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Challenges to implementation of the ECG reading center in ELSA-Brazil

ABSTRACT

Electrocardiography is an established low-cost method of cardiovascular assessment, utilized for decades large epidemiological studies. Nonetheless, its use in large epidemiological studies presents challenges, especially when seeking to develop a reading center. This article describes the process, difficulties and challenges of implementing an electrocardiogram reading center in Brazilian Longitudinal Study for Adulth Health (ELSA-Brasil). Among the issues discussed, we have emphasized: the criteria for selection of the electrocardiography machine and the central for storage and management of the machines; the required personnel; the procedures for acquisition and transmission of electrocardiographs to the Reading Center; coding systems, with emphasis on the Minnesota code; ethical and practical issues regarding the delivery of reports to study participants; and aspects related to quality control.

DESCRIPTORS: Electrocardiography. Diagnostic Techniques, Cardiovascular, instrumentation. Multicenter Studies as Topic, methods. Cohort Studies.

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INTRODUCTION

Electrocardiography is a low-cost, easy to perform method of investigation of the cardiovascular system with diagnostic and prognostic value and great clinical usefulness. Used in many different care provision contexts, from the Primary Care Unit to the Intensive Care Unit, the electrocardiogram (ECG) is a basic tool for several health professionals. Additionally, the progressive complexity and the increasing costs of modern medicine with invasive examinations reveal the need of a rational utilization of the available resources, prioritizing techniques and procedures that have a favorable cost-effectiveness ratio, like the ECG.[15]

The systematic utilization of the ECG in epidemiological studies began in the 1940s, with the first cardiovascular epidemiology cohorts.[6] However, it was soon verified that there were substantial difficulties in standardizing readings and coding, and these difficulties derived from variations between successive readings performed by different observers and also from the lack of an established coding, appropriate to epidemiological and population-based studies.[4] The Minnesota Code was created in this context. Published in 1960,[3] it aimed to provide an objective, reproducible and safe system of electrocardiographic diagnoses that enabled the comparison of epidemiological studies carried out in different populations and countries. The code was validated in subsequent studies and has become the method chosen in epidemiological studies that use electrocardiography.[19]

In the following decades, countless papers were published on the use of ECG in population-based studies, showing the prognostic value of different electrocardiographic alterations to predict death and cardiac events.[5,9] An aggregate analysis of data from eight population-based studies, published in 1978,[17] involved a total of 8,390 male individuals with an average follow-up of eight years. This study confirmed the importance of major ECG abnormalities (which included alterations related to myocardial ischemia, bundle branch blocks, atrial fibrillation and ventricular ectopy) as markers of subclinical cardiovascular disease and predictors of cardiac events, like myocardial infarction and sudden death. Subsequent population-based studies confirmed the prognostic importance of electrocardiographic alterations, including those originally classified as minor alterations.[7,16,26,27] In population-based studies, the ECG is also useful to define prevalent cases at baseline and to detect outcomes, such as silent myocardial infarctions, when it is performed in subsequent visits.

Simultaneously, the evolution of signal processing techniques, with the use of microelectronics and computers, the miniaturization of devices, digitization of signals and automatic interpretation of ECGs, had a great impact on cardiovascular epidemiological studies.[13,24] Systems that are capable of transmitting electrocardiographic tracings over the Internet and software packages that enable automatic analysis and coding of tracings have revolutionized the electrocardiography of population-based studies, enhancing its applications and allowing the study of large populations.

The *Estudo Longitudinal de Saúde do Adulto* (ELSA-Brasil - Brazilian Longitudinal Study for Adult Health) included more than 15 thousand participants aged 35-74 years at baseline. The aim was to monitor participants in order to identify outcomes related to the development and evolution of the main chronic diseases that affect adults, particularly cardiovascular diseases and diabetes. Baseline assessment (2008-2010) included detailed interviews and clinical and laboratory tests to obtain physiological data, especially concerning the cardiovascular system. The follow-up combines annual telephone contacts and re-tests and interviews every three to four years.[2]

The ECG is one of the methods performed at baseline in the ELSA-Brasil study, and it is repeated in the subsequent waves. In view of the complexity of its analysis and coding, it was decided to create a *Centro de Leitura de ECG* (CL-ECG – ECG Reading Center), so as to guarantee the quality of the records and the uniformity and comparability of coding. However, the specific literature describing basic requirements and difficulties related to the implementation of a CL-ECG is scarce.[1,18] The implementation was preceded by a visit to two of the largest ECG reading centers in the world, EPICARE, which was coordinated at the time by Prof. Prineas, at Wake Forest University, in Winston-Salem, North Carolina, USA, and CARE, coordinated by Prof. MacFarlane, in Glasgow, University of Glasgow, Scotland. The present paper describes the process, difficulties and challenges concerning the implementation of the CL-ECG in the ELSA-Brasil.

EQUIPMENT

The centralized reading of the ECG is based on tracings obtained by different electrocardiographs, digital or analog, with the record of one, three or 12 simultaneous leads, with or without automatic interpretation. However, the best tracings are obtained by robust equipment that is exclusively dedicated to electrocardiography, with simultaneous acquisition of 12 high-frequency leads (>500 samples/s per channel), high-resolution thermal print head and automatic measurements of ECG deflections and intervals.

Furthermore, the electrocardiographs must communicate digitally with an ECG management and storage center, with a system that is capable of storing and

organizing the tracings, enabling their editing and detailed analysis. Automatic coding and analyses of electrocardiographic parameters derived from computerized measurements depend on the availability of the tracings at such management and storage centers. Only a few companies have such systems, like GE, Philips, Mortara and Cardiac Science. Apart from these systems' intrinsic characteristics, the way in which tracing transmission is performed between the electrocardiographs and the storage center is relevant. With the current ubiquitous availability of the Internet, the best systems are the ones that send tracings electronically, in a network or using internet protocols.

In the ELSA-Brasil, the 12-lead ECG was recorded in a digital device (Atria 6100, Burdick, Cardiac Science Corporation, Bothel, WA, USA) with automatic reading of the heart rate; duration, amplitude and axes of the P, QRS and T waves; and also of the QT and QTC intervals and QT dispersion. The ECGs were transmitted from the Atria 6100 electrocardiograph to a server of the CL-ECG, located in the *Centro de Investigação de Minas Gerais* (CI MG – Investigation Center of Minas Gerais), where they were stored for subsequent analysis in a Pyramis ECG management system (version 6.2.b, Cardiac Science Corporation, Bothel, WA, USA), with the possibility of editing tracings and measuring intervals beat by beat.

PERSONNEL

The current guidelines indicate that a CL-ECG must have at least one physician experienced in clinical research or cohort studies and in electrocardiography, to assume the function of direction and coordination, with clinical and administrative responsibility.[1,18] The coordination activities can be shared with one or more coordinators, who supervise the technicians' activities, perform quality control and revise the coding.[1] The technical team is composed of electrocardiography professionals who supervise the field activities, and primary and secondary ECG analysts, who are responsible for manual coding (primary analysts), when it is performed, and for reviewing abnormal codes, both in manual and in automatic coding (secondary analysts).[1,18] In addition, the CL-ECG needs to have administrative and information technology support.

The CL-ECG of the ELSA-Brasil had the administrative and information technology support that is provided for the other activities of the CI MG. General coordination (equivalent to the direction described above) was exercised by a senior medical researcher experienced in electrocardiography and clinical research, and the coordination of the works was performed by a cardiologist experienced in electrocardiography and in specific technical coordination, and by secondary analysts.

ELECTROCARDIOGRAM ACQUISITION PROCEDURES

Performing an ECG is a routine procedure in clinical practice and it is described in reference texts available in the medical literature. In the case of epidemiological studies, especially the multicenter ones, it is necessary to standardize procedures and ensure the quality of the resulting tracings, thus minimizing the chance of errors or loss of records. ECG performance in the ELSA-Brasil study followed a routine established in the Operations Manual (Figure), and the electrocardiography technicians of the ELSA ICs were trained and certified by the ECG Reading Center team. The configuration of the electrocardiograph was performed by the CL-ECG when the equipment was installed.

The ECG was performed according to a flow defined by the ICs, during the mornings, at an appropriate place that had low environmental noise and adequate lighting and temperature. Alcohol abstinence since the previous day was recommended; also, the participant should not smoke on the day of the test. The stages of the test were:

- Preparation of the participant for the ECG record, guaranteeing their comfort and that they were informed about the procedure. The participant should feel neither excessive cold nor excessive heat to avoid tension and muscle tremor, which interfere in the record.

- Preparation of the participant's skin, with removal, through mild abrasion, of the skin's most superficial corneal layer, to improve the conduction of the electrical impulse. In the ELSA study, we used the skin preparation sandpaper 3M Red Dot Trace Prep. The tape has a sticky side that adheres to the examiner's index finger, and a rough side, used to abrade the skin. With a small piece of tape adhered to the tip of the index finger, the examiner used the rough side to remove the corneal layer of the skin on which the electrodes would be placed. The prepared skin should become pink, without solution of continuity and without the participant feeling pain. If the obtained trace was not adequate, hair was removed (in men with excessive hair on the chest) and the skin was prepared again, using a piece of gauze soaked with 70% liquid alcohol to abrade the skin.

- Electrodes positioning. The ten electrodes were placed on the body parts that had been previously determined, according to the international recommendations.10 The disposable electrodes that were used were Ambu Blue Sensor SU and 3M model 2223. The chest electrodes deserved special attention due to the possibility of committing a mistake when positioning them. A felt tip pen was utilized to mark the six positions of the electrodes on the chest.

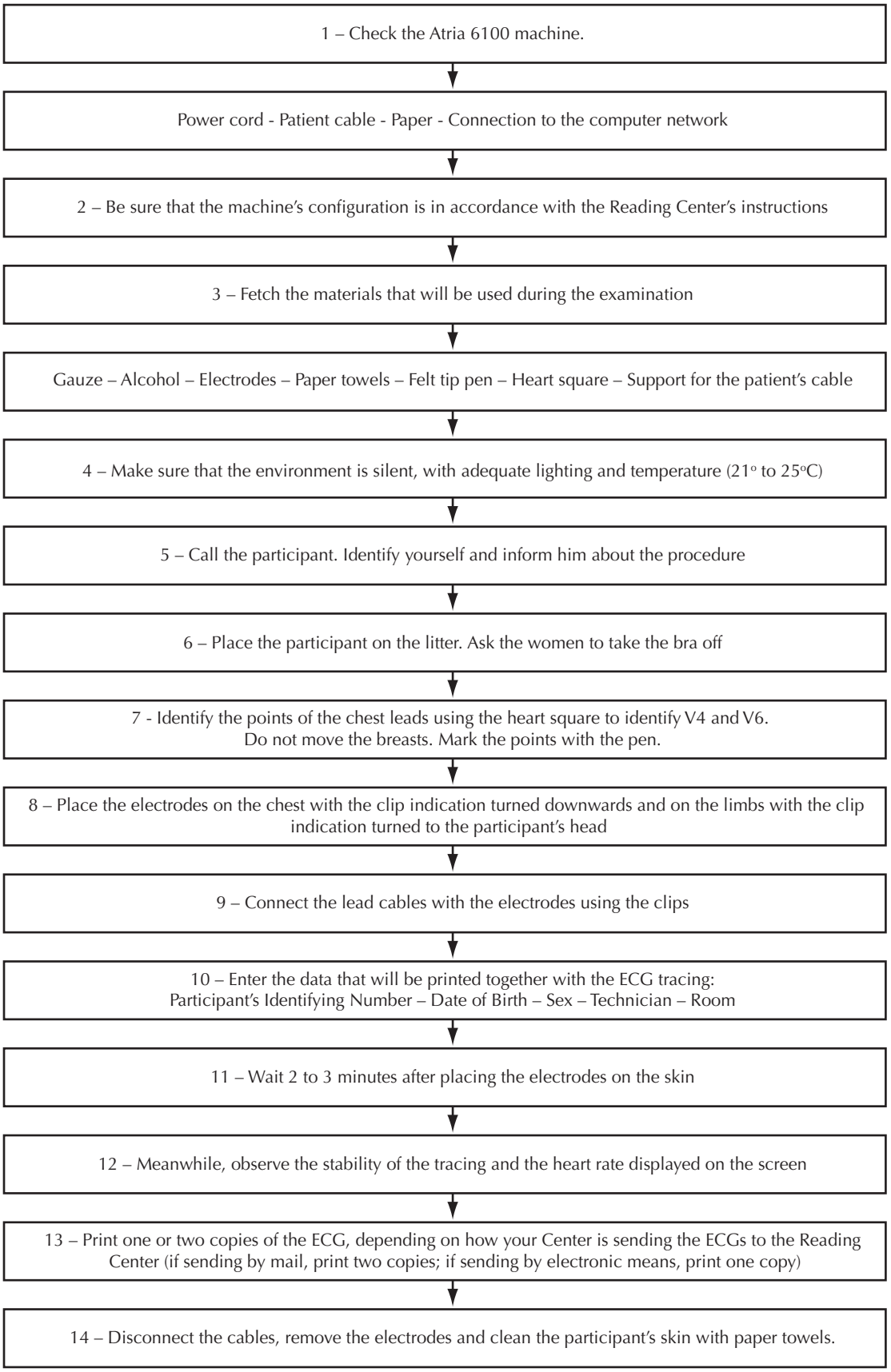

Figure. Routine to perform electrocardiograms in the ELSA-Brasil study.

To locate the V3 to V6 electrodes, a heart square was used, as it helps to standardize the positions.20 The electrodes' positions in women with large or pendulous breasts were determined in relation to the anatomical points, a procedure used in all the participants. Thus, the electrodes were placed on the breast (in the correct position).

- Electrode placement and cable connection. The four electrodes of the limbs were placed on the anterior region of the ankle or pulse, in areas with more subcutaneous tissue, avoiding bone surfaces. The six chest electrodes were placed on the chest marks without overlapping or contact between electrodes. The leads should not apply torsional strain to the electrodes. The cables were connected to record the ECG.
- ECG recording. It was performed in the electrocardiograph by means of a simplified procedure and the 12-lead tracing was printed on A4 paper.
- Transmission of the ECG to the Management and Storage Center, registering and checking the transmission.
- Storage and organization of the ECG at the Management Center for clinical assessment (to be returned to the participant) and coding, for the research purposes.

TRACE CODING SYSTEMS

The ECG coding system that is most frequently used in epidemiological and population-based studies, and also in clinical research, is the Minnesota Code.[3] Divided into classifications that are grouped into nine groups, with rigidly defined criteria, the code has undergone only a few modifications since its initial description.[19] A published manual that is already in its second edition aids in the code application, with detailed explanations about how to perform the measurements and obtain the final coding.[19] The Minnesota code has been used in the majority of the large epidemiological, population-based studies and its prognostic value is already established.[5,7,9,16,17,19,26,27] The Novacode classification system was developed from the Minnesota code, so as to be utilized in serial assessments, and since its conception it has been adapted to automated interpretation.[22,23] In many aspects Novacode is comparable to the Minnesota code, both in terms of the coding system[19] and concerning their prognostic impact.[26,27] The experience that has been accumulated with the Minnesota code, together with its greater simplicity, have made it become the standard coding system in modern epidemiological studies.

In recent years, advances in information technology and in the knowledge that has been acquired about automatic interpretation of the ECG have enabled the development of programs for the automatic coding of tracings through the Minnesota code.[11,12,14,19] Such methods have proved to be particularly attractive to be used in population-based studies, which started to have increasingly large samples. Comparisons between the manual and automatic methods have shown that automatic coding presents lower variability and greater accuracy and it has been recommended for epidemiological studies.[11,12,14,19]

At the CL-ECG, the automatic coding system developed at the University of Glasgow by Prof. MacFarlane[14] was adopted. The software was installed by Cardiac Science in the Pyramis system (version 6.2.b) available at the CL-ECG. The resulting codes were extracted and reviewed by secondary coders, to confirm the results. Next, the records were transferred to the ELSA-Brasil Datacenter. In 382 cases, there was a failure in the transmission of the ECG from the IC to the CL-ECG. In these cases, manual coding was performed at the University of Glasgow, under the supervision of Prof. MacFarlane.

ETHICAL AND PRACTICAL ASPECTS RELATED TO THE DELIVERY OF REPORTS

The literature documents the existence of a strong controversy about the pertinence and need of delivering test results to participants in epidemiological and clinical studies, and also about the way in which the results are delivered.[25] On the one hand, the majority of participants want to receive the results, which can be useful to the early diagnosis of treatable conditions. On the other hand, the meaning of asymptomatic alterations obtained through casual tests is questionable, even regarding established methods such as the ECG.[8,25]

The ELSA-Brasil decided to deliver tests and reports on complementary tests whose clinical use is established, such as the ECG. The reports were made by an experienced cardiologist and both the tracing and the report were delivered to the participants. The results were handed personally, by doctors or qualified health professionals, who provided explanations based on the report. In specific situations, the participant was advised to make an appointment with his/her private doctor in order to follow the propedeutics. In case the ECG result was normal and the participant wanted to receive the report at home, it would be sent by mail.

QUALITY CONTROL

Quality control is an essential aspect of the centralized reading of ECGs, as it guarantees the accuracy and reliability of the performed tests. Quality control at the

CL-ECG of the ELSA-Brasil included the following activities, based on recommendations found in the literature:[1,18,19,21,25]

- Training and certification of the electrocardiography technicians. An initial training with technicians and doctors from the ICs was carried out at the CL-ECG, and the Operations Manual was used as the basic text. The procedures were revised, with extensive practice at the use of the electrocardiograph. At the end of training, a theoretical and practice evaluation was performed. Certification was granted after the professional sent at least five high-quality ECGs. At each clinic, at least one professional was trained to certify new technicians. The local training and certification of professionals followed the program of the CL-ECG, utilizing classroom material and tests provided by the CL. Certification was renewed on an annual basis.

- Quality control procedures regarding the ECGs performed at the investigation centers. Each IC maintained a routine so as to guarantee the quality control of the obtained records. The local ECG technicians filled in the quality control form to each examined participant. The form included information on the use of the heart square, the positioning of the precordial electrodes, and the evaluation of trace quality, with a scale that ranged from 1 to 5 (1 = poor and 5 = excellent). Traces with scores < 3 were repeated. Every two weeks, the local supervisors monitored the performance of one ECG by the professional, using the step-by-step form as a checklist. Finally, the control of the transmission of the ECGs was performed through a weekly record of the ECGs sent by the Atria 6100 electrocardiographs to the Pyramis system. The list of sent ECGs was made by fax to be checked at the CL-ECG. The CL-ECG has spare electrocardiographs for the immediate replacement of defective equipment in the investigation centers.

- Quality control procedures of the CL-ECG. All the ECGs received by the CL-ECG were evaluated concerning the quality of the tracing and the possibility of misplacing the electrodes, especially among the limbs and among the precordial electrodes. In case of a trace of inferior quality or if there was the suspicion that the electrodes had been misplaced, the repetition of the record was requested. The control of the receipt of the tracings was also performed, ensuring that all the transmitted records were received and processed. Finally, the abnormal codes of the obtained and analyzed tracings were reviewed by medical coders.

DIFFICULTIES AND CHALLENGES

The process of creating the CI-ECG underwent a series of difficulties and challenges. We listed below some critical aspects of the creation of the CL, briefly discussing the difficulties.

- Choice of equipment. Although there are dozens of electrocardiograph brands available in the market, only a few devices present the technical characteristics that are adequate to the study, either due to strength and intrinsic characteristics, or because of the need of safe transmission of the tracings to an ECG management and storage center. There are few management and storage centers in commercial systems. The choice should also consider the existence and quality of distributors and technical assistance.

- Team formation. The CL-ECG team must be formed by professionals who have experience in clinical cardiology and electrocardiography, and also in epidemiology and management; good results, in turn, depend on the concatenation of clinical, epidemiological and administrative processes.

- Standardization of the procedure. Standardization is essential so that all the ECGs performed at the different centers have the same quality and can be compared. The routine must be described in detail in a specific manual and the entire team needs to be involved, with period training and certification. The inputs (for example, electrodes, paper) must also be standardized, guaranteeing the uniformity of the results.

- Choice of the coding methodology. Although the advantages of using the Minnesota Code are clear, manual coding is slow and laborious, and requires that coders are trained and experienced in it. This is only justified if the center has a large volume of tracings for coding. On the other hand, automatic reading requires specific analysis software, which is not available in the existing ECG management and storage systems. The practical and technical advantages of automatic reading (with or without *a posteriori* revision) favor the choice of this solution.[11,12]

- Delivery of the result. It is a critical stage, as it is necessary to delimit the conduct so as to meet the participant's demand for receiving the results, as well as to consider the occasional situations in which the test effectively indicates the need of quick medical attention. On the other hand, the risk of iatrogenesis caused by conducts that can be taken in view of an altered result, in the absence of symptoms and without any defined clinical meaning, should be minimized.

- Quality assurance. Quality control procedures should be incorporated into the daily practice, in order to avoid the loss of records and to guarantee the obtention of tracings that can be analyzed.

FINAL REMARKS

In the present study, we described the implementation of an ECG reading center in Brazil, discussing the difficulties and challenges that were faced. It is an original report, for as far as we know, there is no other reading center of academic nature in Brazil or in other Latin American countries that has followed the international recommendations for its implementation.

We would like to emphasize the utilization of a totally digitized system and the automatic coding of the ECGs through an internationally accepted protocol. The CL-ECG of ELSA-Brasil has become one of the few centers in the world that has a software that allows automatic coding by the Minnesota code, guaranteeing that its results are reliable and ensuring comparability with studies carried out in other parts of the world. The results of the ECGs analyzed in the baseline by the ELSA-Brasil study will enable to define the reference parameters for the Brazilian population, the study of the relationship between cardiovascular risk factors and prevailing diseases – such as hypertension – and ECG alterations in the Brazilian population. As the ECG will be repeated in the subsequent waves of the ELSA study, the results will help to understand the natural history of cardiovascular diseases in the Brazilian population.

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