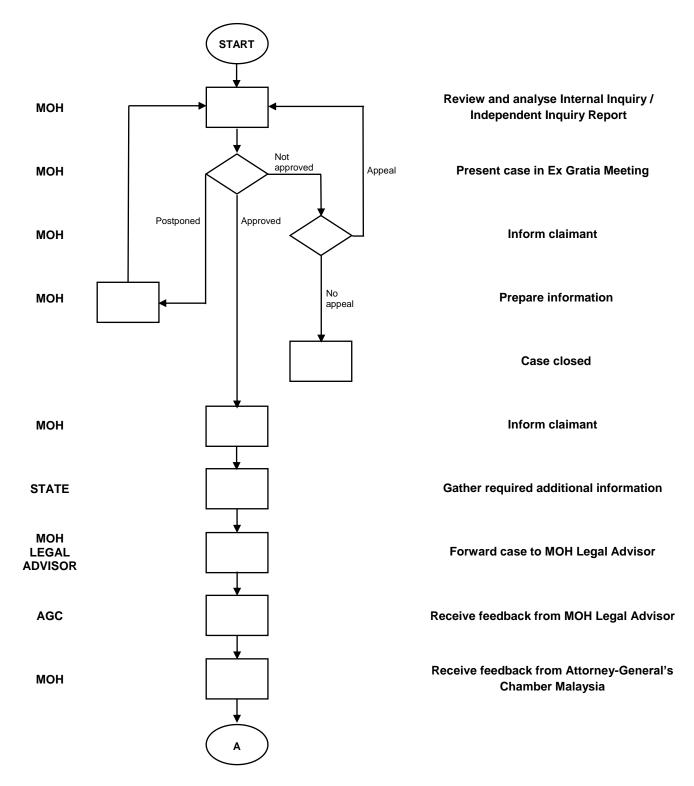
- a. Medico Legal Case Audit and Surveillance Meeting is performed periodically by a team of an external auditor from Medical Practice Division and relevant personnel from the State Health Department.
- b. Objectives:
 - i. To address issues pertaining to medico legal case management; and

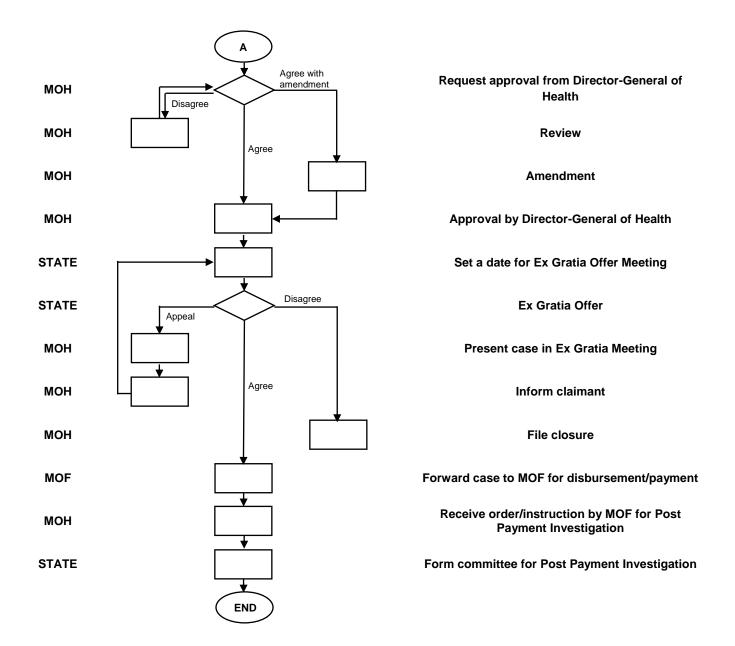
- ii. To discuss proactive, preventive and corrective measures taken by the relevant healthcare facilities and/or State Health Department following the recommendations by the Inquiry Committees.
- c. Committee Members
 - i. Chairperson : Director or Deputy Director (Medical) of State Health Department
 - ii. Committee : i. Officers from Medical Practice Division
 Members ii. Officers from State Health Department
 iii. Director of healthcare facility
 - iii. Secretariat : Appointed from State Health Department
- d. Conduct of the Meeting
 - i. Discussion of medico legal cases.
 - ii. Discussion on relevant preventive and corrective measures taken by healthcare facilities/ State Health Department and sharing of best practices.
 - iii. Discussion on other medico legal issues.
 - iv. Minutes/ report of the meeting will be prepared by the Secretariat and forwarded to Medical Practice Division.

APPENDIX 1: MANAGEMENT OF MEDICO LEGAL COMPLAINTS FLOW CHART

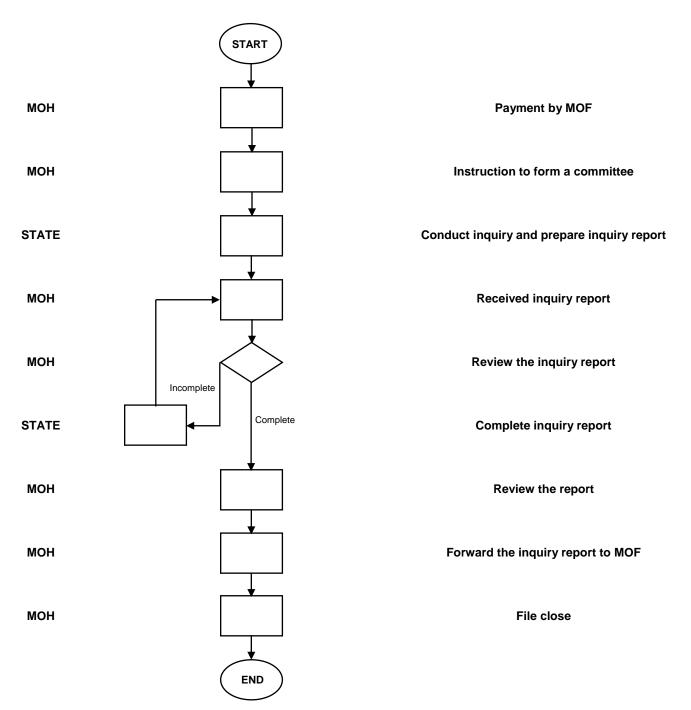


APPENDIX 2: EX GRATIA FLOW CHART

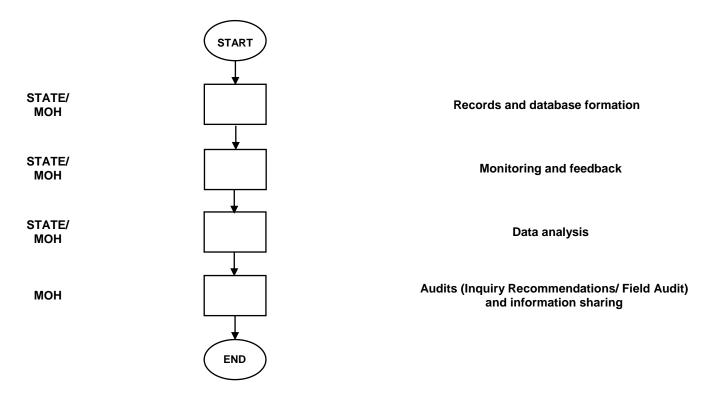




APPENDIX 3: POST PAYMENT INVESTIGATION FLOW CHART

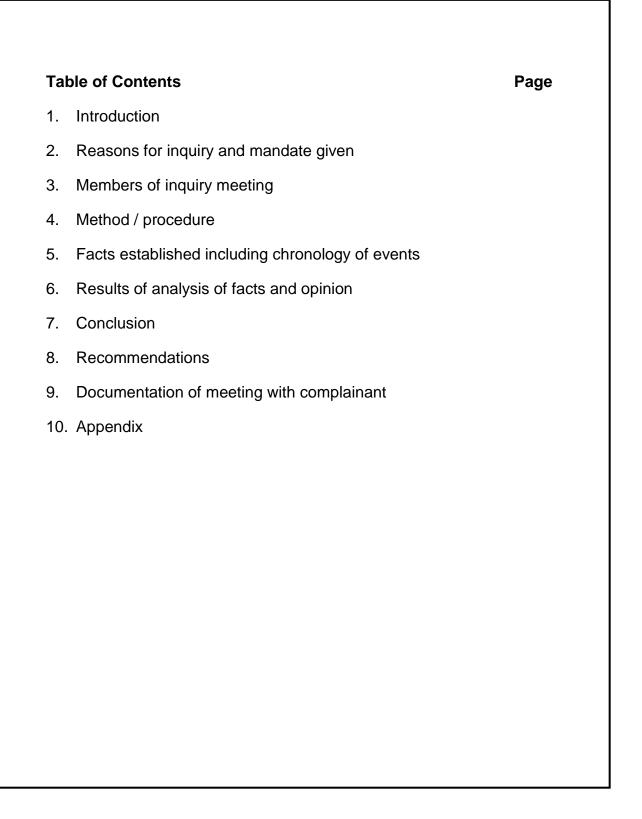


APPENDIX 4: SURVEILLANCE FLOW CHART



APPENDIX 5: INQUIRY REPORT FORMAT

Hospital	:	
Patient's name	:	
Identification no.	:	



1. Introduction

Inquiry date	:
Time	:
Place	:
*Grievance mechanism date	:

Onevance mechanism date
Time
Place
*if done at different date/time

2. Reason for inquiry and mandate given

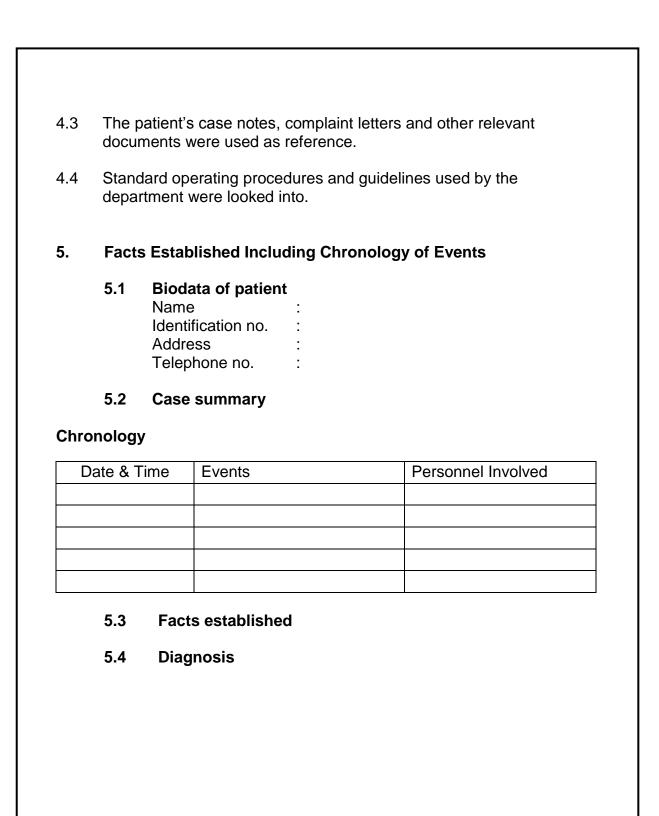
3. Members of inquiry committee

4. Methods / procedures followed

4.1 All the staffs involved in the management of the case were interviewed by the Inquiry Committee.

:

- 4.2 Staffs interviewed:
 - Name IC Number Work Experience Department Education Date of Appointment Years in Service



MEDICO LEGAL SECTION, MEDICAL PRACTICE DIVISION

		Issues	Comments by committee
	6.1	Policy and procedure	e
	6.2	Patient factors	
	6.3	System factors	
	6.4	Care provider factors	S
7.	Conc	lusion	
3.	Reco	ommendations	

MEDICO LEGAL SECTION, MEDICAL PRACTICE DIVISION

9.	Documentation of meeting with complainant
	9.1 Complainant's main concern in the treatment received (information obtained prior to start of inquiry)
	9.2 Complainant is satisfied with the explanation given by the chairperson after the inquiry
	9.3 If complainant is not satisfied, the reason is:
	9.4 Complainant's requests / demands is/are:
10.	Appendix
	 10.1 Complainants Details Name: Identification no.: Contact details: (corresponding mailing address and telephone number) Relationship to patient:
	10.2 SiSPAA information Date of complaint made on SiSPAA (if made directly on SiSPAA)
	10.3 Other appendices

MEDICO LEGAL SECTION, MEDICAL PRACTICE DIVISION

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