



MINISTRY OF HEALTH MALAYSIA

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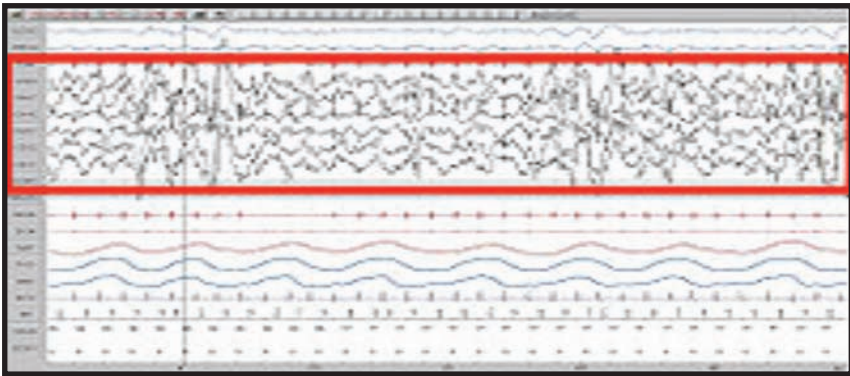
STANDARDS OF SLEEP FACILITY IN MINISTRY OF HEALTH, MALAYSIA



SURGICAL AND EMERGENCY MEDICINE SERVICES UNIT
MEDICAL DEVELOPMENT SECTION
MEDICAL DEVELOPMENT DIVISION
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MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA



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FOREWORD

DEPUTY DIRECTOR OF HEALTH (MEDICAL)

Quality sleep, like nutrition is a daily necessity and healthy sleep restores and nurtures us and hence Sleep Medicine is one of the fast-growing medical specialty which has made tremendous progress around the world in the past 25 years and 10 years in Malaysia.

A generation ago, no one had ever heard of sleep apnoea. Now it has become common among Malaysians and almost everyone would know of a relative or friend who has sleep-related problem. Major problems with sleep in Malaysia stem from social and industrial progress. Lack of physical work and an abundance of food have led to obesity, diabetes, heart disease and sleep-related disorders. People now elect to pursue wake activity during the night. This has led to sleep deprivation in our society with many adverse consequences. To reverse this unhealthy trend there is a need for information and medical expertise relating to sleep disorders to be made readily available to the public.

As observed, Sleep Medicine is a dynamic science and draws momentum from a diversity of disciplines which are otherwise unusual bedfellows. In the Ministry of Health's hospitals, the disciplines practising Sleep Medicine encompass Neurology, Oro-Maxillofacial surgery, Otorhinolaryngology, Pediatrics, Psychiatry, Psychology and Respiratory Medicine. Due recognition must be given to all who have contributed to the success of the service even though in Malaysia it is still in infancy stage as compared to overseas facilities.

The current MOH sleep service is fragmented and under-resourced, given the magnitude of the economic and social costs associated with sleep disorders. The benefits for the community by more adequately addressing the problems of disordered sleep would be significant. MOH must fulfill the two major needs such as the provision of training in sleep medicine and the funding for sleep facility where services should be on-par with the international standards.

On the other hand, there is a clear need to increase awareness of sleep disorders in the general community

and to change the prevalent misconceptions about the hours and quality of sleep that people need. This means education on the importance of adequate good quality sleep and good sleep hygiene as well as treatment available for sleep disorders.

Given the burden of cost on the community imposed by sleep disorders, more funding for sleep research is required. Relative to other medical research published, sleep research in Malaysia is still lacking. Future research should include further studies on the economic and social impact of sleep problems on the Malaysian community and cost/benefit analyses of the treatment of sleep disorders.

For an evolving discipline like Sleep Medicine to progress, institutions such as medical schools, hospitals, professional sleep societies, and industry initiatives are a necessity. Unfortunately we still have to send our specialists overseas to have further training in Sleep Medicine before they are able to conduct courses on sleep medicine locally. The efforts to educate doctors and the public alike are never ending and we look forward

to seeing the implementation of these standards for the

Thank you.

A handwritten signature in black ink, appearing to read 'Hisham', with a long horizontal flourish extending to the right.

Datuk Dr Noor Hisham Abdullah

Deputy Director of Health (Medical)

FOREWORD

CHAIRMAN OF THE DRAFTING COMMITTEE

Sleep is a basic fundamental need of every human being which may not be well understood. In average, a normal adult spends between six to eight hours a day, or about one-third of their lifetime sleeping. Sleep is a transient state of altered consciousness with perceptual disengagement from one's environment. Contrary to popular belief, sleep is an active process involving complex interactions between cortical, brain stem and forebrain structures. Therefore, there is a significant metabolism and oxygen consumption during this state of "rest" and any disruption of oxygenation or interruption of this physiological process may lead to snoring, choking sensations, apnea episodes, or daytime somnolence.

Snoring, the lay term for noisy breathing during sleep, has historically been believed to be just a nocturnal "nuisance" and an obnoxious human habits. It has been reported that one fourth of the world's population snores and in Malaysia, 14.5% of children in Hospital Kuala Terengganu snore.¹ Snoring may be a simple nuisance to the patient or sleep partner when not accompanied

by other symptoms or complaints. However, it may be part of a symptom complex indicating sleep-disordered breathing (SDB).

Sleep-disordered breathing is a spectrum of diseases related to decreased airflow through the upper airway during sleep, due either to complete or partial upper airway obstruction or increased upper airway resistance. Depending on the level of severities, these sleep disorders result in poor sleep quality, fragmented sleep, intermittent nighttime hypoxemia, reduced percentage of slow wave sleep, and increased sympathetic overdrive. The obvious complaints will daytime somnolence, morning headaches, poor concentration, loss of memory, frustration, depression, and even marital discord.

All these patients need treatment in Ministry of Health (MOH) hospitals either medically or surgically and we are obliged to render such treatments to the best of our abilities depending on the availability and capacity of sleep facilities and other related technologies and equipments. Thus, the expertise of our medical professionals is deemed very crucial. The standards developed will be a

guide to ensure the highest quality of care being provided to all patients in need.

Thank you.

Mr Abd Majid Bin Md Nasir

Chairman of the Drafting Committee

■ ■ ■ 1. INTRODUCTION

The broad definition of “Sleep Disorder” is a medical illness or poor sleep behaviour that leads to insufficient amount of sleep or poor quality sleep. The American Academy of Sleep Medicine, reported that sleep disturbances were common in USA, with 46% of the people were having at least mild sleep apnoea, 34% reported frequent snoring, 30% had insomnia symptoms and 25% suffered from excessive daytime sleepiness.² Institute of Medicine in U.S highlighted that 50-70 million Americans were estimated to suffer chronically from sleep disorders that adversely affect their health and mortality.³

In Singapore, sleep related disturbances affect an estimated 20% of adults and children, and are commonly encountered in general practice⁴ while the prevalence of Obstructive Sleep Apnea (OSA) was 2-4% which was highest in Malays.⁵ As for OSA in Malaysia, researchers in University of Malaya in 2007 estimated the prevalence of OSA Syndrome in middle aged men and women to be 9% and 4% respectively while the prevalence of OSA in general population is between 2% and 4%⁶ which are

comparable to the Singaporeans⁴ and Koreans; 4.5% in men and 3.2% in women.⁷

A study was done in Malaysia among the medical students in University Malaysia Sarawak where it was found that daytime sleepiness was 35.5% especially those undergoing clinical postings and 16.1% reported to have bad sleep quality.⁸ In a similar study among nursing students who had only occasional on-call duty, it was found that an overall habitual snoring was 12.3% which is positively correlated with Body Mass Index (BMI) and weight but not significantly correlated with daytime sleepiness and examination results.⁶ In an earlier study, it was noted that there was moderate prevalence of sleep disturbance among nurses working in Melaka Hospital which however was not associated with the work shifts.⁹

Sleep Disorder is a public health issue but poorly recognized by the majority of the population. While there is wide agreement on the significance of the problem, its exact nature, the financial and other costs associated with it and the avenues open to deal with it are made more complex by:

- Differences in the nature of sleep disorders which range from minor to severe;
- Differences in the causes of sleep disorders which can be medical and behavioural; and
- Differences in the outcomes of sleep disorders which vary from medical (e.g. heart disease, accidents) to social problems.

Types of Sleep Disorders include:

- Sleep-Disordered Breathing (SDB)
- Parasomnias and Dyssomnias
- Psychiatric disorders
- Neurological conditions

Behavioural and social causes of sleep disorders are in part driven by modern lifestyles, and include:

- Shift work;
- Increased working hours;
- A broader choice of leisure activities during what were once considered hours of rest (e.g. city night life, Internet, 24 hour television);
- Major life events (e.g. divorce, death of a family member, unemployment);
- Minor psychological disturbances; and
- Poor sleep hygiene.

The sleep facility standards have been developed for the primary purpose of ensuring that the highest quality of care is delivered to patients with a sleep disorder. The remainder of this document will use the term “sleep facility” when referring to sleep disorder centers and/or laboratories for sleep-related breathing disorders for the purpose of clarity and brevity.

In general terms, the standards describe the required structural, professional and human resource, clinical and technical standards, emergency and quality assurance methodologies required by MOH. Sleep facilities achieving these standards should be recognized and accredited in the MOH as a center for sleep medicine.

MOH recognizes that the practice of Sleep Medicine, like all other medical disciplines, is dynamic, complex and requires clinical judgment and these standards are not designed to limit physicians from using their medical judgment, which, in individual patients, may require acceptable deviation from the prescribed standards. However, all sleep facilities will be expected to document instances and reasons for requiring such deviation(s).

Quite a number of MOH facilities or hospitals have already developed their own sleep facility upon realizing the needs of Malaysians. As more Malaysians are aware of the importance of having good sleep, more sleep facilities will be required. Thus the standards of sleep facility in MOH are deemed mandatory for a diagnostic and therapeutic sleep center.

■ ■ ■ 2. OBJECTIVES

2.1 General

2.1.1 To ensure high quality care is given to all patients with sleep disorders (refer to Appendix 1 for the Patient Flow)

2.1.2 To standardize the sleep facility practices in MOH to be on par with the international standards

2.2 Specific

2.2.1 To determine the epidemiology of sleep disorders among Malaysians

2.2.2 To highlight the disease burden of sleep disorder and its cost to MOH for it to be recognized as a public health issue and therefore a part of the national agenda

■ ■ ■ 3. **GENERAL MOH REQUIREMENT OF SLEEP FACILITY**

- 3.1 All sleep facilities in MOH must comply and adopt these standards.
- 3.2 The sleep facility has to be managed by a multidisciplinary team, headed by a clinician trained in sleep medicine.
- 3.3 Any new sleep facility application must go through the Medical Development Division for approval
- 3.4 The Hospital Director has to set aside budget for the operation of such a sleep facility from the hospital management activity budget and not from the individual department

- 3.5 Workload data including the service performance must be sent to the Director of the Medical Development Division on a 6 monthly basis for monitoring and planning purposes (refer Monitoring Format in Appendix 2)
- 3.6 A sleep facility committee chaired by the Hospital Director has to be set up at the hospital level and meet regularly. The committee discusses operational issues such as staffing and training, other resource needs, future planning, performance and complaints.
- 3.7 Patients' satisfaction survey has to be conducted at least twice a year, analyzed and reported to the Hospital Director.
- 3.8 Any potential medico-legal cases must be notified immediately to the Hospital Director.

3.9 All cases must be referred to the sleep facility and appointments shall be given. The waiting time must be reasonable and shall not exceed 8 weeks.

3.10 All cases must be properly documented.

■ ■ ■ 4. PERSONNEL REQUIREMENTS

All staff must have a valid practicing certificate and are required to follow the Code of Ethics of the Malaysian Medical Council (MMC).

4.1 Clinician In-charge

Each sleep facility must designate a Clinician In-charge as a coordinator who is a physician with a valid Annual Practicing Certificate (APC)

Responsibilities of the Clinician In-charge

- a. Is appointed by the sleep facility committee and is responsible for the direct overseeing of testing
- b. Is responsible for the validation and training of all medical and technical personnel
- c. Provides clinical governance and responsible for the overall management of the sleep facility including the future planning for expansion.
- d. Works with other health professionals for patient education programs and research

Given the size and nature of current gaps in the sleep medicine locally and the magnitude of the changes required, the Clinician In-charge must work with Medical Development Division to:

- Provide effective advocacy on sleep health issues with other government agencies, employing agencies, road safety authorities and other organizations;
- Raise public awareness about sleep health issues and treatments available;
- Organize targeted education and service delivery programs.

Clinician In-charge Continuing Medical Education (CME)

The Clinician In-charge must participate in at least 7 days of CME per year in Sleep Medicine. Compliance with CME requirements must be documented.

4.2 Sleep Specialist

Responsibilities of a Sleep Specialist

The designated sleep specialist:

- a. Must supervise directly the testing protocols and the quality of testing

- including the proper operations and calibrations of the equipment,
- b. Must review, report and modify as necessary the facility's quality assurance program on a 6 monthly basis,

Sleep Specialist Continuing Medical Education
The sleep specialist must participate in at least 7 days of CME per year in sleep medicine. Compliance with CME requirements must be documented.

4.3 Para-medical Personnel

Para-medical Personnel Requirements

BLS certification is required for all technical staff, regardless of their duties.

4.3.1 Sleep Technicians

Sleep facilities must maintain appropriately trained, supervised, sleep technicians. Staffing must be adequate to address the workload and the safety of the patients.

This includes a maximum patient to technician's ratio of 2:1 under usual

circumstances for attended polysomnography.

4.3.2 Certified Sleep Technicians.

Each sleep facility should have a minimum of one sleep technician who is certified.

Sleep Technician Continuing Medical Education

The sleep facility's technical staff must each participate in sleep-related CME activities.

■ ■ ■ 5. PATIENT POLICY

5.1 Patient Acceptance

The sleep facility's Policy and Procedures Manual must include written patient acceptance policies which comprise of:

- a. Age limitations
- b. A mechanism for admissions and referral
- c. Criteria for exclusion
- d. Information required from a physician prior to any sleep testing in the sleep facility.

Patients must be informed that they are being screened for their own safety.

5.2 Practice Parameters

The clinical evaluation of patients accepted for sleep testing to be conducted in the sleep facility must be standardized in clinical protocols such as 'Practice Parameters

with the Indications for Polysomnography
and Related Procedures’.

5.3 Patient flow as in Appendix 1

■ ■ ■ 6. FACILITY REQUIREMENTS

6.1 Building requirement

All sleep facilities must be of easy access and convenience.

6.2 Phone line

The hospital must have a separate phone line(s)/direct line into the sleep facility; at least a Line B in addition to internal phone and intercom system.

6.3 Signage

There must be appropriate signage identifying the “sleep facility” and it should be disabled-friendly.

6.4 Use of Space

A single sleep facility is generally defined by the physical space used primarily for conducting sleep study. All of the elements required to conduct sleep study must be available within the defined testing space. The administrative office(s) and / or

specialist office(s) of the sleep facility may be separate from the laboratory testing site.

In circumstances of mixed use, testing rooms being used for other medical testing or examination during non-sleep testing (daytime) hours, the testing room(s) must meet all of the space and equipment standards of a single use sleep testing.

6.5 Testing Bedrooms-physical characteristics

All testing bedrooms must be for single occupancy, private and comfortable, sound-treated, a privacy door that opens directly to a corridor or common use area such as that the patient can access the testing bedroom without having to pass through another testing bedroom.

6.6 Testing Bedrooms and Emergency Care

Patient testing bedrooms must not have any obstructions to the delivery of emergency care. The patient testing rooms:

- a. Must be of sufficient size to accommodate emergency personnel

access with a minimum of 24 inches of clear space available on 3 sides of the bed,

- b. Must include a testing bed with a mattress not smaller than a standard Intensive Care Unit (ICU) bed.

6.7 Bathroom Facilities

The sleep facility must have clean bathroom with a minimum ratio of one bathroom for every three testing rooms; these bathrooms must each contain a toilet and a sink. Each bathroom will have a working privacy door. Sole access to a shared bathroom shall not be through a testing bedroom.

6.8 Testing Bedroom and Bathroom for the Disabled

At least one testing bedroom and bathroom must be disabled-friendly.

6.9 Control Room

The size of the control room must not be less than 1,200 sq cm in total or 600 sq cm per testing bedroom, whichever is larger.

■ ■ ■ 7. EQUIPMENT REQUIREMENTS

7.1 Communication

The facility must maintain a two-way communication system between the patient bedroom and the control room and /or sleep facility personnel.

7.2 Video Recording

Each testing bedroom in the facility must have a mechanism for visual monitoring and video recording of patients during testing. The recordings must be kept in safe and secure space for at least 7 years.

7.3 Polygraph Equipment

The facility must maintain polygraph equipment capable of recording and storing physiologic parameters using sensor recommended or alternative derivations in digital format or manual form which can be easily reproduced.

7.4 Positive Airway Pressure (PAP) Therapy

The facility must maintain equipment for the delivery of positive airway pressure therapy for sleep apnea, including remote control of the device (pressure output, device mode).

■ ■ ■ 8. POLICIES AND PROCEDURES

The sleep facility must maintain written protocols, in paper or electronic form, for all testing procedures conducted in the facility.

8.1 Policy and Procedures Manual

Sleep facilities must maintain a Policy and Procedure Manual that is easily accessible, in paper form or electronically, at the control room. The manual must contain all policies, procedures, protocols specific to the sleep facility, and all current guidelines or practices endorsed by MOH

8.2 Protocols: PSG, MSLT, MWT, and PAP Titration

The sleep facility must maintain written, paper or electronic format, protocols for comprehensive polysomnography (PSG), multiple sleep latency test (MSLT), maintenance of wakefulness test (MWT) and titration of positive pressure therapy (PAP).

8.3 Other Protocols

Sleep facilities that test patients under the age of 18 years must maintain population specific protocols in the Policy and Procedures Manual for comprehensive polysomnography, titration of positive therapy and capnography.

8.4 Equipment Maintenance

A written planned preventive maintenance (PPM) for monitoring of all patient-related equipment for electrical and mechanical safety is required. The written PPM plan must include specific instructions regarding documentation of compliance.

■ ■ ■ 9. DATA AND PATIENT MANAGEMENT

9.1 Data Acquisition, Scoring and Reporting

The signals collected and the equipment used for comprehensive polysomnography must be in compliance with the International Standards.

9.2 Conducting MSLT and MWT

The multiple sleep latency test and maintenance of wakefulness test must be conducted using international protocols

9.3 PSG Scoring

Each epoch of every polysomnogram must be scored manually.

9.4 PSG Reports

Reports of polysomnography must be done by trained clinicians.

9.5 Patient Evaluation and Care

9.5.1 Patient Management

Patient management must include appropriate follow-up

9.5.2 Documenting Patient Evaluation/ Management

The sleep facility medical personnel must document ongoing evaluation and management of patients with sleep disorders.

■ ■ ■ 10. PATIENT RECORDS

10.1 Bed Head Ticket (BHT)

Sleep facilities must maintain appropriate BHT/medical record for each patient evaluated by the sleep facility medical personnel and for directly referred patients. Medical records of patients seen by sleep facility medical personnel must have the documentation of all patient interactions in the sleep facility, including initial evaluation, testing (if any), diagnosis, treatment and follow-up.

Prior to testing, all patients' records must include: history and physical examination or patient questionnaires, or other screening assessment. Written indication that either a physician or designated sleep specialist has reviewed and approved the proposed evaluation must be noted in the records.

10.2 Positive Airway Pressure (PAP) Assessment

Patients prescribed with positive airway

pressure treatment by the sleep specialist must be followed-up and managed according to the response.

10.3 Database

The sleep facility must maintain a cumulative database.

■ ■ ■ 11. EMERGENCY PROCEDURES

11.1 Emergency Plan

Sleep facilities must have a written emergency plan accessible in paper or electronic format that delineates the following:

- a. Mechanisms and specific details for contacting emergency personnel
- b. The sleep facility personnel to be contacted in an emergency
- c. Personnel and procedures for responding to after office hours' questions and technical problems encountered by patients undergoing monitoring are to follow existing standard procedures
- d. Outline the specific responsibilities of the technical staff

11.2 Emergency Equipment/drugs

The sleep facility must have access to appropriate emergency equipment and drugs to address all possible emergencies.

■ ■ ■ 12. QUALITY ASSURANCE

12.1 QA Program

Sleep facilities must have a quality assurance program:

12.1.1 Waiting Time for PSG (Standard: 80% within 2 month)

12.1.2 Waiting Time for PSG reports (Standard: 80% in 2 weeks)

12.2 Reporting QA Program

All quality assurance metrics must be reported and reviewed by the sleep facility's Clinician In-charge or the designated sleep specialist, at a minimum frequency of once in every 6 months. The reviewer of the report must sign and date the report; a copy of the signed report must be kept in file for a minimum of seven year. Annual Report must be produced yearly and submitted to the Director of Medical Development Division including the statistics of cases handled.

■ ■ ■ 13. MISCELLANEOUS

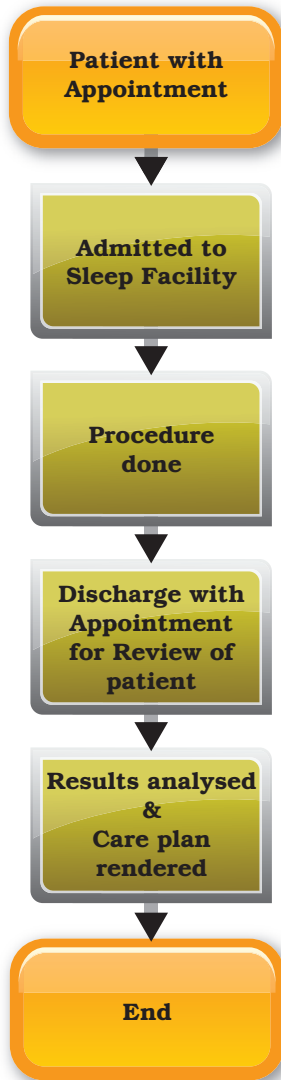
13.1 Charges: The patient is registered and admitted as In-patient and the charges must follow the Fee Act 1951 & 1982.

13.2 Meals shall be provided according to the eligibility of the patients

13.3 Sleep facility must be secured as according to the local hospital policy.

APPENDIX 1

PATIENT FLOW



APPENDIX 2

Monitoring Format of Sleep Facility, MOH

Hospital:			
Parameters	Paediatric (≤ 18 years old)	Adults	Achievement
No of attendances			
No of PSG procedures done			
No of 'no shows' at the sleep facility			
No of PAPs used			
No of complaints received			
Waiting Time for PSG (Standards:80% within 2 month)			
Waiting Time for PSG reports (Standards: 80% in 2 weeks)			

N.B. Any death in sleep facility has to be reported as Sentinel Event
Annually reporting is required

Reported by:

Name:

Designation:

(Please fax to Medical Development Division at 03-88831155)

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