Developing a cooperative multicenter study in Latin America: Lessons learned from the Latin American Study of Nutrition and Health Project

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ABSTRACT
This report examines the challenges of conducting a multicenter, cross-sectional study of countries with diverse cultures, and shares the lessons learned. The Latin American Study of Nutrition and Health (ELANS) was used as a feasibility study involving the most populous cities of eight countries in Latin America (Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Peru, and Venezuela) in 2014–2015, about 40% of the population of the Americas. The target sample included 9 000 individuals, 15–65 years of age, and was stratified by geographic location (only urban areas), gender, age, and socioeconomic status.

Six principal challenges were identified: team structuring and site selections; developing a single protocol; obtaining ethics approvals; completing simultaneous fieldwork; ensuring data quality; and extracting data and maintaining consistency across databases. Lessons learned show that harmonization, pilot study, uniformity of procedures, high data quality control, and communication and collaboration across sites are imperative. Barriers included organizational complexity, recruitment of collaborators and research staff, institutional cooperation, development of infrastructure, and identification of resources. Consensus on uniform measures and outcomes and data collection methodology, as well as a plan for data management and analysis, communication, publication, and dissemination of study results should be in place prior to beginning fieldwork. While challenging, such studies offer great potential for building a scientific base for studies on nutrition, physical activity, and other health topics, while facilitating comparisons among countries.

Keywords
Multicenter study; nutritional surveillance; nutrition surveys; Latin America.
Growing interest in community-based public health and policy interventions that reduce obesity and improve nutrition has prompted multicenter studies to understand population-based behaviors and outcomes. In contrast to multi-site studies whose main purpose is to obtain a larger sample, multicenter studies are designed jointly by Principal Investigators (PIs) at all sites. This means that all are involved in planning the study protocol and procedures, are scientifically responsible for the study results, and participate actively in manuscripts and other dissemination activities. These studies have been increasingly valued due to large sample sizes, ability to explore differences across sites, and the increased generalization of results (1). Multicenter collaborations also allow recruitment of more diverse populations, within a much shorter time frame. While challenging, such studies offer great potential for building a scientific base for the study of obesity and for planning health policies and intervention programs. However, such studies require heightened attention to detail, simultaneity, comprehensive planning, and collaboration with colleagues (2).

Several large, multicenter, observational studies have been conducted to investigate the nutritional and physical activity status of various populations (3 – 6). The majority of these studies have been performed separately by each country and unified later. In most cases, differing methodologies were used to assess food consumption and physical activity, or samples of each country were not representative of specific populations. In Latin America, few studies have been conducted that represent the reality of each country and region.

The Latin American Study of Nutrition and Health (ELANS), however, is a cross-sectional, multicenter study, that was conducted simultaneously in the urban populations of the most populous cities of eight countries in Latin America. This paper highlights the principle lessons learned from the ELANS, including the key decisions, challenges and barriers, and logistical strengths and limitations encountered during the design process, data collection, and data entry.

SURVEY METHODOLOGY

ELANS is a household-based, multinational, cross-sectional survey that aims to describe the nutritional status of people in Latin America and to investigate food and nutrient intake, as well as physical activity levels among representative samples of urban populations. The total population of the eight study countries—Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Peru, and Venezuela—represents about 40% of the population of the Americas. The target sample included 9,000 individuals, 15 – 65 years of age, and was stratified by geographic location (only urban areas), gender, age, and socioeconomic status. The rationale and design of the study are reported in more detail elsewhere (7). In brief, the ELANS protocol was designed to collect data at the individual level using questionnaires (sociodemographic, dietary intake, and physical activity) and objective measurements (accelerometry and anthropometry).

CHALLENGE 1: STRUCTURING A TEAM AND SELECTING SITES

Selected ELANS countries differed in demographic and some socioeconomic indicators, reflecting the differences present in Latin America (Table 1).

Key factors in the ELANS project implementation were the selection of team members and the inclusion of multidisciplinary professional, technical, and scientific advisors with complementary expertise in epidemiology, energy balance, physical activity, and statistics. PIs were selected based on their ability to conduct epidemiological studies (investigator fieldwork experience, research background, and academic support structure for research) and diversity of geographic location in Latin America.

All of the academic/research teams were composed of researchers, undergraduates, and postgraduate health science students based in universities or in association with universities, with the exception of one based at a research institute (Table 2). The organizational structure had three branches: academic team, technical support team (physical activity and food intake assessment, anthropometrics), and operational team (Figure 1). The organizational structure of the ELANS was defined during the first design meetings among the researchers, including the scope of the study, the complexity of communications, and what agreements would have to be reached. The study management and quality control strategies are described elsewhere (7).

It is important to highlight that project coordination was centralized in an international team composed of two chairpersons, a co-chair, and two international project managers. This centralized approach ensured that any barriers that arose would be resolved rapidly, that communication among all teams would be effective, and that research uniformity would be maintained. By bringing together expert researchers in the field of physical activity and statistics, the

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**TABLE 1. Site characteristics of the eight countries participating in the Latin American Study of Nutrition and Health, 2013 - 2014**

| Argentina | Brazil | Chile | Colombia | Costa Rica | Ecuador | Peru | Venezuela |
|-----------|--------|-------|----------|------------|---------|------|-----------|
| Population size* | 43 132 000 | 205 620 000 | 18 006 000 | 48 584 000 | 4 832 000 | 16 205 000 | 30 814 175 | 30 620 000 |
| Urban population% | 92% | 85% | 89% | 76% | 76% | 64% | 76% | 89% |
| GDP$ | 12 509 | 11 384 | 14 528 | 7 903 | 10 415 | 6 345 | 6 541 | 12 771 |
| GINI Indexa (22) | 42.3 | 52.9 | 50.5 | 53.5 | 49.2 | 47.3 | 44.7 | 46.9 |
| Obesity in adultsb | 26.3% | 20% | 27.8% | 21% | 24.3% | 18.7% | 21.1% | 24.8% |

*Source: Prepared by the authors based on the study literature.

*Census reports from the country’s national statistical offices.

*Percent of the country’s total population (22).

*Gross Domestic Product per capita in current US$ (23).

*Measure of statistical dispersion, intended to measure the distribution of wealth in a country (21).

*Body Mass Index > 30 (24).

*World Bank 2012; all others, 2014.

*2006; all others, 2013.
ELANS gained greater detail and depth. Additionally, an external advisory board experienced with similar epidemiological studies provided decision-making guidance required to continue moving the project forward.

Lessons learned:

(a) A collaborative, multidisciplinary team of experts with extensive scientific experience and effective communication tools is essential.

(b) Supervision by an international team is crucial. The appointment of an experienced and proactive coordinating investigator to mentor and counsel other sites ensures consistency and support where it is needed.

(c) Designating/assigning an international project manager who provides overarching communication and can ensure issues are quickly detected and measures are continuously improved.

CHALLENGE 2. DEVELOPING AND IMPLEMENTING A SINGLE STANDARDIZED PROTOCOL

At the start, when the decision to collect common data across the sites was made, it became apparent that a single protocol and a uniform set of data

| Study name | Argentina | Brazil | Chile | Colombia | Costa Rica | Ecuador | Peru | Venezuela |
|------------|-----------|--------|-------|----------|-----------|--------|------|-----------|
| Estudio Argentino de Nutrición y Salud | Estudo Brasileiro de Nutrição e Saúde | Estudio Latino Americano de Nutrición y Salud-Chile | Estudio Latino Americano de Nutrición y Salud-Colombia | Análisis del balance energético y factores de riesgo de obesidad en la población costarricense | El estudio del balance energético de una muestra poblacional, Ecuador | Estudio Latino Americano de Nutrición y Salud-Perú | Estudio Latino Americano de Nutrición y Salud-Venezuela |
| Type of institution | Research institution and university | Private children's hospital and federal university | University | University | University | University | Research institution | Research institution and university |
| Number of researchers on team | 7 | 7 | 10 | 5 | 3 | 3 | 12 | 12 |
| Number of cities evaluated | 12 | 23 | 9 | 11 | 7 | 9 | 10 | 13 |
| Participants (total; accelerometer) | 1 200; 319 | 2 000; 569 | 870; 308 | 1 230; 405 | 790; 282 | 800; 268 | 1 100; 360 | 1 134; 368 |
| Administration mode | Tablet | Tablet | Tablet | Tablet | Tablet | Paper | Tablet | Paper |
| Fieldwork period | October 2014 – July 2015 | October 2014 – July 2015 | September 2014 – July 2015 | October 2014 – July 2015 | November 2014 – July 2015 | September 2014 – May 2015 | March 2015 – February 2016 |
| Number of fieldwork interviewers | 45 | 40 | 25 | 42 | 13 | 22 | 36 | 36 |

Source: Prepared by the authors based on the project survey.
collection tools would be required. The process of creating a single protocol involved 15 months of collaborative work with in-person meetings and conference calls with the PIs. All decisions were guided by scientific evidence and fieldwork logistics. The advice from experienced external advisors with differing expertise was important.

Considering the large number of sites, eight in this case, a tools standardization process was developed to ensure equal standards for data collection (8) at every site. The choice of dietary method used in the ELANS was based on existing survey studies, such as NHANES (9) and HELENA (3), as well as the experience of some of the PIs. Repeated 24-hour recalls (24hr) are considered useful tools in providing national- and group-level estimates of usual dietary intakes of individuals, as well as in describing usual intake distributions of populations, using appropriate statistical approaches and controlling for intra-individual variability.

The standardization of procedures for 24hr administration and analysis was necessary to ensure equivalence of the dietary outcomes across participating centers. The Multiple Pass Method (10) was unanimously chosen. All PIs agreed to use the Nutrition Data System for Research software (Minnesota University, Minneapolis, Minnesota, United States; NDSR) to allow ELANS inter-country comparisons. An extensive process of harmonization was initiated, as described elsewhere (11).

The International Physical Activity Questionnaire has been validated in countries of Latin America; however, the Mexican (Spanish) version, (12) adapted by the International Study of Physical Activity and Built Environments was selected for use after cultural adaptations for wording and examples (13, 14).

The objective measure of physical activity was a crucial aspect of the ELANS that provided accurate estimates of physical activity and energy expenditure in this Latin American population. Due to logistic and financial matters, efforts were made to ensure that a range of 25% – 40% of each sample would wear the accelerometer for 7 days.

A major concern was that all sites should use the same or equally-reliable equipment validated by previous studies. It is noteworthy that the PIs faced many problems with the purchase of imported equipment (e.g., accelerometers, scales, stadiometers). Due to customs and mail delivery problems, all sites had to delay the start of the fieldwork.

The socioeconomic questions used in ELANS were designed based on questionnaires used by each national statistics office, or otherwise used most frequently by each country (15 – 20). Due to differing variables used across countries to determine Socioeconomic Levels (SEL), a rule was developed to equate the different classification systems of the eight countries (Table 3). Based on this, three levels of classification were established for SEL and included equivalent characteristics for all countries: high, medium, and low. The same procedure was performed to establish equalization across levels of educational in the eight countries, and also resulted in three classifications: primary to incomplete secondary schooling; complete secondary to incomplete higher/tertiary education (technical/university); and complete higher education (technical/university).

### TABLE 3. Socioeconomic and educational level equalization between eight countries participating in the Latin American Study of Nutrition and Health, 2016

| Socioeconomic level* | Argentina | Brazil | Chile | Colombia | Costa Rica | Ecuador | Peru | Venezuela |
|----------------------|-----------|--------|-------|----------|------------|---------|------|-----------|
| High                 | A, B, C1  | A1, A2, B1 | A, B, C1 | 5 / 6 | A, B, C1 | A, B | A | A, B, C+ |
| Medium               | C2, C3    | B2, C   | C2, C3 | 3 / 4 | C2, C3 | C+ | B | C |
| Low                  | D1, D2    | C2, D, E | D, E   | 1 / 2 | D1, D2 | C+, D | D | D, E |

#### Educational level

- **Primary – incomplete secondary schooling**
  - Illiterate
  - Complete or incomplete primary
  - Incomplete secondary

- **Complete secondary – incomplete higher/tertiary education**
  - Complete secondary
  - Incomplete tertiary
  - Incomplete university

- **Complete higher education**
  - Complete tertiary
  - Complete university
  - Post-graduate

*Classifications according to those provided by National Institutes of Statistics of each country.

Source: Prepared by the authors based on the project survey.
Lessons learned:

(a) Input from local teams is essential during protocol development and planning of field work to ensure achievable goals.

(b) Developing a feasible and realistic protocol may be more difficult than first expected. Standardization and harmonization of foods in software require extensive and innovative work. The use of accelerometers requires caution, as compliance is difficult to achieve. Measurement and definitions of socioeconomic status and educational level across countries require close attention to ensure comparability.

(c) Equipment availability and procurement in different countries requires prior planning and ample time. Possible delivery delays and customs tariffs should be included in the schedule and budget.

CHALLENGE 3. OBTAINING ETHICS APPROVALS

The process for ethical reviews and timeframes for obtaining approvals vary greatly among countries. To address this challenge and to reduce the burden of conducting multiple local ethics reviews, an external institutional review board (IRB) was selected to perform a centralized review of the protocol, the informed consent template, and other study documents. In this case, Western IRB (WIRB, Puyallup, Washington, United States) was chosen as an independent international organization. However, to obtain WIRB approval, each site also had to submit the protocol and informed consent through a local IRB. After approval of local IRBs, ELANS received WIRB approval.

Lesson learned:

(a) Obtaining ethics approvals for a multicenter study must be carefully planned and, preferably, centralized, with extra time allotted for reviews at multiple levels.

CHALLENGE 4. ACCOMPLISHING SIMULTANEOUS FIELDWORK

During the common protocol design, the complexity of the logistics—a large number of interviewers performing field data collection simultaneously at differing sites—it became apparent that a standardized and uniform application of questionnaires and measurements was needed. These led to the decision to use a Contract Research Organization (CRO) with offices in all eight countries involved in ELANS. This CRO was responsible for all participant sampling and recruitment and data collection and entry, except for dietary recalls, which were managed by each local institution. All procedures were continuously monitored by the international team, and a weekly meeting of PIs was held throughout the fieldwork.

Frequent contact with field supervisors was necessary to ensure quality data collection. At the start, there were many mistakes due to the interviewers’ lack of experience; later, there seemed to be less attention to detail. To accomplish the data collection on time, local interviewers were hired and trained to work in different parts of each country simultaneously. Interviewers with previous health research experience produced better quality interviews. Faster fieldwork was experienced in some countries, such as Chile, where interviewers were health science students.

Standardized training and operating manuals were designed for use in all countries; however, revisions by the international team were made on an as-needed basis to ensure equivalent measures, described elsewhere (7). Three operating manuals provided well-structured guidance for interviewers on anthropometric measurements, dietary intake recalls, and accelerometer use and preparation. A fourth operating manual was designed to ensure proper use of the NDSR software by researchers working with the dietary data. The interviewers’ work was continuously supervised during the data collection period.

To ensure functionality of data collection procedures, a pilot study was performed before fieldwork began. It tested the tools and accompanying procedures at all the sites and identified performance differences across them (8). One of the main difficulties during the pilot study was a refusal to participate, due to time constraints, lack of interest, or fear of strangers. To overcome this, several strategies were used: leaflets on the ELANS project were distributed in the neighborhoods prior to selection of households; interviewers showed an official identification badge to prospective participants and wore an identifying apron; and during the first visit, an informative letter, including the researchers’ contact information, was provided to each participant. Other issues identified during the pilot study were discussed and corrected, as needed.

Lessons learned:

(a) A pilot study is important to ensuring feasibility, efficiency, and adherence to protocols and procedures. Although it delayed the study start, the pilot proved to be important in preventing measurement errors and improving participant compliance.

(b) Thorough training is fundamental for interviewers and ample time should be allotted for this purpose. Interviewers with experience or training in health sciences are preferable.

(c) Continuous supervision of interviewers’ tasks is critical for maintaining the data quality of the fieldwork.

(d) A good relationship and open communication between the academic/research team and the CRO are key to conducting efficient supervision and monitoring procedures.

CHALLENGE 5. ENSURING DATA QUALITY

Data reliability and credibility are essential to the success of ELANS. Threats to data quality were identified during the protocol design process, the pilot study, and the first weeks of the fieldwork. Thus, the coordinating investigators/chairs proposed adopting procedures in all sites to ensure high-quality data and reliable information. These included preparatory meetings; detailed operating manuals; site visits; and concurrent query management and fieldwork supervision; partial database generation; inconsistency checks of anthropometric, physical activity, and food intake data; and when possible, a return visit to the participant’s household to correct unclear, incomplete, or questionable responses.

Monthly, each center sent information on the status of interviews, entry of 24-hr food records in NDSR, and the accelerometer files, plus reported any
difficulties or impediments to the coordinating center. It is worth noting that considerable effort went into food-matching between local foods/recipes and the foods available in the NDSR database, as described by Kovalskys and colleagues (11).

Lessons learned:

(a) Maintaining regular, study-wide communication among PIs, the CRO, and the accelerometer, nutritional, and statistical centers is critical to data quality.

CHALLENGE 6. EXTRACTING DATA AND DATABASE CONSISTENCY

In all countries, except Ecuador and Venezuela, the CRO had computer tablets available for data collection. When the electronic form was created, internal consistency checks were already programmed into the software to alert the interviewers to outliers and other issues during real-time data entry.

Throughout the fieldwork, data quality-control was carried out periodically.

The types of inconsistencies that were found led the team to develop a second phase of consistency-checking post data collection. Each academic/research site team was responsible for this second phase. A specified procedure was used to detect possible errors of data consistency before the generation of each final database (Figure 2). All data collected were simultaneously reviewed by the CRO, the accelerometer center and its Physical Activity consultant team (PA), and each academic/research site team. The PA consultants and each academic/

FIGURE 2. Flowchart for fieldwork closure in the Latin American Study of Nutrition and Health, 2016

![Flowchart](image)

Source: Prepared by the authors based on the project survey.

* Physical activity.
* Control Research Organization.
* Subject identification.
* Database.
Lessons learned:

(a) Extensive expertise in dietary assessment among the researchers is important because this sensitive part of the data collection required the greatest number of corrections to inconsistencies.

(b) Data cleaning demands close attention to detail and collaboration of multiple stakeholders.

(c) Correct use of accelerometers relies on thorough interviewer training so that they can, in turn, effectively instruct participants. Timely delivery of data to the PA team by the CRO is needed for corrections to be made. A 70% accelerometer compliance rate should be taken into account, with fewer valid versus measured cases in the final sample.

(d) A data analysis and publication plan that ensures appropriate data management and dissemination must be developed with input from all team members and be followed meticulously through the end of the study.

FINAL CONSIDERATIONS

The development of a multicenter household cross-sectional survey of the nutritional and physical activity status of adolescents and adults in eight countries of Latin America was an innovative and fundamental step toward better understanding behaviors and their relationship to health in the region. This survey contributed to several lessons learned regarding the organization of a multicenter study. The feasibility of performing such a study depends on many considerations, including standardization of data collection, maintenance of high data quality, and collaboration across sites. Among the greatest barriers to conducting studies such as this one are the inherent organizational complexity, recruitment of collaborators and research staff, institutional cooperation, development of infrastructure, and identification of resources. By implementing the various strategies detailed, this project overcame various challenges to ensure the integrity of its cross-site data collection.

The entire research team at each participating center and the coordinating center—the PIs, local investigators, consultants, coordinators, research assistants, data managers, system analysts, statisticians, network managers, and accountants—proved to be essential to study development and performance. Ideas and solutions, as well as planning for analysis and interpretation of results, arose naturally when coming from a team thinking and working together. The institutions involved all benefited from the exchange of knowledge among researchers, the equipment acquisitions, the use of internationally-recognized methodology, and wider study dissemination.

Multicenter cooperative studies while challenging, offer great potential for building a scientific base for studies on nutrition and health. Considering the methods and experience of other multicenter studies while developing the study design of the ELANS was important for surmounting possible obstacles and allowing faster progress. To this end, the lessons learned during ELANS provide new perspectives for better planning of financial, staff, and technological resources for similar future studies.

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RESUMEN

En este informe se examinan los retos de llevar a cabo un estudio transversal multicéntrico en países con culturas diversas y se transmiten las enseñanzas extraídas. Se usó el Estudio Latinoamericano de Nutrición y Salud (ELANS) como un estudio de factibilidad realizado en el período 2014–2015, que incluyó las ciudades más pobladas de ocho países de América Latina (Argentina, Brasil, Chile, Colombia, Costa Rica, Ecuador, Perú y Venezuela) y abarcó a cerca de 40% de la población de la Región de las Américas. La muestra establecida incluyó a 9 000 personas de 15 a 65 años de edad, y fue estratificada según la ubicación geográfica (solo zonas urbanas) y por sexo, edad y situación socioeconómica.

Se encontraron seis retos principales: estructurar los equipos y seleccionar los sitios; preparar un protocolo único; obtener las aprobaciones éticas; terminar simultáneamente el trabajo sobre el terreno; velar por la calidad de los datos y extraer datos y mantener la uniformidad en todas las bases de datos. Las enseñanzas extraídas muestran que la armonización, los estudios piloto, la uniformidad de los procedimientos, el riguroso control de la calidad de los datos y la comunicación y colaboración entre todos los sitios son imperativos. Los obstáculos incluyeron la complejidad de la organización, el reclutamiento de colaboradores y personal de investigación, la cooperación institucional, el desarrollo de infraestructura y la definición de los recursos. Antes de comenzar el trabajo sobre el terreno, se debe llegar a un consenso acerca de mediciones y resultados uniformes y la metodología de recopilación de datos, así como un plan para la gestión y el análisis de los datos y la comunicación, publicación y difusión de los resultados del estudio. A pesar de que estos estudios constituyen un desafío, hacen posible establecer una base científica para los estudios sobre la nutrición, la actividad física y otros temas de salud, al facilitar las comparaciones entre los países de América Latina.

Palabras clave

Estudio multicéntrico; vigilancia nutricional; encuestas nutricionales; América Latina.
RESUMO

Elaboração de estudo cooperativo multicêntrico na América Latina: ensinamentos do Projeto do Estudo Latino-americano de Nutrição e Saúde

Neste relato se examinam os desafios de realizar um estudo transversal multicêntrico em países com culturas diversas e os ensinamentos tirados. O Estudo Latino-americano de Nutrição e Saúde (ELANS) serviu de estudo de viabilidade, englobando as cidades mais populosas de oito países da América Latina (Argentina, Brasil, Chile, Colômbia, Costa Rica, Equador, Peru e Venezuela) em 2014–2015, representando cerca de 40% da população das Américas. A amostra pretendida compreendeu 9.000 indivíduos com 15 a 65 anos de idade e foi estratificada por localização geográfica (exclusivamente áreas urbanas), sexo, idade e nível socioeconômico.

Os seis principais desafios identificados foram: estruturar as equipes e selecionar as sedes, elaborar um único protocolo, obter as aprovações dos comitês de ética, realizar trabalho de campo simultâneo, assegurar a qualidade dos dados e extrair os dados e manter a consistência em todas as bases de dados. Os ensinamentos tirados demonstram serem imprescindíveis harmonização, estudo-piloto, uniformidade dos procedimentos, ótimo controle da qualidade dos dados e comunicação e colaboração entre as sedes. Entre as barreiras estão a complexidade organizacional, recrutamento de colaboradores e pessoal de pesquisa, cooperação institucional, desenvolvimento de infraestrutura e identificação dos recursos. Antes do início do trabalho de campo, deve-se chegar a um consenso sobre medidas e resultados uniformes e metodologia de coleta de dados assim como um plano para o gerenciamento e análise dos dados, comunicação, publicação e disseminação dos resultados dos estudos. Apesar da sua complexidade, tais estudos têm um grande potencial de fundar uma base científica para estudos de nutrição, atividade física e outros tópicos relacionados à saúde, ao mesmo tempo que facilitam comparações entre os países da América Latina.

Palavras-chave: Estudo multicêntrico; vigilância nutricional; inquéritos nutricionais; América Latina.