



The nutritional status of children living within institutionalized care in 5 countries:
An observational cross-sectional study

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SIGNATURE PAGE

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Sponsor

Holt International has provided the use of their routinely collected deidentified secondary data for this research project.

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None

This protocol describes The nutritional status of children living within institutionalized care in 5 countries: A cross-sectional study and provides information about procedures for entering participants. The protocol should not be used as a guide for the treatment of other participants; every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study, but centres entering participants for the first time are advised to contact the trials centre to confirm they have the most recent version.

Problems relating to this trial should be referred, in the first instance, to the study coordination centre.

This trial will adhere to the principles outlined in the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines, protocol and all applicable local regulations.

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GLOSSARY OF ABBREVIATIONS

BMI:	Body Mass Index
CC:	Community children, children living with their biological families
CDC:	Centers for Disease Control (USA)
CLS:	Children living on the streets
FBC:	Family-based care, orphaned, separated, or abandoned children living in family-based care settings like foster care or kinship care.
HAZ:	Height/length-for-age z-score
IBC:	Institution-based care, children living in institutional care/ residential care facilities.
LBW:	Low Birth Weight
NCHS:	National Center for Health Statistics (USA)
WAZ:	Weight-for-age z-score
WHO:	World Health Organization
WHZ:	Weight-for-height/length z-score

KEYWORDS

Child nutrition, orphanage, children with disabilities, anthropometry, institutionalized care, residential child care, nutritional deficiency, malnutrition

STUDY SUMMARY

TITLE The nutritional status of children living within institutionalized care in 6 countries: An observational cross-sectional study

DESIGN Cross sectional study

AIMS Describe the nutrition-related epidemiology of children living within institutionalized care.

OUTCOME MEASURES Anthropometry

POPULATION A deidentified, anonymized data set of children's health screenings from 6 countries.

ELIGIBILITY All children in an already compiled database of Holt's Child Nutrition Program admitted to Holt supported CNP databases

1. INTRODUCTION

1.1 BACKGROUND

[To include: review of previous studies, disease or area particulars, incidence, current treatment options, risks and benefits]

There are millions of orphaned and vulnerable children (OVC) around the world living within institutionalized care. A previously completed systematic review indicates that there is very limited evidence about this vulnerable population and their nutritional and health status. The review further concluded that children living in care are at risk of malnutrition, especially infants and children with disabilities who make up a large population of this group. Without good nutrition, there can be many consequences including impact to their health, development, and future potential. Without a strong evidence base of the status of this group, it is hard for countries and sites to be able to meet the needs and specialized care required from this vulnerable population. In order to improve the care of children living within institutionalized care, this project aims to survey the routinely data collected from children in programs supported by Holt International.

1.2 RATIONALE FOR CURRENT STUDY

[To include: research question and hypothesis, as well as potential risks and benefits]

Describe the nutrition-related epidemiology of children living within institutionalized care.

This study aims to fill the gaps identified in the phase 1 systematic review by completing a multi-country, analysis of the nutrition status of children living within institutionalized care. This will be especially valuable for children with disabilities who although a significant portion of this population, remain vastly underrepresented in the literature.

We will also complete comparisons to national standards and to other groups of children in foster care and community programs to better understand children in care's health in both a local and global context. The intended value of this project is to provide an evidence based to support recommendations for current and future programs to better meet these children's needs and thereby support the health and development of these children.

The data set contains demographic (incl. age, disability status, gender, birth history), clinical records (incl. height, weight, hemoglobin) and dietary information (feeding issues, feeding methods, special diets or vitamins/ minerals).

2. STUDY OBJECTIVES

1. Explore the quality of the data from Holt International's Nutrition Screening System (NSS) database;
2. Describe the data regarding the nutritional status and anthropometric measurements of children in the NSS database;
3. Describe the epidemiology of children's nutrition status between/within countries and over time between 2013 and 2020, e.g. nutritional status and variability due to age or disability status.

3. STUDY DESIGN

An observational cross sectional study using anonymised and deidentified data from Holt International. STROBE Checklist will be followed for this study.

Following the data user agreement and data management protocol, the data will be securely held and analyzed using STATACorp 16. The data will be aggregated and a quantitative analysis will be conducted.

3.1 STUDY OUTCOME MEASURES

Factors associated with anthropometric status.

3.2 RISKS AND BENEFITS

Although the data is deidentified, strict adherence to the data management protocol (as outlined in the data management plan) will need to be followed. This is secondary data that is already been collected in a database held by Holt International.

9. METHODOLOGY

i. Methods

The cross-sectional study will follow the STROBE Checklist. Study methods will include information on the setting, participants, variables analyzed, data sources and measurement techniques, bias, and the statistical methods used. Anonymized routinely collected Holt International data will be shared with ED as determined through Data User Agreement. Following the data user agreement and data management protocol, the data will be securely held and analyzed using STATACorp 16. The data will be aggregated and a quantitative analysis will be conducted.

Children's baseline screenings will be used and the following variables will be analyzed at the country level;

1. Countries: Mongolia, China, the Philippines, Ethiopia, India, Vietnam
 - a. Disability, age (0-2, 2-5, 5+) and care type breakouts
 - i. General Characteristics: Age, gender, disability, HIV rates, LBW, Premature, length of stay in care, age at admission
 - ii. Frequency Distribution of anthropometric z-score categories
 - b. Comparisons
 - i. World average and country averages
 - ii. Foster Care or Community Care vs. Institution Care

9. STATISTICS AND DATA ANALYSIS

The data was collected as part of routine child health screenings as part of programs funded by Holt International. This project is an audit of routinely collected data that is used to inform routine clinical care as part of programs. This project does not ask/ utilize any other non-routine data.

Data analysis will be done using STATA/IC Version 16 (StataCorp). We will focus on a descriptive analysis exploring simple associations of anthropometry with age, sex, disability and care type.

Data will be held indefinitely on Holt International's server and site data backups in addition to retention policies with Datto systems. Please see the attached Data Management Plan for more information.

11.2 ETHICS APPROVAL

This study seeks approval from the LSHTM Research Ethics Committee and any substantial amendments will be require further approval from the ethics committee. This study will send notification at the end of the analysis.

11.3 CONSENT

Holt International has given consent for the analysis of previously collected audit data which will be deidentified. A data user agreement was signed between LSHTM RD student and primary investigator, Emily DeLacey, and Holt to analyse the deidentified data. Please see the Data User Agreement for more information.

11.4 CONFIDENTIALITY

Any participants' identifiable data collected by the Study Coordination Centre will be stored securely and their confidentiality protected in accordance with the Data Protection Act 1998.

The data set will be deidentified and provided as part of a limited data user agreement with the primary investigator, Emily DeLacey. Holt International will retain the original data set on their secure servers. The limited data set will be either held in a protected folder on Holt International's servers or on an encrypted laptop owned by Holt International. Analysis will be done using STATA/IC Version 16 (StataCorp). Please see Data User Agreement and Data Management Plan attachments for more detailed information. Emily DeLacey is an employee of Holt International and has signed confidentiality agreements with them.

11.5 INDEMNITY

N/A Use of secondary deidentified data

11.6 SPONSOR

Holt International is providing use of the deidentified data for this research project.

11.7 FUNDING

None

11.8 AUDITS AND INSPECTIONS

N/A secondary analysis of data which was already collected by Holt International. The study may be subject audit by the London School of Hygiene & Tropical Medicine, the Study Coordination Centre and other regulatory bodies to ensure adherence to GCP.

11.9 PROTOCOL DEVELOPMENT

This protocol was developed by the following investigators who are responsible for the development of, and agreeing to, the final protocol.

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13. PUBLICATION POLICY

This study will be written up as part of a PhD program by the chief investigator, Emily DeLacey. The study will also include the involvement of Dr. Marko Kerac, Dr. Cally Tann of LSHTM. Publications will be agreed by the author team and we aim to publish in open access journals.

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EXAMPLE APPENDICES

See Leo Ethics Form for additional appendices.