Clinical Movement Analysis Society – UK and Ireland

Clinical Gait Analysis Standards
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Contents

Introduction

CMAS aims to promote quality in the provision of movement analysis services by the development of standards relating to clinical gait analysis services. A longer term aim is to monitor the implementation of these standards by auditing and accrediting clinical gait analysis laboratories.

This document details the standards developed by the Standards Working Group of CMAS. The work was carried out from March 2002 up to February 2004. Standards will be reviewed at regular intervals with revisions being made where needed.

Conformity to a standard allows accuracy or quality to be judged by auditing the processes against a checklist of key points stated in the standard. Details of the procedures carried out locally will be detailed in a protocol. The protocols should be sufficiently detailed to act as a guideline for all staff performing the stated task. Examples of protocols are appended to this document.

A clinical gait analysis lab will be required to maintain its own set of written protocols conforming to the associated standards for the procedures relevant to that lab, or as stand alone protocols where indicated in the list in the clinical gait analysis procedure document. Standards contain references to protocols where appropriate. They will also be required to maintain checklists of procedures carried out to ensure compliance with the standard.

Where appropriate, reference will be made to local trust policy e.g. appointments, consent, risk assessment.

Hyperlinks are provided between references to standards and the standard.

NB: the Audit Standard is still under development and thus not included in this document.

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Clinical gait analysis procedure

This section outlines the key procedures of a generic clinical gait analysis (CGA). It will be used to identify the standards and protocols that apply to a particular lab.

Note that the order of processes may vary from this outline.

CGA process stage	Protocol / standard	Details
Lab details	Standard	Environment equipment and staffing standards
Patient Administration	Standard	Administration
Set up of equipment prior to patient arrival	Protocol	Preparation of subject equipment
	Standard	Equipment
Preliminary meeting on arrival at lab	Standard	Environment
Clinical examination	Standard	Clinical Examination
Patient history	Protocol	Patient history protocol
	Standard	Data collection standard
Patient preparation	Protocol	Selection of data to be collected: • dependent on referral, compliance of subject, clinical examination results
	Protocol	Marker / electrode placement
	Standard	Gait data collection
Statement of system parameters	Protocol	System parameters for subject • marker model, axes orientation, equipment make / model, length of walkway (ref: gait data collection, data processing and equipment standards)
Acquire data	Standard	Gait Data Collection
		Environment (data storage)
Preliminary validity checking	Standard	Data Processing and Verification
Process data	Standard	Data Processing and Verification
Saving / storing data	Protocol	Data storage • identification, traceability and storage / backup of files • maintenance of patient confidentiality • safety of data (i.e. it does not get lost / corrupted) • compliance with future software versions
	Standard	Data Processing and Verification
		Environment (data storage)
Present and interpret results	Standard	Interpretation of Data and Reporting
		Normal Data
Additional general points	Protocol	Risk assessment
	Standard	Staffing
		Auditing

Document Control Standard	
Official Documents	• Lab must have ready access to the latest version of the CMAS standards.
Local Protocols	• The lab should have a list of all current protocols, clearly stating the issue date and version number. • The list should be signed by the head of department/service at each reissue of a protocol. The signature is then valid for two years, or until the protocol is replaced. • Protocols should be readily available to all staff.
Local Recording Forms	• The lab should have a list of all current recording forms/records, clearly stating the issue date and version number. • Blank forms should be readily available to all staff trained in their use.
Document Storage	• The lab should have a list of all the controlled storage locations, where current versions of any documentation can be found. Locations should be specified for, – Local protocols – Blank recording forms – Completed recording forms eg patient notes, equipment/software logs, calibration results. – Internal audit checklists. – Internal and external audit reports • Controlled documents may be kept in paper or electronic format.
Archiving	• All current documentation should be kept securely, with electronic documents kept under password and edit control and subject to backup procedures. • Copies must be kept of previous versions of all protocols and forms for at least 5 years after they are replaced.

STANDARD: Environment	
Facilities	• Gait Laboratory facilities to be accessible, safe and suitable for adults and children attending. • Facilities to have access for the disabled. • Facilities to have controlled access for security purposes during patient assessment. • Facilities to comply with local Health and Safety regulations. • The examination couch to have a firm surface, adjustable height, and appropriate width to allow access for examiner and security for the patient. • A minimum 7 metre walking space is necessary for gait data collection. 10 metres walkways are required for new facilities. • Room temperature should be appropriate for the partially dressed patient. • The environment should be quiet and non-distracting. • A designated area should be provided where the patient can both change and be examined in privacy. • Patient toilet facilities, including toilet for the disabled, to be available. • Adequate seating facilities available for patient and families. • Adequate lighting at frequencies that do not interfere with data collection • Mains electric filtering and surge protection where necessary • Adequate work space and facilities to allow data processing and reporting • Staff hand washing facilities to be provided to comply with local infection control precautions. • Floor surface to be cleaned regularly, be non-slip and level, free from obstacles • Examination couch to be cleaned/covers replaced after each patient assessment

STANDARD: Staffing	
Professional registration	• Staff to have current registration with the Health Professions Council / General Medical Council or other appropriate state, academic or national registration equivalent; or alternatively will be under the supervision of a practitioner with current registration, according to the appropriate regulatory body.
Health and safety	• Staff must have knowledge of, and comply with, all mandatory health and safety requirements of the employing body (e.g. Fire, Manual Handling, Resuscitation).
Specialist Training/ Experience	• Staff to have relevant professional membership and appropriate educational qualifications or peer acknowledged experience to perform the tasks in the laboratory. Details have not yet been formally identified, at present a relevant professional qualification and attendance at a recognised (ESMAC / GCMAS / SIAMOC) gait course desirable for staff new to gait analysis. • Break down into competencies for separate tasks (e.g. data collection, patient history, data interpretation, recommendations, clinical examination etc.) • It is necessary to have a mixture of scientific, technical and clinical skills. with clinical support appropriate to the labs area of speciality.
CPD/Audit	• Evidence of maintenance of core skills by attendance at courses and conferences. • Evidence of practice in line with current clinical research and development. • Adherence of staff to written protocols for all procedures

CMAS strongly recommends that a minimum of two staff are employed to run the laboratory.

STANDARD: Equipment	
Reference	• traceable record of equipment manufacturer, make and model. • traceable record of equipment software and versions. • manufacturer's contact details. • manufacturer's operational guidelines. • statement of equipment compliance with relevant national safety standards (e.g. electrical testing) and in accordance with local policy • all equipment to be CE marked unless exempt due to age of equipment
Staff	• all relevant staff will be familiar with the operation of the equipment (Clinical Negligence Scheme for Trusts, CNST)
Acceptable results for tests	• 3 tier results advised with details of derivation (advise on limits to established): o statement of acceptable limits of results (no action needed) o statement of warning limits of results (preventative action needed) o statement of failure limits of results (immediate action required – equipment not to be used clinically).
Test data collection	• systematic approach – e.g. test 3D and force individually before combined testing. • data to be collected under the same conditions that is used for subjects (e.g lighting, acquisition rate). • frequency of testing to be establish in house – will be dependent on local equipment – labs must be able to justify testing frequency. • Every clinical session to include data integrity check
Suggested minimum tests to perform - this list is not exhaustive, *protocols* for all equipment use clinically are required. CMAS recommends that basic checks are carried out at the start of each session in addition to less frequent more rigorous checks. CMAS to advise on quantifiable limits in the future:	
Force plate tests	• absolute force values in all measured directions • centre of pressure
3D position	• absolute marker position in capture volume - static and dynamic • relative marker position in capture volume - static and dynamic
EMG	• timing delay • frequency response
Video vector	• centre of pressure • relative value of force – vector proportional to load on all settings
Pedobarograph	• linearity of pressure measurement • equality of cell response
System	• synchronisation of all data sources • relative spatial positions of relevant equipment (e.g. force plates and 3D)
Recording and	• data files (testing and subject) to be archived for reference in secure

reporting data	environment • record of acquisition parameters (e.g. sample rate etc) according to *protocol*. • record of processing parameters (e.g. filtering, re-alignments etc) according to *protocol*. • details of tests performed including date, time, staff, environmental conditions documented according to *protocol* with record of test results and troubleshooting, remedial action and retest results where necessary.
Reliability	• inter-rater and intra-rater reliability to be demonstrated where applicable. • reliability in differing environmental conditions to be demonstrated (e.g. temperature). • see **Audit Standard** .

STANDARD: Administration	
Referral	• State the information necessary for acceptance of referral • State policy on acknowledgement of referral in accordance with local policy • Make initial decisions on what tests need to be performed during the assessment on the basis of the referral
Appointments	• State procedures for allocation of appointments, strategies for non-attendance in accordance with local policy • State information to be sent to the patient regarding the appointment
Arrival	• Explain procedures and sign consent forms • • Explain timing and procedure for the circulation of report

STANDARD: Clinical Examination	
Facilities	• See **Environmental Standard**
Equipment	• Any equipment necessary for the examination, as described in the *protocol*, to be at hand. • Equipment to be regularly checked and calibrated where appropriate to produce accurate measurement, according to *protocol.*
Subject	• The patient to be suitably dressed (e.g. shorts and T-shirt), to allow access to the body part(s) being examined.
Staff	• See **Staffing Standard.**
Data collection	• A systematic approach to testing to be adopted in accordance with a documented *protocol* using tests in common practice where possible. • Tests to be performed sequentially, in standardised positions to maximise repeatability and minimize changes in patient position. • Assessment techniques appropriate to the diagnosis/pathology of the patient will be selected.
Recording	• See **Interpretation of Data and Reporting Standard.** • Record factors influencing the reliability of testing e.g. compliance, emotional state, comprehension.
Reliability	• Documentation of current inter and intra-rater reliability of tests to be updated annually. • See **Audit Standard.**

STANDARD: Gait Data Collection	
Space and equipment	• See **Environment Standard**. • Appropriate hardware and software for data acquisition, processing, storage and report generation (**Equipment Standard** / *protocols*). • Calibration of equipment according to local protocols • Adequate supply of necessary disposables.
Subject	• Specify minimum ability for each data collection • Suitably dressed to allow observation of movement e.g. swimwear/shorts.
Staff	• See **Staffing Standard**.
Data collection	• Documented verification procedures e.g. EMG skin preparation and testing for location/cross-talk, location of knee marker / varus wave, footswitch location (*protocols*). • Subject preparation and instructions, including written informed consent for specified gait data collection, according to *protocols*. • Take relevant patient history as described in the protocol • Activity/repetitions appropriate to patient diagnosis and tolerance and referral question(s). • Avoid targeting of force plates and allow adequate rest periods for acquisition of representative data e.g. normal speed and style (**Data Processing and Verification Standard**).
Reporting	• Document hardware and software used for data collection (**Equipment Standard**). • Type of data (the number of variables) recorded, assistance required and the validity of the data. (**Report Standard**). If walking is assisted by means other than those normally used by the subject this must be stated in the report (e.g. person assisted, alternative walking aid). • Any compromise to data collection e.g. impaired comprehension and/or compliance should be stated.
Reliability	• See **Equipment Standards**) • See **Normal Data Standard** • See **Audit Standard**. • See **Staffing Standard**.

CMAS recommends that the patient is able to walk for minimum of 10 metres with their own walking aid or independently, with a significant load taken through the feet.

STANDARD: Data Processing and Verification		
Reference	Staffing	• See **Staffing Standard**.
	Computational parameters	• See **Equipment standard** and *protocols.*
	Data collection protocols	• See **Data Collection Standard** and *protocols*.
Pre Assessment	Verification of system calibration	• See **Equipment Standard** • Records of checks and relevant calibrations to be recorded with session data.
During Assessment	Verification of static trial	• Static trial viewed to ensure all segments can be reconstructed correctly before collection of the dynamic trials. • Static trial saved immediately in locally used file format.
	Verification of the quality of data during patient trials *protocol*	• Ensure first complete trial is examined to ensure that all markers are being reconstructed. • Ensure a pre-defined minimum number of gait cycles are collected and checked for marker continuity and clean force plate strikes when applicable. A minimum of 3 gait cycles per leg is required. • When possible sample kinematic and kinetic curves should be checked as being representative while patient is still present. • Record video footage to assist with checking for changes in marker placement or behaviour that may have affected data
	Verification of EMG signals	• Verify that EMG signals give appropriate recordings of muscle firing..
Post Assessment	Data Tracking	• Rectify any problems with marker tracking such as marker label switching.
	Processing steps	• Specify all processing steps in *protocol* (eg. filters and parameters, models).
	Identification of foot fall parameters	• Verification of clean foot contact on the force plate, if appropriate, with no contact from other foot or walking aid. • Rationale for the identification of initial contact and toe off (if automatic, verification of the accuracy required).

	Variability	• Ensure that no unrepresentative data trials are included. i.e. through fatigue or distraction; OR: ensure different trials are marked as such and interpreted with this knowledge. • Check consistency of kinematics and kinetics (minimum 3 trials, 6 recommended). • Ensure any variability can be accounted for, for example, check for consistency in walking speed.
	Graphical representatio n	• Patient code/name and date of analysis must be included on all graphical printouts. • Review graphical output to identify any data processing artefacts, which should be corrected or their effect on results reported. • Review all graphs to evaluate the extent of wand or marker misplacement. The results of these should be documented and their effect on the graphic outputs reported. • Any adjustments should be documented.

STANDARD: Normal Data	
Scope	• Kinematics • Kinetics • Temporal parameters • EMG • Clinical Examination ROM • Energy consumption • Plantar pressure
Data Collection	• Data should be collected in conditions according to the written protocols of the lab.
Subjects	• Normal data used for comparisons to take into account relevant factors including: o Age o Walking speed o Height / leg length • A group average should contain a sufficient number of subjects and trials to be representative of the group
Presentation	• Averaged data for kinematic and kinetic curves for normal reference range to be displayed +/- 1SD or other preferred method of showing variation, which must clearly labelled • Reference data of variability between trials in young children to be available when appropriate.
Validation	• Normal data to be checked for validity against published results* and references to literature should be documented where applicable. • Normal database to be checked/updated with changes in staffing, protocols or equipment.
Recording	• Details of all subjects in reference and averaged normal data to be recorded including: age, sex, date & assessors.

*References:

DH Sutherland et al (1988) "The Development of Mature Walking", *Mac Keith Press, Oxford*
J Perry (1992) "Gait Analysis – Normal and Pathological Function", *SLACK Incorporated, NJ USA.*

STANDARD: Interpretation of Data and Reporting	
Equipment	• See **Equipment Standard**
Staff	• See **Staffing Standard**.
Subject	• Report to include pertinent details of patient's medical history, walking and functional ability etc. This will be recorded according to a local *protocol*.
Data records – technical details of assessment, graphs and details of test conditions.	• Report on the conditions under which data was collected, the subject's ability to comply with data collection and whether walking in the laboratory was considered to be representative of the subject's normal walking pattern • Record staff involved in each process • Record explicitly the technical and clinical limitations of the data presented • Interpret data within its known consistency and reliability (**Data Processing and Verification Standard**) and identify artefact • Use agreed terms to describe the data, as defined in local *protocols* • Describe deviations from data obtained from a matched group or individual (**Normal Data Standard**).
***Summary & Recommend-ations**	• Summary and recommendations will be limited by the areas of expertise of the reporting team. • Suggested treatment recommendations will be based on problems identified in the report.
***Documentation**	• Report to show patient name, date of birth, date of analysis and referrer (and where appropriate hospital number and NHS number). Patient name or identifier, and date of analysis on each page. • Report to be signed and dated by those taking responsibility for content of report. • Identify normal comparison group where used (**Normal Data Standard**). • Graphs labelled with trial number, date, units and walking condition. • Clinical examination sheet to be included in report as appropriate (**Clinical Examination**) • All data and reports to be stored according to local policy on data protection (Equipment Standard).
Reliability/QA	• Report to be filed in patient medical records with traceability of data and staff involved in the process, and to be made available to the patient on request. • Copy of the report to be kept in the laboratory. • Electronic reports to have secure back-up files. • Patient identity on each page of the report. • See **Auditing Standard**

* These sections refer to information that is to be included in a final report sent to the referrer / medical notes.

STANDARD: Auditing the CMAS standards	
Auditors	• Each lab should have at least 2 internal auditors. • External auditors will be appointed by CMAS from another accredited gait laboratory. • An internal auditor(s) will be appointed by the lab itself from within its own organisation. This person should be a health professional but need not have experience of gait analysis. • If internal auditors come from the gait laboratory staff then more than one will be required. • All auditors will have received guidance/training in audit from CMAS or another body where appropriate.
Audit method	• External audit will be conducted using selected points from the checklists produced by CMAS. It will include an assessment of internal audit procedures. • External audit checklists will cover fundamental issues only. • The labs themselves will adapt check lists for their internal audits. • Internal audit checklists should cover all aspects of the standards in some detail, along with local protocol requirements.
Audit frequency	• External auditors will visit the lab twice in 2 years, as arranged by CMAS. • CMAS can request additional external audits if there is any cause for concern. • Internal audit will be performed at least 4 times in two years on a timetable drawn up by the laboratory. • Internal auditors will cover all aspects of the lab's work over the 2 year cycle. (This means that a single audit need not cover everything. A lab could produce 4 checklists covering the whole process which are then used in rotation).
Audit Reporting	• The results of any audit will be recorded and reported by the auditor. They will also be signed by the laboratory manager. • All audit records will be kept for at least 5 years. • Copies of internal audits will be held by the laboratory. • Copies of external audits will be sent to CMAS in order that accreditation can be renewed.
Dealing with problems	• Both internal and external auditors will have direct access to CMAS if problems arise. • Problems raised at an internal audit will be documented and reported to lab staff by the auditor. The lab is then required to put a plan in place to deal with the problem. The internal auditor will then monitor progress at the next audit. • Major problems raised at an external audit must be reported to CMAS. The lab is then required to put a plan in place to correct the problem within 6 months. A follow up external audit will be arranged for that time. Minor problems can be passed to the internal auditor for follow up.