



The Mycetoma Research Center, University of Khartoum WHO Collaborating Center on Mycetoma & Skin NTDs

Good Clinical Practice Guide

Table of content

- 1 This Guide
- The Outpatient Department
- 3 Good Clinical Practice
- 6 Patients Satisfaction
- 9 The Patient Journey
- Patient Assessment and Management Process
- 13 SOPs

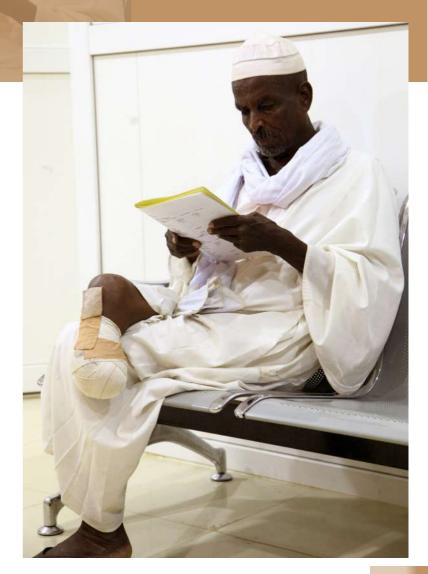
This Guide

This guide is crafted to establish and uphold exemplary clinical practices at the Outpatient Department of the Mycetoma Research Center. Its goal is to refine patient care, streamline procedures, and boost team efficiency. The objective is to improve the efficiency and quality of outpatient services, aligning them with international standards and guidelines.

Comprising a comprehensive overview, this guide delineates best practices for the outpatient department. It encompasses critical aspects such as capacity optimisation, patient-centric services, appointment scheduling, records management, and staff collaboration.

A patient-centric approach is essential in delivering top-notch outpatient services. Recognising each patient as an individual with unique values, concerns, and preferences is fundamental to the department success.

Regular reviews and updates of this guide are recommended to ensure sustained adherence to best practices and a continual enhancement in patient care.



The Outpatient Department



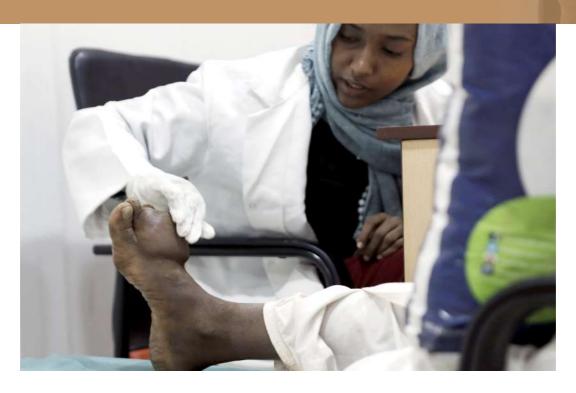


The significance of the Outpatient Department at the Mycetoma Research Center lies in its role as the primary platform for patients to interact with healthcare professionals, discuss their medical conditions and explore treatment options. Emphasising a patient-centric approach is vital for delivering high-quality outpatient services, recognising each patient as a distinct individual with unique values.

The department engages in various activities, including patient clinical examinations, investigations, treatments, wound care, and minor surgical procedures. Moreover, health education sessions are conducted, offering pharmacy care advice, assessing patients socio-economic status, and providing necessary support.

To ensure the department success amid healthcare challenges, continuous improvement and a focus on individual patient experiences are imperative. Ongoing efforts to enhance services and consider each patient unique needs are critical in maintaining the department effectiveness within the broader healthcare landscape.

Good Clinical Practice



Delivering high-quality medical care and services requires the effective management of all aspects of service delivery, including addressing the educational, training, and professional development needs of the diverse members of the multidisciplinary medical team. In the realm of outpatient clinics, providing high-quality medical care necessitates adopting a holistic, patient-centered approach across all facets of service delivery.

To maximise the capacity of outpatient services, it is crucial to map the entire patient journey, measure patient flow at each stage, and analyse these data to pinpoint areas where quality improvement initiatives can significantly impact patient care. Varied speeds and capacities along the patient journey can result in delays and queues, impacting the overall care pathway. Identifying these holdups enables the effective implementation of improvement programmes, ultimately elevating patient care.

Minimising delays and improving the patient experience involves reducing the number of steps in a patient journey. Adopting appropriate care models and principles of good clinical practice to discern when appointments are unnecessary benefits both patients and reduces the overall cost of care. Offering a high-quality, convenient service that minimally disrupts patients lives is crucial. Improved processes, reduced waiting times, staff training and engagement, and a focus on enhancing the patient experience are essential in alleviating this burden and utilising resources more effectively. Fundamental tenets of medical practice involve treating patients as unique individuals and showing them respect. By understanding and addressing patient needs, the outpatient department can deliver a more attended and improved service for its patients.

Professionalism

Medical professionalism is a cornerstone of healthcare, embodying a commitment to the principles of ethics, integrity, and excellence in practice. It involves adherence to a set of standards and behaviours that prioritise patient welfare, confidentiality, and informed consent. This professionalism requires continuous learning, self-regulation, and accountability, ensuring that medical practitioners remain competent and up-to-date with the latest advancements in their field. Additionally, it fosters a culture of respect, empathy, and communication, essential for building trust and effective relationships between healthcare providers and patients. Ultimately, medical professionalism is vital for maintaining the public's trust in the healthcare system and delivering high-quality, patient-centered care.

Medical ethics

It is the moral principles and guidelines governing the practice of medicine. It encompasses a wide range of issues, from patient confidentiality and informed consent to end-of-life care and the fair allocation of scarce resources. Central to medical ethics are the principles of autonomy, beneficence, non-maleficence, and justice, which guide healthcare professionals in making decisions that respect patients> rights, promote well-being,

avoid harm, and ensure equitable treatment. These ethical frameworks ensure that patient care remains compassionate, respectful, and just, balancing the complexities of modern medical practice with foundational moral values.

Effective Teamwork

In line with the principles of Good Medical Practice, it falls upon the staff to cultivate a positive working environment and foster effective medical teamwork that enhances team performance, resulting in favourable outcomes for patient safety. In the often stressful and potentially chaotic outpatient department setting, the importance of good teamwork and leadership cannot be overstated to ensure excellent patient care.

Communication Excellence

Highly efficient teams demonstrate timely, clear, open, and respectful communication. The significance of communication extends to interactions within individual team members and among different teams. Team members should feel empowered to express their thoughts, offer perspectives, and have confidence that their contributions will be recognised and valued. Successful communication hinges not only on

accurately and clearly conveying content but also on the style and proficiency of communication.

Secure Interpersonal Atmosphere

Team members are more likely to demonstrate commitment and engagement when they feel secure on an interpersonal level. Establishing mutual trust and respect is critical in creating a safe interpersonal environment. In such a setting, team members feel at liberty to articulate their opinions, challenge one another, and voice concerns without the apprehension of ridicule, attack, or recrimination. The environment also encourages open discussion about errors and mistakes. The primary focus is on team results, which are devoid of personal agendas, and the overall atmosphere is non-threatening.

Group Patients Sessions

These sessions have effectively educated patients on their medical conditions, the progression of their diseases, and the potential outcomes of their treatments. They empower patients to make informed decisions, a prerequisite for valid consent. Additionally, such sessions can enhance patient confidence and contribute to an overall improved healthcare experience.



1.Streamline Appointment Scheduling and Reduce Waiting Times

Implement an Efficient Appointment System

Use an online appointment booking system to reduce waiting times and allow patients to schedule or reschedule appointments easily.

Send automated reminders via SMS or email to reduce no-show rates.



Optimise Clinic Workflow

Conduct time-motion studies to identify bottlenecks and optimise staff allocation.

Introduce a triage system to prioritise patients based on the severity of their condition.

2.Enhance Communication and Patient Education

Improve Communication Skills

Provide regular training for staff on effective communication, cultural sensitivity, and empathy.

Ensure all staff members, from receptionists to doctors, understand the importance of patient-centered care.

Offer Comprehensive Patient Education

Develop easy-to-understand educational materials about mycetoma, treatment options, and preventive measures. Conduct regular workshops or informational sessions for patients and their families.

3.Improve Physical Environment and Comfort

Upgrade Facilities

Ensure the waiting area is clean, comfortable, and equipped with adequate seating, water dispensers, and informative reading materials.

Maintain a comfortable temperature and provide free Wi-Fi for patients.

Enhance Accessibility

Ensure the facility is accessible to patients with disabilities, including ramps, elevators, and accessible restrooms.

Provide clear signage in multiple languages to guide patients throughout the facility.

4. Ensure Quality and Continuity of Care

Continuity of Care

Assign a primary care provider for each patient to ensure continuity and build a trusting relationship.

Maintain comprehensive and up-to-date medical records accessible to all relevant healthcare providers.

Quality Assurance

Regularly review and update clinical protocols to ensure adherence to best practices.

Implement a system for monitoring and addressing patient feedback and complaints.

5.Foster a Patient-Centered Culture

Engage Patients and Families

Involve patients and their families in care planning and decision-making processes.

Create a patient Advisory Council to provide ongoing feedback and suggestions for improvement.

Recognise and Reward Staff

Establish a recognition programme to reward staff members who demonstrate exceptional patient care and service.

Encourage a team-based approach to care, fostering collaboration and mutual support among staff.

6.Utilise Technology and Innovation

Implement Electronic Patient Records (EPR)

Transition to EPRs to improve accuracy, efficiency, and accessibility of patient information.

Use EPR data to identify trends, improve care processes, and monitor patient outcomes.



Telemedicine Services

Develop telemedicine services to provide remote consultations, follow-ups, and patient education. Ensure secure and user-friendly platforms for telemedicine to enhance accessibility for patients in remote areas.

7. Monitor and Evaluate Performance

Patient Satisfaction Surveys

Conduct regular patient satisfaction surveys to gather feedback on various aspects of care and service.

Analyse survey results to identify areas of improvement and implement necessary changes.

Key Performance Indicators (KPIs)

Establish KPIs for patient satisfaction, wait times, treatment outcomes, and other relevant metrics.

Regularly review performance against KPIs and take corrective actions as needed.

The Patient Journey



To deliver high-quality medical care and services and optimise output capacity, it is essential to have a thorough understanding the complete patient journey. Each patient journey involves a care process with numerous interconnected steps or actions. Mapping out each step in a care process is vital for identifying areas that need improvement. Commencing with a comprehensive processmapping exercise is crucial for understanding how patients navigate the care system. The involvement of multiple sources is necessary for this exercise to ensure the inclusion of all steps in the process.

Walking the patient pathway

To comprehend the stages of the patient pathway, a valuable exercise involves department newcomers with ample clinical expertise. It is crucial to meticulously follow each step of the path, documenting them on a proforma and noting any evident issues that may impact the respective step. Following the completion of this exercise, the pertinent metrics for each step in the process can be assessed and analysed to pinpoint the origins of the identified issues.

The Team

A well-trained and competent team with medical, health, social and management backgrounds manages the department to deliver state-of-the-art medical and healthcare services and social support. The team comprises a lead consultant, general surgeons, radiologists, pathologists, clinical pharmacists, rotating medical trainees, laboratory and ultrasound technicians, medical photographers, nurses, social workers, administration and logistic staff, information/booking staff, and designated information analysts.



Patient Assessment and Management Process

The One-stop Clinic Approach

The department employs the One-stop clinic style, which integrates multiple services delivered simultaneously or sequentially to offer patients all aspects of their outpatient care during a single visit. This approach aids patients in receiving care with minimal disruption to their work or other commitments while reducing the stress and cost associated with multiple hospital visits and mitigating the risks of hospital-acquired infections.

During a single outpatient visit, the following activities are carried out:

- Initial medical assessment
- Requesting and performing various diagnostic tests
- Designing the treatment plan
- Conducting health education
- Offering socio-economic support
- Booking the next visit

By following this structured approach, the Outpatient Department, of Mycetoma Research Center, ensures a thorough and patient-centered process, enhancing the overall quality of care and patient satisfaction.

Initial Assessment and Documentation

Upon arrival, the patient is first seen by the clinic nurse, who takes the vital signs. A detailed history is then taken, encompassing the patient's demographic characteristics, disease history, predisposing factors, concurrent diseases, and family and trauma histories.

Following this, a comprehensive physical examination is conducted, including both general and local examinations. All this information should be meticulously recorded in the patient file. Photographs of the affected site in various views should be taken by medical photographers.

Diagnostic Testing

During the initial visit, general investigations are requested, including a full blood count and assessments of renal and hepatic functions. Imaging examinations such as x-rays and ultrasounds of the affected areas are requested. A cytologist then performs a fine needle aspiration for cytology, with or without ultrasound guidance. Swabs are taken from the open sinuses for secondary bacterial infection identification and treatment. All diagnostic tests should be requested by using standard request forms. At this stage, a diagnosis may be established based on the collected data.

Sample Collection and Further Testing

A tru-cut needle biopsy is performed under local anaesthesia for histopathological examination, grains culture and molecular diagnosis. The results of all tests should be thoroughly documented in both the patient's physical file and electronically.

Treatment Planning and Patient Education

Once the diagnostic results are available, the treatment plan is discussed with the patient and the family if necessary. The patient is then referred to the pharmacy department to receive their medication. A clinical pharmacist provides detailed advice on the medication, including potential side effects, dietary considerations, drug-drug interaction and the importance of medication compliance. For women of childbearing age, specific advice on contraceptives is given, and they are instructed to stop treatment and report to the clinic immediately if they become pregnant. Patients should

receive guidance on wound care and dressing. Booking the patients for surgery should be done in collaboration with the surgical team.

Advanced Disease Management

For patients with advanced disease, an MRI is requested to determine the extent of disease spread along tissue planes.

Health Education

Throughout the patient's journey in the department, social workers conduct health education sessions to enhance patient understanding and compliance with treatment protocols.

Follow-up

The patient is scheduled for routine outpatient follow-up visits to ensure continuous clinical and medication monitoring and ongoing care. The standard interval for these visits is six weeks, but this can be adjusted based on each patient's condition.





Number: 001/CLIN/MRC/2024

On June 7, 2024.

Standard Operating Procedure (SOP) for Doctors at the Mycetoma Clinic

Background

Mycetoma predominantly affects impoverished individuals in remote communities with low socio-economic status and limited health education. Living in isolated areas, they encounter numerous obstacles in accessing the mycetoma clinic. Many resort to traditional medicine due to its local availability and affordability. Additionally, diagnosing mycetoma is challenging, invasive, and costly. The treatment is lengthy, has numerous side effects, is often inaccessible and unaffordable, and does not always yield satisfactory results. This prolonged treatment process necessitates special care and consideration to support patients and their families through this difficult, expensive, and arduous journey.

Objective

To ensure a consistent, comprehensive, and high-quality standard of care for patients diagnosed with mycetoma, encompassing clinical examination, laboratory and imaging investigations, medical prescriptions, socio-economic support and follow-up care.

Scope

This SOP applies to all staff working at the Mycetoma Clinic.

Responsibilities

Doctors: Dealing with patients and families. **Surgeons:** Perform the biopsies and surgery.

Cytotechnologist/Pathologist: Interpreting the aspirated samples and histopathological biopsies examinations.

Nurses/Assistant: Preparing the patient and assists the physician during the procedure.

Infection Control Officer: Ensures adherence to infection control protocols.

Supporting staff: Supporting the patients treatment journey

Procedure

1. Patient Clinical Examination

Initial Assessment

- Greet the patient and introduce yourself.
- Confirm the patient's identity using at least two identifiers (e.g., name, file number, date of birth).
- Take a comprehensive medical history, including:
- Patient demographic characteristics include age, gender, occupation, residence to the village level.
- Disease onset, duration, and progression of symptoms.
- Previous treatments and outcomes.
- Relevant personal, family, trauma, geographic travel history.
- Perform a thorough physical examination, focusing on:
- Inspection of the affected area(s) for swelling, sinuses, discharge, and grains.
- Palpation to assess tenderness, consistency, and extent of the lesion.
- Check for regional lymphadenopathy and other systemic signs.

Documentation

- Record all findings in the patient's medical record promptly and accurately.
- Include detailed descriptions, measurements, and photographs of the lesions.

Requesting Laboratory Examinations

Laboratory Tests

Request necessary laboratory tests, including but not limited to:

- Microbiological cultures.
- Biopsies histopathological examination.
- PCR tests.
- Haematological and chemical pathological
- Complete the laboratory request forms with detailed clinical notes to guide the laboratory staff.

Sample Collection

- Obtain relevant samples (e.g., grains, pus, tissue biopsy, swabs) using sterile techniques.
- Ensure proper labeling with patient identifiers and date/time of collection in collaboration with laboratory staff.

Requesting Imaging Tests

Imaging Modalities

Based on clinical assessment, request appropriate imaging studies, such as:

- X-ray.
- Ultrasound.
- MRI or CT scan for deeper tissue involvement assessment.

Coordination

- Ensure proper coordination with the surgery, imaging, pathology, and cytology departments for timely scheduling.

Medical Prescription

Pharmacological Treatment:

- Prescribe antifungal or antibacterial agents based on the confirmed causative organism.
- Follow current clinical guidelines and protocols for dosage and duration.
- Consider patient-specific factors such as age, weight, renal function, pregnancy, and potential drug interactions.

Supportive Care

- Prescribe analgesics, anti-inflammatory agents, or other supportive medications as needed.
- Provide detailed instructions on wound care and hygiene.

Patients Follow-Up

Scheduling

- Schedule follow-up appointments to monitor treatment response and manage any side effects.
- The frequency of follow-up visits should be based on the severity of the condition and treatment plan.

Monitoring and Documentation

- During follow-up visits, reassess the patient's clinical status and update medical records.
- Review laboratory and imaging results
- Adjust the treatment plan as necessary.
- Document all changes in therapy, patient responses, and any adverse events.

Patient Education

- Educate the patient and caregivers on the disease nature, treatment plan, and the importance of adherence.
- Provide written and verbal instructions for medication use and wound care.

Multidisciplinary Collaboration

Consultations

- Refer patients to other specialists (e.g., surgeons, physicians, infectious disease experts) as needed.
- Ensure clear communication and documentation of the consultation findings and recommendations.

Team Meetings

- Participate in regular multidisciplinary team meetings to discuss complex cases and treatment outcomes.
- Share insights and collaborate on optimising patient care strategies.

Record Keeping and Confidentiality

Medical Records

- Maintain accurate and up-to-date patient records, including all clinical notes, test results, and correspondence.
- Ensure records are stored securely, and confidentiality is maintained at all times.

Data Privacy

- Adhere to legal and ethical standards regarding patient privacy and data protection.

Walk the Patient Journey

- All newcomers should go through the various stages and aspects of the patient journey within the department. They should acquaint themselves with its units, staff, and activities before beginning patient management.

Review and Updates

- This SOP should be reviewed annually or as needed to incorporate new clinical guidelines and best practices.
- Feedback from clinic staff and patients should be considered for continuous improvement of the SOP.

Quality Control and Safety

- Ensure all equipment and instruments are sterilised and in good working condition.
- Adhere to strict aseptic techniques to prevent infection.
- Use the appropriate investigation request forms
- Regularly review and update this SOP to incorporate new evidence and best practices.

References

- Mycetoma Policies and Management Guidelines www.mycetoma.edu.sd
- The Mycetoma Nursing Guidelines www.mycetoma.edu.sd
- Mycetoma Good Clinical Pharmacy Practice Guidelines 2024- www.mycetoma.edu.sd
- The Mycetoma Laboratory Safety Policies 2024 www.mycetoma.edu.sd
- Alhaj AAM, Ahmed ES, Hassan A, Fahal AH. Epidemiological observations and management challenges in extrapedal mycetoma: A three-decade review of 420 cases. PLoS Negl Trop Dis. 2024 May 10;18(5):e0011841. doi: 10.1371/journal.pntd.0011841. PMID: 38728359; PMCID: PMC11111073.
- Fahal AH. Mycetoma: a thorn in the flesh. Trans R Soc Trop Med Hyg. 2004; 98(1):3–11. doi: 10.1016/s0035-9-00009(03)9203 DOI PubMed
- Fahal A, Mahgoub ES, El Hassan AM, Abdel-Rahman ME. Mycetoma in the Sudan: an update from the Mycetoma Research Centre, University of Khartoum, Sudan. PLoS Negl Trop Dis. 2015. Mar 27; 9(3). doi: 10.1371/journal. pntd.0003679 DOI PMC PubMed

ins Standard Operating Proc	edure has been prepared, reviewed and	арргочест Бу.
Or Mumark Mohamed	Consultant Surgeon	Mumark
Or Bouthine Mamoun	Senior Consultant Surgeon	Bouthine
Prof Ahmed Fahal	Center Director	Fahal



The Mycetoma Research Center, University of Khartoum WHO Collaborating Center on Mycetoma & Skin NTDs

