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Methodological description and preliminary results of a cohort study on the influence of the first 1,000 days of life on the children's future health

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ABSTRACT

The aim of this report is to describe general and methodological characteristics of a cohort study in southern Brazil (*Coorte Brasil Sul*), aimed at understanding the impact of the first 1,000 days of life on children's health. It is a cohort study involving all children born in 2009 and their families living in the municipality of Palhoça, State of Santa Catarina, Brazil. Face-to-face interviews with parents at home using a structured questionnaire and children's physical and clinical examinations at schools have been carried out. Cross-sectional analyzes, longitudinal comparisons and hierarquical regression analysis will allow understanding if the first 1,000 days of life can influence on 6-year-old children's health. The *Coorte Brasil Sul* is in its retrospective phase together with the children's physical data collection. Preliminary data (n=1270) related to nutritional status point to a high prevalence of overweight (16.4%) and obesity (15.5%). With the continuity of the study, it is expected to evaluate if the first phases of life can influence health during adolescence and in adult life, mainly in relation to chronic diseases.

Key words: Health surveys, cohort studies, social determinants of health, child health.

INTRODUCTION

Children's cognitive and physical development is influenced by the first 1,000 days of life, which comprises the nine months of pregnancy plus the first two years after birth (Fall et al. 2013, Cunha et al. 2015). During this period, biological, behavioral and socioeconomic factors may influence children's growth and development and may cause future damage or benefits for their health (Kattula et al. 2014). Understanding the complex interaction between these factors is essential, allowing health policy planning and prevention programs that can reflect in adult life (Black et al. 2013).

Longitudinal studies are appropriate designs to investigate outcomes related to life course, exploring the interaction between social, environmental, biological and behavioral aspects involved in the onset and development of various outcomes, especially chronic diseases (Kuh et al. 2003). Thus, cohort studies allow unraveling the mechanisms and the web of relationships that link socioeconomic, gestational and environmental factors to late changes that can lead to illness or increased risk of its occurrence (Sichieri et al. 2008).

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The cohort study (named *Coorte Brasil Sul*) presented in this article is grounded on theories claiming that experiences during pregnancy, childbirth and early stages of life will determine children's health- and disease-related processes and can affect adults' health later. In order to better understand the interaction between children's health determinants, this cohort study sought inspiration from Barker's Theory (Barker 1998, Barker et al. 2010, Eriksson et al. 2010), Life Course Theory (Kuh and Ben-Shlomo 2004, Blane et al. 2007, Kuh et al. 2014), Theory of Fundamental Causes (Link and Phelan 1995, Phelan et al. 2004, 2010) and the first 1,000 days of life approach (Wadsworth 1997, Bathia et al. 2013, Black et al. 2013, Kattula et al. 2014) to support and consolidate the hypotheses that are under investigation.

Barker's theory holds that events in intrauterine period or early days in life have long-term effects on morbidity and mortality from chronic diseases. Nutritional and environmental conditions during intrauterine life and childhood would program risks for heart disease, hypertension, diabetes and increased cholesterol among other disorders, in adults (Barker 1998).

Life course theory directs attention to accumulation of risks during life, without refuting Barker's assumptions. According to this theory, chronic diseases result from environmental, social and behavioral cumulative risks during life span (Kuh and Ben-Shlomo 2004). Adverse childhood conditions contribute to increased risks of chronic diseases in adult life (Wadsworth 1997, Kuh et al. 2003, Kuh and Ben-Shlomo 2004). It emphasizes the interaction between biological and social factors in different phases of life rather than the current lifestyle. It focuses both on biological and psychosocial factors at certain critical stages of life. Biological factors including low birth weight and growth in poor socioeconomic circumstances in early childhood are examples of possible influences on certain health-related behaviors in adulthood (Bartley et al. 1997).

The theory of fundamental causes, in turn, associates socioeconomic status to various health outcomes that may change over time (Link and Phelan 1995). It assumes that availability of educational and financial resources and access to services, for example, influences health-disease determination, increasing or decreasing either risks or protective factors (Wadsworth 1997).

The approach that focuses on the first 1,000 days of life emphasizes that nutrition during the fetal period and the first 24 months after birth are important determinants of development during early childhood (Fall et al. 2013). It also suggests that nutritional deficit during this period is associated with a number of consequences throughout the life cycle, such as cognitive development and reduced school performance, loss of economic productivity, and increased risk of chronic diseases (Black et al. 2013).

Grounded on these theories, the *Coorte Brasil Sul* started in 2015 in the municipality of Palhoça, State of Santa Catarina, Brazil. The aim of this article is to describe general and methodological characteristics of the *Coorte Brasil Sul* study and some preliminary results.

METHODS

An overview of the methodological approach is shown in Figure 1. The breakdown of topics includes the following topics.

TYPE OF STUDY, LOCATION AND POPULATION

It is a cohort study involving schoolchildren and their families living in Palhoça, State of Santa Catarina, Brazil. The retrospective phase has provided data for the first 1,000 days of children's life. The first follow-up has collected data from 6-year-old children enrolled in the first year of elementary school. Subsequent follow-up studies on the same population will be conducted every three years.

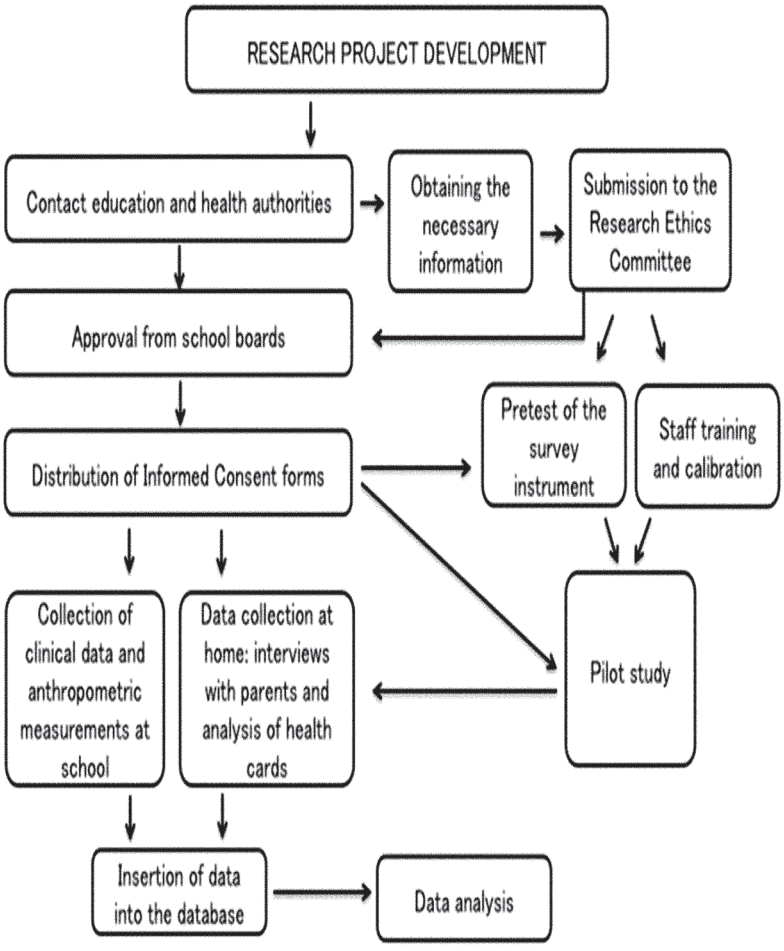

Figure 1 - Synthesis of the methodological approach.

The municipality of Palhoça, which is part of the greater Florianópolis area, is located 14 km from the state capital of Santa Catarina. The 2017's estimated population is 164,927 inhabitants, of whom 98.5% living in urban area. The municipality covers an area of 395.1 km^2 and the population density is 347 inhabitants/km^2 (IBGE 2017). The Human Development Index (HDI) is 0.757, ranking the municipality 43rd in Santa Catarina and 420th in the country. The education component had the lowest HDI scores (PNUD 2017). Palhoça experienced a strong colonization of Azorean origin, and the main productive sectors are services and industry.

The study population consists of all children born in 2009 and their families, regularly enrolled in the first year of elementary public and private schools in the city. A preliminary survey was conducted in 37 public and 19 private primary schools of Palhoça to locate the study population.

The minimum sample size required to reach 80% power to detect a difference of 5% in the incidence of various health outcomes studied - 15% exposed and 10% non-exposed subjects to a less favorable biological and socioeconomic situation during the first 1,000 days of life - which generates a harzard ratio of 1.5 at a significance level of 0.05 was 1,444 students. A 20% addition was made for possible losses and refusals, which resulted in a total sample of 1,733 students. As the calculated sample size was similar to the total of first year of elementary school students, it was decided to

perform a census. In this way, this census covered two generations, given that information was gathered from both the children and their mothers (or primary caregivers). Thus, the study population consisted of 1,756 children and their mothers or caregivers.

SENSITIZATION STRATEGIES TO IMPROVE PARTICIPATION IN THE STUDY

The following strategies were undertaken for raising awareness about the importance of this study: a) to call attention to non-communicable chronic diseases and highlight the importance of the first 1,000 days of life for a healthy development; b) to divulge the project among the community, encouraging citizens to participate in the study; c) to disseminate the specialized health services provided by the Universidade do Sul de Santa Catarina; d) to engage the Municipal Health Service in different actions such as the promotion of refresher courses for physicians, dentists, community health agents and other health professionals, covering topics of this study.

Local radio stations, newspapers and other available media were used to disseminate information and call for participation. Meetings were held with community leaders and authorities such as the Municipal Secretaries of Health and Education.

DATA COLLECTION, OUTCOMES AND INDEPENDENT VARIABLES

Data collection was conducted through interviews, documentary reports, and physical and clinical examinations of children. Interviews were carried out with children's mothers or, in their absence, with primary caregivers. Documentary data were extracted from children's health cards and medical records in the Basic Health Units. Physical and clinical examinations of children were performed in schools.

An interview questionnaire was designed to collect information relating to the first 1,000 days of life, child life course and current status. The instrument was developed by a committee composed of 3 PhDs and 5 doctoral students of the Postgraduate Program in Health Sciences of Universidade do Sul de Santa Catarina. Considering the outcomes studied and based on the theories that support the *Coorte Brasil Sul* study, the instrument consisted of 9 sections and 211 questions. The sections are identified in Table I. A pre-test study was conducted on 18 families from other municipalities with children aged 6 and 7 years. As a result, minor adjustments were required to facilitate questionnaire administration, as well as to improve understanding by interviewees.

A clinical and epidemiological chart was prepared to collect physical and clinical data from schoolchildren, mainly related to oral health and anthropometric measures. Weight and height were measured by using a digital scale and a stadiometer, according to recommendations of the Brazilian Ministry of Health (Ministério da Saúde 2002). Body mass index were calculated according to standards of the World Health Organization (WHO 1995). In oral examination, information about dental caries, malocclusion, dental trauma, enamel defects and oral breathing were collected, according to internationally established criteria (WHO 2013). The independent variables of the study are indicated in Figure 2 in levels 1 to 4. The dependent variables, in levels 5 and 6 of the same Figure.

FIELD TEAM TRAINING FOR DATA COLLECTION AND QUALITY CONTROL

The application of questionnaires in the homes is being carried out by a team of researchers assisted by community health agents of the municipality of Palhoça, who underwent a training process with 30 hours/activities. The training focused on data collection strategies in epidemiological studies,

TABLE I
Sections and information covered by the survey instrument.

SECTIONS		INFORMATION COLLECTION
Section A	General conditions of children's health and family history	- Infectious/chronic diseases - Use of medications - Family history of allergic diseases
Section B	Oral health status of children	- Hygiene habits - Infant sucking habits - Mouth breathing - Dental trauma - Dental-related pain - Oral health perception
Section C	Eating habits	- Breastfeeding - Nutrition standard in early years - Sugar consumption
Section D	Childbirth-related conditions of mothers	- Maternal demographics - Diseases during pregnancy - Use of tobacco/alcohol/drugs during pregnancy - Prenatal consultations - Childbirth complications
Section E	Study of allergic diseases	ISAAC questionnaires*: - Module 1 - asthma - Module 2 - rhinitis - Module 3 - eczema
Section F	Environment	- Household environmental conditions during pregnancy and current period
Section G	Socioeconomic conditions of the family at child's birth	- Parents' occupation - Parents' education level - Type of household - Basic sanitation - Income household
Section H	Childbirth-related conditions	- Child's health card data - Diseases/complications after birth
Section I	Children's physical activity	- Brazilian version of the Netherlands Physical Activity Questionnaire**

* International Study of Asthma and Allergies in Childhood (1992).
** Bielermann et al. (2011).

emphasizing the interview processes in order to minimize possible measurement biases.

Seven teams of dentists and assistants were selected for the collection of clinical data on oral health status. A nutritionist performed weight and height measurements. These teams underwent a calibration process with 12 hours/activities to assess inter- and intra-examiner reliability (Peres et al. 2001). Instruction manuals were provided to assist the field team in data collection process. The study included supervisors from the Postgraduate Program in Health Sciences of Universidade do Sul de Santa Catarina, who provided the field team with training, calibration and supervision.

Detailed protocols have been developed for each phase of the research to standardize data

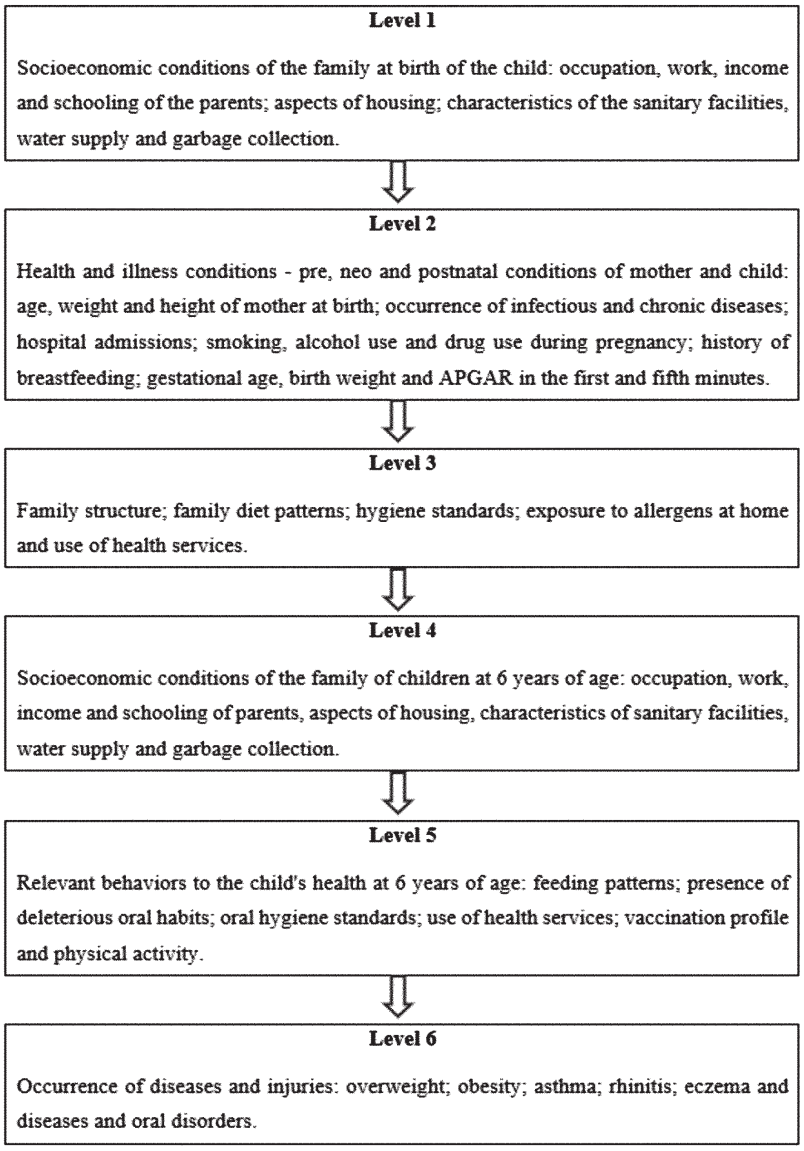

Figure 2 - Theoretical framework for data analysis.

collection, ranging from the approach to school authorities, community health agents, parents in their households and children in schools, organization, transportation and handling of equipment and instruments, bio-security standards (WHO 2013), data collection order, and checking and organizing the data collection instruments. Physical and clinical examinations are being collected in duplicate for 5% of sampled subjects to ensure quality control and monitor diagnostic reliability of examiners.

Before the field team members started their work in the community, a pilot study was conducted on 5% of the total sample (n=88) including children aged above the target age of this study. The goal was to test the proposed methodology, define logistics, and make necessary adjustments.

In this study, children whose mothers or primary caregivers were not found at home after three visits, including one in weekend, were considered losses. Also, those who refused to sign the inform consent form were considered losses.

ETHICAL ASPECTS

Ethical approval was obtained from Ethic Committee of Research of Universidade do Sul de Santa Catarina under the protocol CAAE: 38240114.0.0000.5369. Upon invitation to participate, children's parents or caregivers were informed about objectives and methods of the study, and potential risks associated with their participation. This information was provided in informed consent forms, which must be signed by those who voluntarily agreed to participate. Identity of participants will be kept private, and they could discontinue participation at any time without penalty. Their personal information will not be identified in any reports or publications resulting from this study. Children who presented problems or any alterations in the examinations are being referred for treatment at health clinics of the university or of the municipality.

DATA PROCESSING AND ANALYSIS

Data are being entered into Excel spreadsheets and then exported to SPSS 18.0 software to be analyzed. The resulting database has been undergone data cleaning process to detect incomplete data or other inconsistencies. Double typing is occurring in order to identify differences in insertions, and thus ensure quality of the data.

Descriptive statistics will be used to describe basic features of the population and study variables. The following analyses will be performed based on the study design and theoretical background: 1) cross-sectional analysis to estimate the prevalence of different health outcomes studied; 2) longitudinal comparison between two time periods: the first 1,000 days and 6 years of age, which will allow to analyze trajectories of health-related risk and protective factors at age 6; 3) hierarchical regression analysis to examine predictors of 6-year-old children's health according to the model shown in Figure 2. The hierarchical model was based on Victora et al. (1997) who described the conceptual hierarchical framework of risk factors for infectious diseases in developing countries. According to the authors the general principles apply to a number of other health problems both in developed and less developed countries. These analyses will indicate whether early years are critical for the associations found.

PRELIMINARY RESULTS AND DISCUSSION

As the research is currently under way, and as the main goal at this moment is to present methodological aspects adopted in the study, only a few partial and preliminary results of prevalence are presented in Table II. The rates of overweight and obesity of children were determined by obtaining anthropometric data collected at school. The high prevalence of overweight (16.4%) and obesity (15.5%) observed in children, although partial, refers to a concern, due to the social and psychological problems that can be triggered, problems related to self-esteem and the risk of bullying (Moreira et al. 2014). In short and medium term, besides psychosocial disorders, children and adolescents may present hypertension, dyslipidemia, diabetes, orthopedic and respiratory problems. In long term, mortality from all causes of obesity and coronary heart disease has been increased in individuals who were obese in childhood and adolescence (Moreira et al. 2014).

By conducting the *Coorte Brasil Sul* study, we expect to improve understanding of social determinants on children's health, specially at the Brazilian context. Specifically, we expect to determine whether factors related to pregnancy, childbirth, and early years of children's life may be contributing to the health-and disease-related processes at age 6, and possibly in further stages of life to be identified in prospective follows-up. The identification of significant affecting factors in the course of life may also indicate risk accumulation. The results from this study will help in planning

TABLE II
Preliminary results of events and injuries selected from the *Coorte Brasil Sul* study, Palhoça / SC. (n=1,270).

EVENTS/INJURIES	%
Child conditions	
Low birth weight (2,500 grams or less)	6.1
Vaginal delivery route	55.5
Use of antibiotics in the first two years	60.4
Hospital stay for the first 29 days	8.9
Hospital admission in the first two years	16.3
Child attended day care	79.8
Complete vaccination card at six years	95.9
Was breastfed	91.2
Exclusive breastfeeding for at least six months	56.9
Mother reports that the child prefers to play on the street or patio in relation to indoors or school	51.8
Mother reports that the child is less physically active compared to children of the same age	22.5
Overweight at 6 years old	16.4
Obesity of the child at 6 years old	15.5
Report of allergic diseases in children	
Report of occurrence of wheezing in the first two years	33.2
Report of occurrence problems with sneezing, runny nose or nasal obstruction in the first two years	22.7
Report of occurrence of itchy spots on the skin (eczema) in the first two years	11.8
Child coexists with fur animals or feather indoors	52.9
Aspects of the child's oral health	
Drink chocolate with sugar during the week	65.7
Take soda during the week	64.0
Started toothbrushing before two years	83.5
Had toothache in the past 30 days	20.6
Already fell, hurting the mouth or the teeth	38.3
Never went to the dentist	26.4
Habits and socioeconomic conditions of the mother	
Mother reported having ingested alcohol during pregnancy	6.5
Mother reported having smoked cigarettes during pregnancy	13.9
Mother worked during pregnancy	49.2
Family receives *Bolsa Família*	13.9
Mother's education of at least eight years of full study while becoming pregnant	46.9
Current mother's education of at least 8 years of full study	50.4

control measures and interventions to reduce risks and mitigate consequences.

On the other hand, the use of a theoretical model for the analysis of the collected data based on ideas and findings of the Pelotas Birth Cohort (Barros and Victora 1999, Barros et al. 2008) the Brazilian cohort with the highest international recognition, strengthens our study. Theoretical understanding that socioeconomic conditions, such as distal determinants, can determine or influence intermediate or proximal determinants that increase or decrease the risk of occurrence of disease is not new, but holds explanatory power for understanding health outcomes. Thus the conceptual similarity

between the study proposed here with other cohorts developed in Brazil, such as the cohorts of Pelotas/RS (Barros and Victora 1999, Barros et al. 2008) or the BRISA cohort of Ribeirão Preto/SP and São Luis/MA (Figueiredo et al. 2014) that study determinants of the health-disease process throughout the life cycle is not a casual one, but a sign of sharing of theoretical bases.

FINAL CONSIDERATIONS

Based on the guiding theories and results from this study, we intend to respond to different questions related to children's health- and disease-related processes. The findings may provide useful information for development of public policies directed to improving health conditions and quality of life of the population.

As a reflection for this moment where the research is under way, it is possible to emphasize how much it was necessary the involvement of all researchers in an interesting experience of multidisciplinary work. Being a longitudinal and population-based study, we are aware of the great challenge of this research. Another salutary aspect was the approach including together the University and the Health and Education Secretariats of the city for the proposal of a partnership in research, triggering other processes of mutual aid.

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