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A proposed quality assurance program for the clinical use of surface electromyography in the chiropractic office

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This paper presents a proposed quality assurance (QA) program for chiropractors using surface electromyography (SEMG) in their offices. The paper examines in detail the various aspects of the program including both the technical and professional components. The technical component has three sub topics: equipment, technical procedures and data processing; as does the professional component: qualification/certification, compliance/peer review and patient selection. These are also further broken down to discuss the aspects dealing with quality and also other basic components necessary to understand the effective use of SEMG in the chiropractic office. The rationale for such a program is presented first and the details of the various aspects later. The complete program is represented in a number of charts which form a blueprint for the total QA program. As this is a proposed program, the authors invite feedback and criticism so that it may be optimized.
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KEY WORDS: chiropractic, electromyography, quality assurance.

Le présent article expose un projet de programme d'assurance de la qualité (AQ) pour les chiropraticiens utilisant l'électromyographie de surface (SEMG) dans leur cabinet de consultation. L'article examine en détail les différents aspects du programme, y compris les composants technique et professionnel. Le composant technique comprend trois volets : l'équipement, les modalités techniques et le traitement des données. Quant au composant professionnel, il comprend la compétence/certification, la conformité/l'examen par les pairs et le choix des patients. Ces sujets sont davantage subdivisés afin de discuter des aspects relativement à la qualité et à d'autres composants de base nécessaires pour comprendre l'usage profitable de l'électromyographie de surface dans un cabinet de chiropratique. Les motifs d'un tel programme sont d'abord exposés, puis les détails des différents aspects sont étudiés. Le programme complet est représenté par des diagrammes formant un plan global du programme d'assurance de la qualité. Étant donné qu'il s'agit d'un programme proposé, les auteurs souhaitent recevoir des réactions et des critiques afin que le programme puisse être optimisé.
(JCCA 1996; 40(4): 203–213)

MOTS CLÉS : chiropratique, électromyographie, assurance de la qualité.

Introduction

Laboratory findings often constitute a significant component of a patient's data. The accumulated information necessary to form a diagnostic impression should derive from tests and measures with known reliability, validity, sensitivity and specificity. Consequently, quality assurance programs in the management of laboratories are essential for the clinician to have confidence in the results of tests on patients. There are also legal and scientific obligations that can only be addressed by pre-existent quality assurance programs.[1,2]

There are no published quality assurance (QA) pro-

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grams for the chiropractic clinical use and interpretation of surface electromyography (SEMG). One of the recommendations of the Glen Erin Consensus Conference (as published in Clinical Guidelines for Chiropractic in Canada[1]) and of the Mercy Center Conference in U.S.A.[2] was the necessity of QA programs in the application of this technology.

The Canadian Chiropractic Association established a committee to investigate various aspects of SEMG and to make recommendations for the next round of consensus conferencing. One of the tasks with which the committee was charged was to formulate an SEMG quality assurance program. The x-ray quality assurance program which had been previously established by the CCA[1] provided an excellent basis for a model for QA in SEMG. Beyond merely establishing a rationale, the Committee undertook to develop a rationale which could be easily understood and effectively implemented.

The development of a series of organizational charts (Figures 1 through 3) for the various components of the QA program was seen as a means of providing an overview of the whole program as well as providing an opportunity for additions and/or modifications. These charts allow for the development of an implementation program which can be easily introduced into the clinical environment thus facilitating practitioner compliance.

Rationale

The chiropractic profession recognizes that whenever a diagnostic technology is utilized in patient care, there is an onus on the user for a high quality of service. Whether this service is provided in radiology, haematology or surface electromyography, it is absolutely necessary that all laboratories have a quality assurance program in place. The validity of findings as well as the reliability on an intra- or inter-examiner basis can only be controlled through active quality assurance programs.

In surface electromyography, there are essentially two components to the quality assurance program (Figure 1). These components are:

1 a technical component, and
2 a professional component.

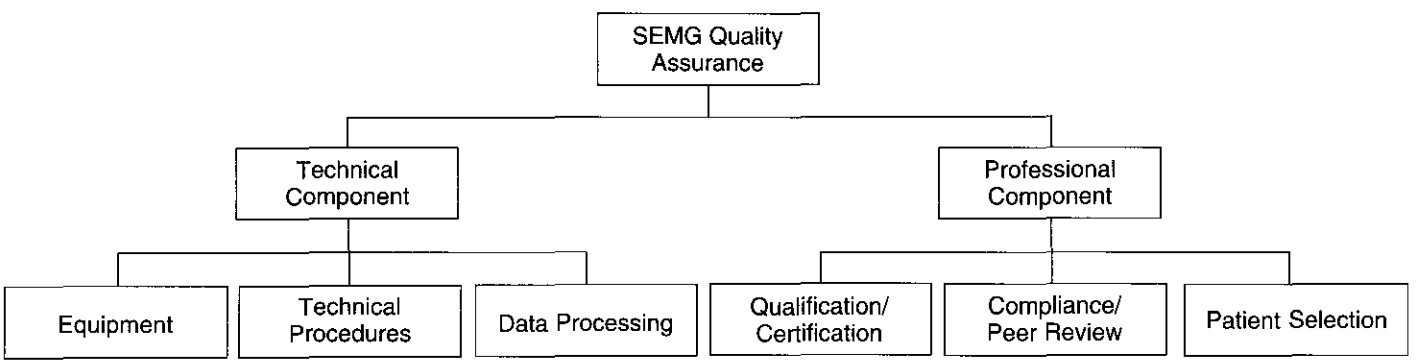
The technical component addresses the facilities, equipment, resources, personnel, supplies and the support needed to perform and produce a high quality SEMG study. The professional component represents the services rendered by the chiropractor to perform and interpret each study and to document the diagnostic conclusions of the study in a formal, written report.

These two components can be further subdivided into the following applied areas within the context of a quality assurance program:

1 Technical Components:
   a. the collection, processing and recording equipment,
   b. the technical procedures involved in subject preparation and run-up to data collection, and
   c. the processing of the collected data to yield valid and reliable information.

2 Professional Components:
   a. personnel qualifications,
   b. compliance and peer review, which would include standards and continuing education. Under these would be review of report quality, records, interpre-

Figure 1 SEMG Quality Assurance Program



tation and reporting, billing practices and professional responsibilities,

c. patient selection including the indications and contra-indications for the use of SEMG and informed consent.

The components of the QA program are summarized in Figure 1.

Discussion

The fundamental objective in performing an SEMG study is to supply additional objective information to assist the chiropractor in making the best clinical decision possible. Under these terms, a functional quality assurance program should be in place requiring achievement of the following objectives:

1 There is appropriate selection and preparation of the patient as well as observance of proper protocols.
2 The equipment is operated by qualified personnel.
3 The technical specifications of the equipment meet the requirements for accuracy and reliability.
4 Assurance that the equipment is functioning properly and is calibrated, as required, on a regular basis.

The frequency of conducting procedures for preventative maintenance and calibration is highly dependent upon the equipment being utilized. Preventative maintenance and calibration control procedures must be performed and recorded in order to protect for electrical safety, mechanical safety and equipment accuracy. This proposal suggests that it is not unreasonable for all owners of SEMG equipment to register their equipment with the appropriate licensing board in their political jurisdiction. The operation of any laboratory demands that the licensing body be apprised of the operator's qualifications as well as the equipment specifications. This is consistent with the professional responsibility of owning and operating any facility where human subjects are examined.

The following components are an important part of any QA program associated with the clinical use of SEMG.

1 Technical Components

1a Equipment

Accessories. Before performing an SEMG evaluation it is

Figure 2 Technical Component

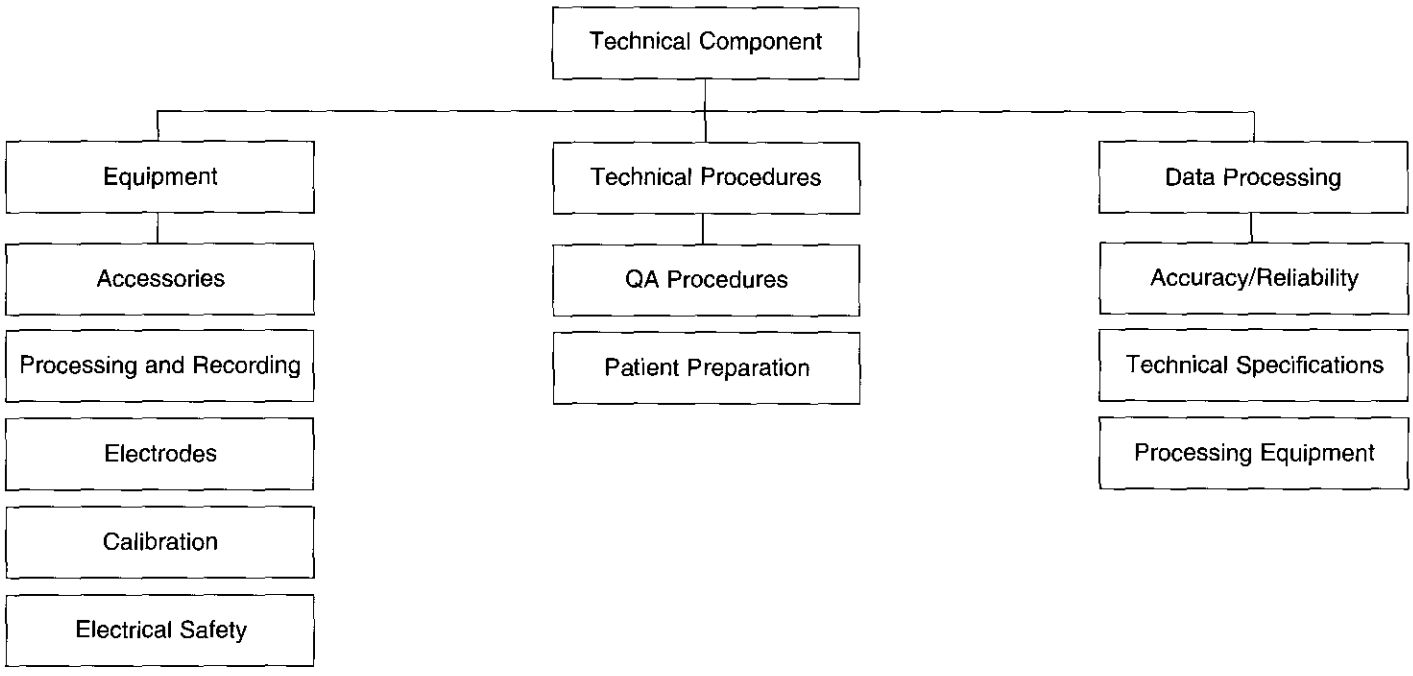
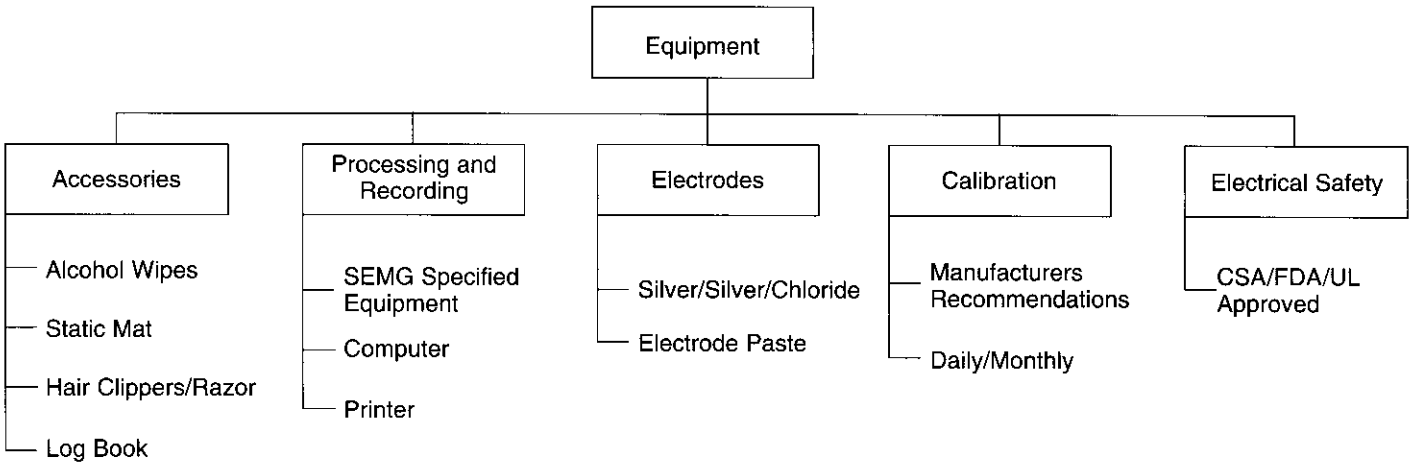


Figure 2a Technical Component – Equipment



important to have a number of accessories available to allow for a quality intervention with the patient. Alcohol wipes should be available to clean the skin of all patients at the electrode sites. A pair of clippers or razor should also be accessible to shave any hair from the electrode sites. All patients should stand on an anti-static mat to reduce the effect of static electricity on the readings obtained. Also a log book should be kept noting all information concerning the patient and the session with respect to the SEMG study.

Processing and Recording. Undoubtedly, as equipment and technology advance, the technical specifications will constantly be undergoing change and improvement. The following minimum technical specifications are recommended:[3,4,5,6]

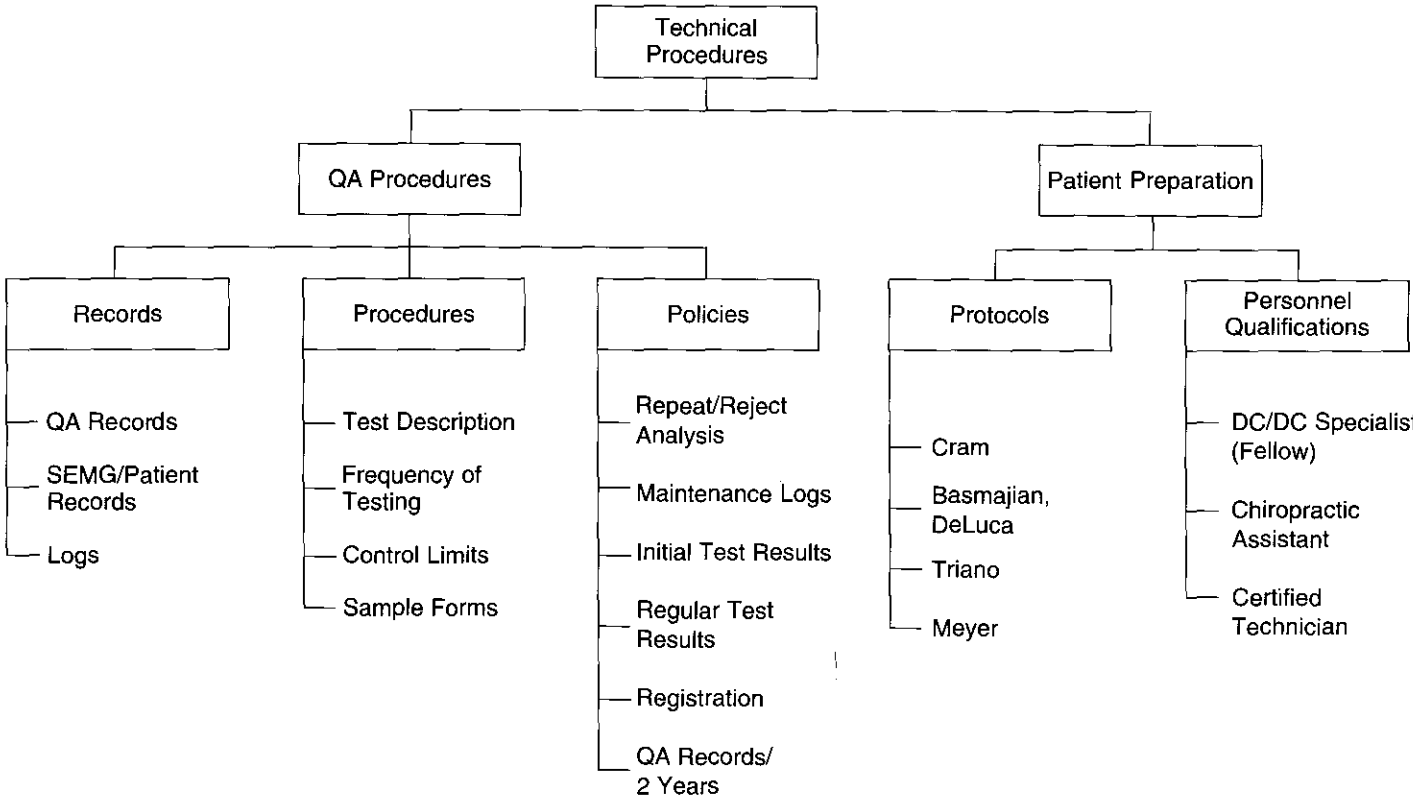
(a) Input impedance – greater than 10^{10} ohms
(b) Broad band filtration – 20–500 Hz
(c) Gain – to allow output amplitude of ± 1 volt (input is normally between 0.1–500 μV)
(d) Analog to digital conversion – 10 bit
(e) Common mode rejection ratio – > 100 dB
(f) Input bias current – as low as possible (typically < 50pA)
(g) Noise – Less than 2μV rms when measured with inputs connected together through a 10 Kohm load or shorted.
(h) Optical isolation – 5000 volts to meet UL544 standard or equivalent CSA standard
(i) Minimum 4 channel capability.

The equipment should bear a label that shows it has met specific requirements of the Underwriter's Laboratory, the Canadian Standards Association or the American Standards Associations. Currently, there are no Canadian manufactured systems that are suitable in the chiropractic office setting. Consequently Canadians must look to foreign systems to serve their needs. There are a number of American and other foreign designs that are suitable; however, only a limited number are aimed at the chiropractic clinical practice setting.

Electrodes. Electrodes should be non-reusable, disposable self-adhesive silver/silver chloride electrodes with a conductive medium (electrode paste or gel) included in the sterilized package. The silver/silver chloride electrodes are consistent with current scientific standards.[3] Other types of electrodes, for example, stainless steel, are not suitable or sufficiently accurate for clinical investigations. The size of the electrode will vary, depending on the type of study being undertaken. A standard 2 cm electrode is suitable for most investigations of the spinal musculature. It is important that there is moist electrode gel on the electrode to ensure a good skin electrode interface.

Calibration. All SEMG equipment should be calibrated on a regular basis, generally depending on the manufacturers specifications. In general it is good practice to calibrate on a daily basis or on every day that patients are being

Figure 2b Technical Component – Procedures



evaluated, unless otherwise indicated by the manufacturer.

Electrical Safety. All electrical components of the instrumentation (processor, amplifiers, computer and printer) should be approved by a suitable standards organization such as the Canadian Standards Association (CSA) or an analogous foreign safety standards association.

1b Technical Procedures

QA Procedures. With all equipment, there is a need for maintenance and quality assurance procedures that insure the integrity and safety of the procedures being performed. The procedures in the following section address the issues of quality assurance with respect to the equipment utilized in SEMG. These procedures are proposed to assist the practitioner in maintaining high standards of patient care. The specifics of many of the issues should be established in the particular jurisdictions by the appropriate bodies.

All owners of an SEMG should register the equipment with the appropriate stautory authority in their jurisdiction. Registration should take place prior to the facilities being operational.

To ensure the continuous monitoring of the quality process, the following procedures should be incorporated into all offices conducting SEMG studies:

1 Written policies regarding SEMG should address the following:
   (a) the need for repeat examination,
   (b) patient preparation protocols,
   (c) need for initial examination.
2 Quality procedures to be performed include:
   (a) description of each test procedure,
   (b) the frequency for each test,
   (c) control limits for each test and samples of forms used.

3 Records for each SEMG piece of equipment should include:
   (a) A completed copy of the proposed application for registration of the equipment,
   (b) Initial equipment acceptance testing results,
   (c) Records of regular testing of the equipment,
   (d) Results of preventative maintenance of the equipment over the past 2 years and results of calibration for the past 2 years.
4 Records of SEMG quality control for the past two years should include maintenance logs for the SEMG equipment.
5 The results of repeat/reject analysis conducted every month should include the results of corrective actions taken and the numbers of repeat/reject analysis.
6 All facilities with SEMG equipment should have the following:
   (a) calibration device,
   (b) An anti-static mat,
   (c) Alcohol and skin cleansing wipes,
   (d) Self-adhesive, or reusable silver/silver chloride electrodes,
   (e) Hair clips,
   (f) Shaving equipment.
7 The following procedures need to be carried out on a timely basis for all equipment used in the SEMG procedures.

Daily Requirements:
Certain SEMG quality control procedures must be performed every day of operation before the first patient examination. Included in these procedures should be the following minimal requirements:
   (a) Calibration of instruments.
   (b) Electrical safety inspection.

Monthly Requirements:
The following procedures should be performed in all facilities every month:
   (a) Document repeat/reject analysis for purposes of taking corrective action to overcome operational deficiencies (see 5 above)

Annual Requirements:
The following procedures should be performed on an annual basis.
   (a) Preventative maintenance,
   (b) Check the integrity of all electrical cables,
   (c) Check other procedures recommended by the manufacturer.
   (d) Report/Processing Equipment. Report processing should be consistent with the recommended computer processing equipment by the manufacturer. This equipment must be kept in optimal working order.

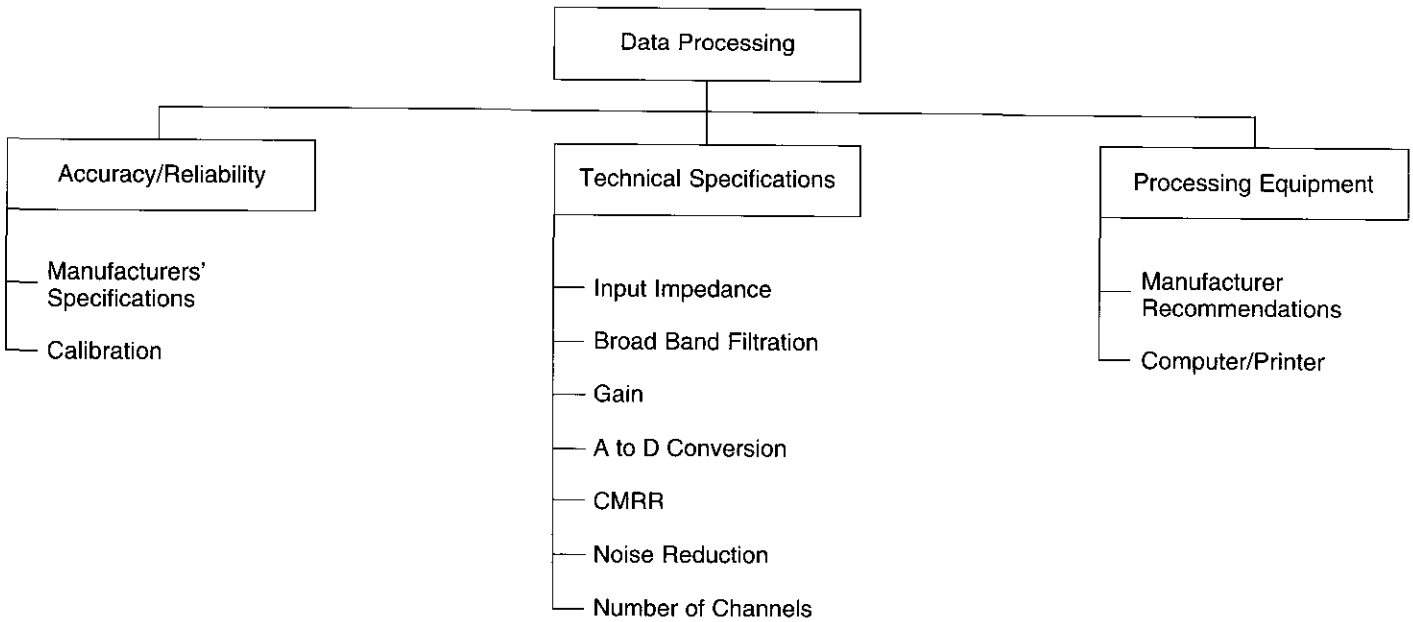
Patient Preparation. The protocols for the preparation of the patient for an SEMG evaluation are well documented in a number of publications.[3,5,8,9] The physical preparation involves the cleaning of the skin and placement of electrodes. There is also a need to psychologically prepare the patient by explaining the procedures to be performed and what the SEMG is measuring and telling the doctor about the patient's condition. This is especially important before the initial SEMG evaluation. The only person who should prescribe an SEMG examination for any patient is the chiropractor. The chiropractor should have a specialty designation (FCCS, FCCSS, etc.) which has incorporated SEMG as part of the program, or as a minimum, the chiropractor must have completed an approved program in SEMG through a CE program from a CCE accredited College.

Other office personnel may be involved in the physical part of the SEMG examination, such as the application of the electrodes, putting the patient through the various protocols and the removal of the electrodes. These personnel should have sufficient training to understand the nature of the SEMG examination and should be a qualified chiropractic assistant, kinesiologist or trained technician. Only the chiropractor should interpret the results and discuss these with the patient.

1c Data Processing

The processing of data from surface electrodes depends on the evaluation process required. In most clinical applications the signal is processed as an average amplitude, integrated EMG which provides a clean, continuous signal to evaluate the amplitude of the SEMG.[5,6] This type of processing is also useful in the flexion/relaxation protocol for examining back pain patients.[7] Other methods such as deriving linear envelopes and median frequency analysis are described in detail in Basmajian and DeLuca[3] and have specific applications depending on the interest of the investigator. There are three main areas of importance with regard to the processing of the data.

Figure 2c Technical Component – Data Processing



Accuracy/Reliability. It is important that the derived data is both accurate (valid) and reliable. These properties can be ensured through following the manufacturer's specifications for all equipment used and by calibrating the equipment as recommended, generally on a daily basis when exams are being held.

Technical Specifications. The technical specifications have already been mentioned and documented under 1a. Equipment, Processing and Recording. It is important that any equipment purchased for the recording, processing or printing of information with respect to an SEMG meet the minimum standards as described for input impedance, filtration characteristics, gain, A to D conversion capabilities, common mode rejection ratio for noise reduction and have at least four channel capability.

Processing Equipment. The processing equipment that is used should meet all the specifications of the manufacturer of the SEMG equipment. In general, a suitable computer to allow for the processing of the 4 channel EMG signal with the software accompanying the SEMG equipment is needed to accurately portray the data and to supply sufficient space for record keeping and running a printer. The printer should have colour capacity, however a high quality black ink printer may suffice, once again depending on the software supplied with the SEMG equipment. Although a laser printer produces high quality graphs and charts, an ink jet printer is highly suited to most software and provides colour options at a reasonable price.

2 Professional Component

2a Qualification/Certification

The qualifications for performing an SEMG examination were previously discussed under the section on patient preparation. Once again, SEMG examinations should only be prescribed by doctors of chiropractic and not the assisting staff. The chiropractor should have received postgraduate training in SEMG with respect to standards of quality, clinical indications for SEMG, and the interpretation of SEMG. He/she may perform all components of SEMG services including the technical and professional components. The general practitioner may delegate the technical component to a qualified SEMG technologist or to a chiropractic assistant who is educated and trained to perform appropriate SEMG diagnostic studies on the requisition of a duly licensed practitioner.

Certain fellowship programs contain specialized training in the use and interpretation of SEMG within the curriculum. A graduate of this type of specialty program would be a chiropractor who would or has achieved a specialty standard (FCCS, FCCR, etc.) with advanced and

Figure 3 Professional Component

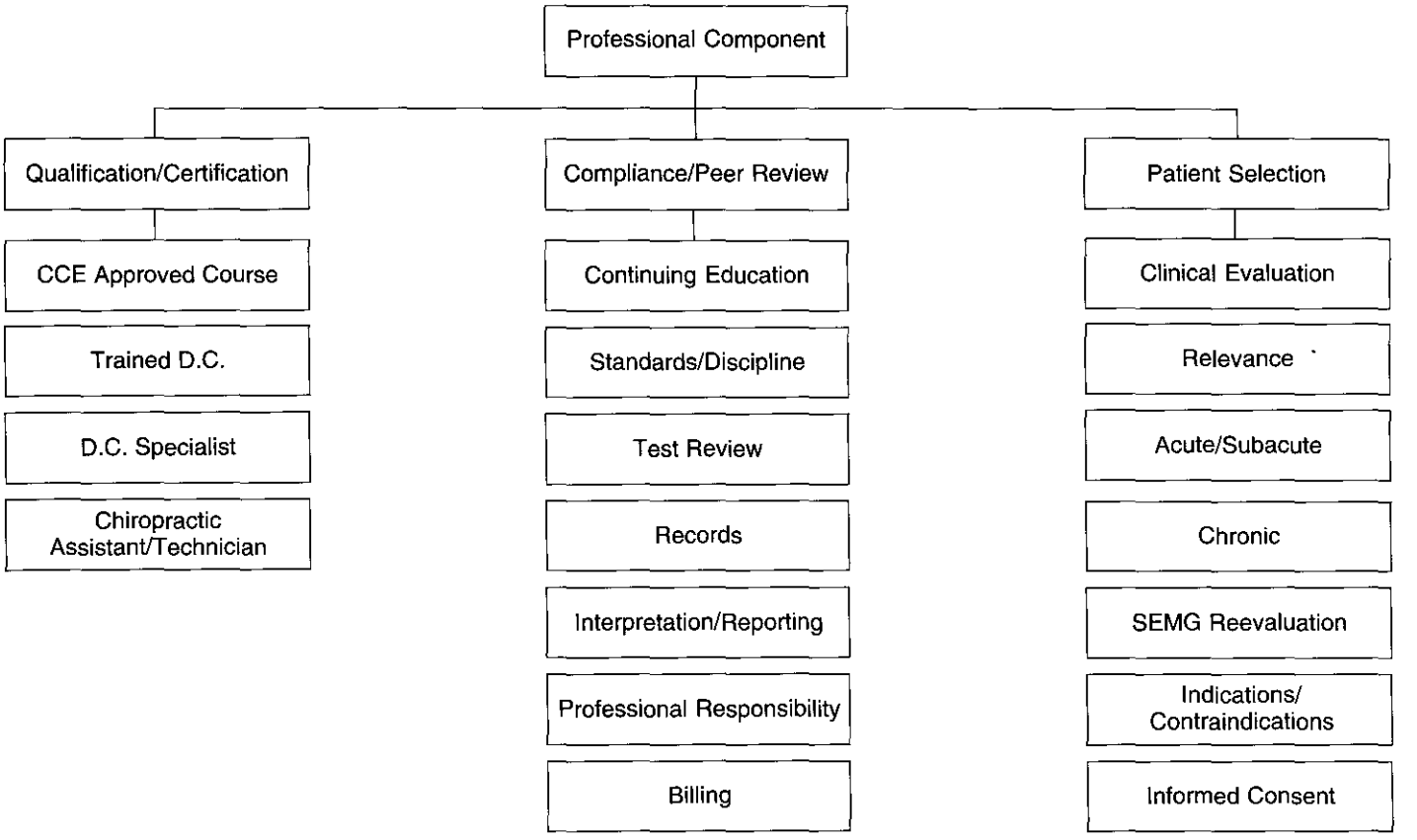
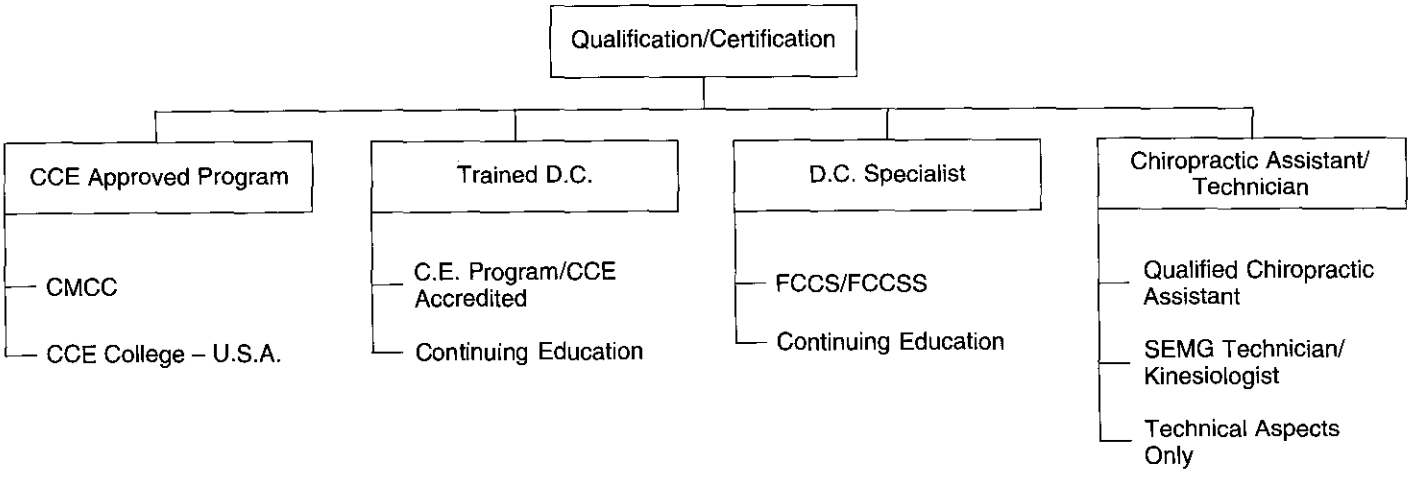


Figure 3a Professional Component – Qualification



interpretive skills accompanying all aspects of SEMG but with particular emphasis on spinal SEMG.

In all cases, the technologist and/or Doctor of Chiropractic who is performing the SEMG evaluation should have completed a continuing education program from a chiropractic college that has CCE accreditation. The course must be approved by the curriculum committee of the chiropractic college and must include portions requir-

ing proficiency in:
(i) technical performance and
(ii) interpretation.

Certification from other post-secondary schools, educational institutes and manufacturers are only acceptable if they meet and/or exceed the standards approved by a CCE accredited college of chiropractic.

2b Compliance/Peer Review

Continuing Education. All chiropractors who perform SEMG evaluations should have received training through a continuing education course on SEMG offered by a CCE accredited College or the equivalent. Doctors should also look forward to continuing education courses every three years to update and remain current in the technology and issues surrounding the use of SEMG in the chiropractic office.

Standards. Licensing boards that are responsible for quality assurance are in a position to enforce standards and to discipline for non-compliance. Boards should develop and modify quality assurance, peer review and continuing education programs in consultation with the qualified professionals, in their jurisdiction, utilizing SEMG.

The provinces may wish to enact continuing educational requirements with respect to SEMG as a prerequisite to accreditation or the renewal of the licensure of accreditation of an SEMG laboratory.

Test Review. Chiropractors who operate an SEMG facility should participate in the SEMG review and request by the licensing board. This would typically consist of a request for certain studies, the log sheets associated with these studies and the quality assurance records for the period in which the SEMG's were performed.

Records. An SEMG record sufficiently detailed for audit should be maintained on each patient and in addition to information identifying the patient, it should contain:
(a) a recent history,
(b) the results of a chiropractic, neurological/orthopaedic examination performed by the chiropractor,
(c) clinical indicators for SEMG assessment,
(d) specific reasons for which the SEMG examination is being conducted, such as a differential diagnosis or planning indicators as well as the interpretation and

Figure 3b Professional Component – Compliance

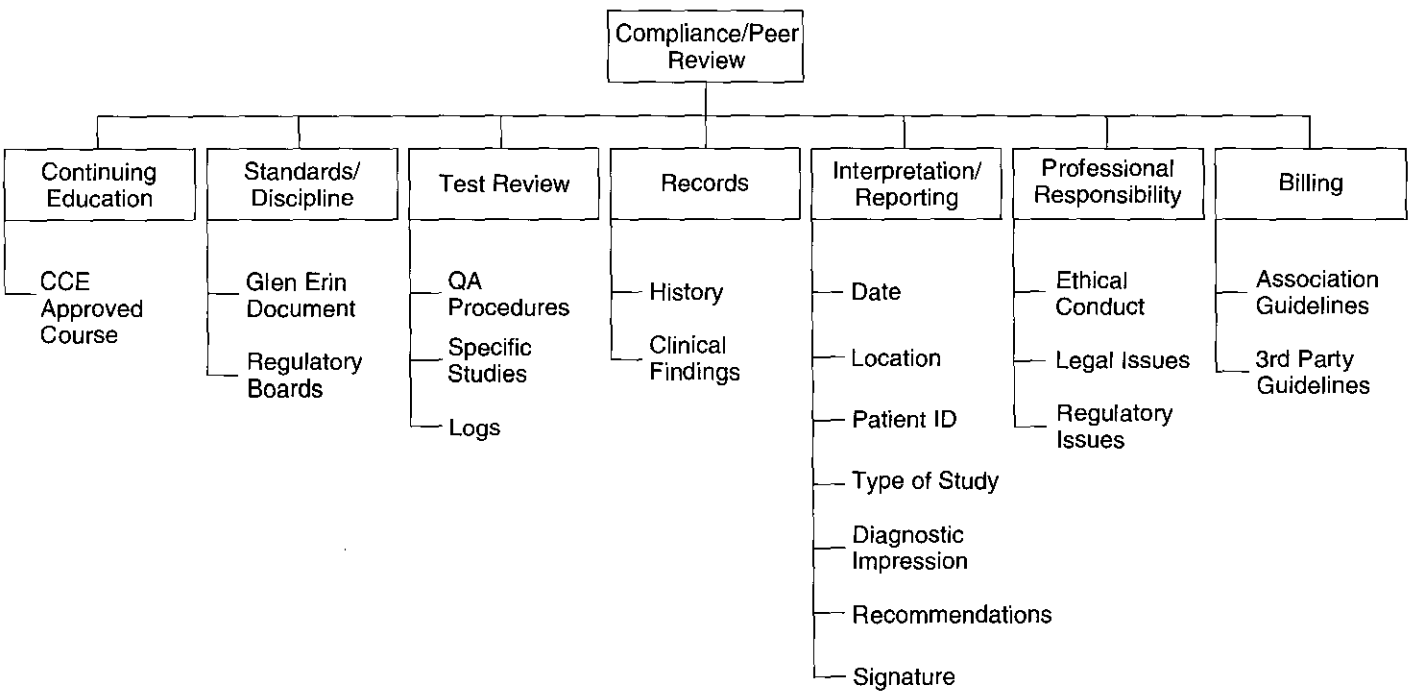
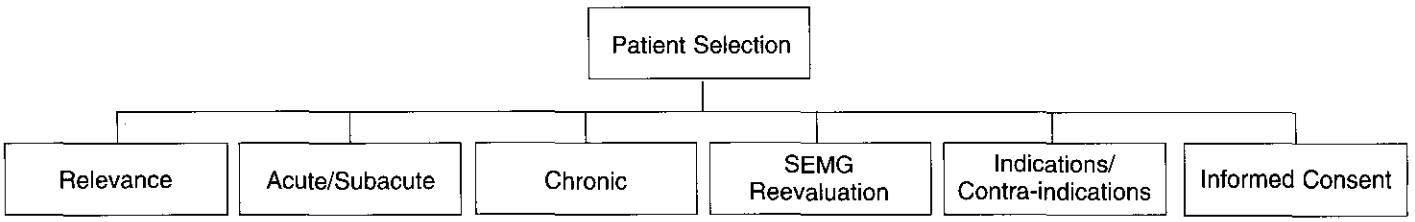


Figure 3c Professional Component – Patient Selection



the action recommended as a consequence of the SEMG examination.

Each SEMG facility should maintain an SEMG log book with the patient's name, sex, date, and description of the test taken. Provincial law provides a period of time during which SEMG's must be kept. It is recommended that these records be retained for the lifetime of the patient.

Interpretation and Reporting. A written interpretation of each SEMG should be included as part of the patient's permanent health record. Reports should be signed and dated by the individual performing the interpretation. Components of the formal written report include patient identification, location where the studies were performed, the study dates, the types of studies, diagnostic impressions, SEMG findings and a signature including the professional qualifications. A report may contain recommendations for further studies.

Professional Responsibility. Individuals or institutions are responsible for the level of services provided. The technical component is the responsibility of the technologist and the facility providing the services while the professional component may be performed by a chiropractor or a chiropractic or medical technologist certified in SEMG. Practitioners performing this professional service are held responsible to the appropriate level. Each patient must be informed in advance of the need for the nature of the SEMG examination to be performed and information may be conveyed in part through the use of standardized forms to be signed by the patient or in the case of minors and others not competent to give consent, by the parent or guardian.

Billing. Invoicing may be for the technical service, the professional service, or both. Subdividing the basic service or maintaining a two tier system for the purpose of billing third party payers is inappropriate.

2c Patient Selection

Relevance. The number, sequence and type of SEMG evaluation for an examination should be problem-oriented and have clinical efficacy in terms of impact on the diagnosis, treatment or prognosis. A proper history and clinical evaluation of each patient must be formed to establish the necessity of an SEMG examination.

The history and clinical evaluation is a guide to not only which portion of the body should be evaluated but also how many different SEMG tests should be undertaken. In using SEMG as a diagnostic aid, all necessary tests should be completed. Repeat or serial examination should be performed only to help confirm clinical suspicions of change which need to be known for the benefit of the patient. If the patient is making an adequate clinical recovery, additional SEMG evaluations would not normally be indicated. Exceptions would be to check on the rate of progress for modification of the clinical program of therapy that the patient is undergoing or for medical/legal reasons.

Acute/Subacute. Clinical SEMG is indicated to objectify myoelectric impairment as an essential part of a differential diagnosis.

Chronic. If signs and symptoms persist or an unsatisfactory response to chiropractic care in excess of 12 weeks is evident, a re-assessment using SEMG may be necessary to determine whether the treatment to date has had any impact on the myoelectric activity and recruitment patterns. The following signs may be helpful in the selection of patients for SEMG: Hypo/hyper-mobility, aberrant motion, instability, paradoxical motion, continuing muscle spasm, etcetera.

SEMG Reevaluation. If the patient has failed to respond to clinical management or if there has been an exacerbation, an SEMG re-examination should be limited to the

area in question, using only those positions and manoeuvres which previously demonstrated the abnormality.

Indications. Some of the indications for dynamic SEMG include muscle spasm,[3] aberrant spinal curvatures,[10] marked motor disturbances of the spine and pelvis,[11] suspicion of neuro-muscular pathology[12] and significant trauma as well as developmental or congenital defects.[13] The frequent incidence of inter-related biomechanical spinal pelvic lesions and multiple symptom complexes, altered spinal curvatures and suspicion of pathology and significant trauma results in increased justification.[10, 11, 12]

Contra-indications. Some of the contra-indications for dynamic SEMG would be pre-established serious malignancy and pathology, previously diagnosed fractures, dislocations or certain pathological processes that may weaken restraining structures or osseous architecture and severe neurological deficit or restrictive spasm. Essentially any condition which precludes the patient's capacity to carry out the dynamic movement required for the test without serous consequence would be a contra-indication. Further a patient's inability to carry out the range of motion requested due to a physical or mental state that prevents proper compliance with the necessary motion would preclude the benefit of the examination.

Informed Consent. Before performing any SEMG examination or evaluation, informed consent must be received from the patient, preferably in written form. The consent form should include a description of the test, including all components of electrode placement and removal, any risks or discomforts, and a description of the outcome in terms of the charts. Also the patient should be informed as to how the information obtained is to be used. This informed consent should be kept in the patient record.

Conclusion

Self-imposition of a quality assurance program will preclude regulation and mandatory reporting to regulatory boards. The privileges of professionalism are commensurate with professional responsibilities. Challenges and innuendos threatening professionalism in SEMG laboratories can be pre-empted by addressing these issues beforehand and assuring consistency across clinics with evidence-based usage of SEMG in all clinics.

This report presents a proposed SEMG quality assurance program including Rationale, Flow Chart and Implementation. It is the intent of the authors to present a proposed structure for QA within the SEMG framework in a chiropractic clinical setting. The authors invite criticism and commentary as the process to include a standard statement for SEMG in the next round of standard assessment continues.

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