



Wheelchair User's Voice- Research protocol

A longitudinal study about the impact of
the WHO-8 steps for wheelchair
provision in El Salvador

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Abbreviations

ACCESS	Accelerating Core Competencies for Effective Wheelchair Service and Support
BAC-Q	Breakdowns and Adverse Consequences Questionnaire
IDB	Inter-American Development Bank
CHART	Craig Handicap Assessment and Reporting Technique
CLASP	Consolidating Logistics for Assistive Technology Supply & Provision
UNCRPD	United Nations Convention on the Rights of People with Disabilities
DL	Data Logger
CSC	Current Standard-of-Care
FUNTER	Foundation Pro Rehabilitation Telethon
ISSS	Salvadoran Social Security Institute
ISWP	International Society of Wheelchair Professionals
ISWP-MUD	ISWP Mobility and Wheelchairs Questionnaire
MINSAL	Ministry of Health of El Salvador
MIT-CITE	Massachusetts Institute of Technology-Comprehensive Initiative on Technology Evaluation
WHO	World Health Organization
PHI	Protected Health Information
PPI	Poverty Probability Index
UCPW	United Cerebral Palsy Wheels for Humanity
UN	United Nations
USAID	Agency for International Development of the United States
WHOQOL-BREF	WHO Quality of Life Assessment
WMT-Q	Wheelchair Maintenance Training Questionnaire
WSTP	Wheelchair Service Training Package
WSTPb	Wheelchair Service Training Package Basic Level
WST-Q	Wheelchair Skills Test Questionnaire
VWU	Wheelchair User's Voice
ZBI	Zarit Burden Interview

Principal Investigators

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Introduction

Without personal mobility, human rights cannot be fully exercised. Mobility allows for a dignified, independent and more productive life since it facilitates access to school, health services, labor, and cultural and recreational inclusion (WHO, 2008).

The wheelchair is one of the most used assistive devices to improve personal mobility. An appropriate wheelchair is one that adapts to the physical needs of the person and their environment, provides postural support, is safe, durable, and is provided with a cushion and the necessary services, it is a precondition to inclusion and social participation (WHO, 2008).

An appropriate wheelchair not only favors personal mobility and higher levels of activity, but also, with a cushion and adequate user training, aids the user to stay healthy by preventing the development of pressure ulcers, decreasing the possibility of premature death, and reducing health expenses. Evidence shows that the life expectancy of a person with a recent spinal cord injury who lives in a developing country is 20 to 29 years less than that of a person with the same medical condition who lives in a developed country (Wyndaele & Wyndaele, 2006; Razzak, Helal, & Nuri, 2011), this is very likely due to the appearance of secondary conditions such as pressure ulcers.

The postural support provided by a well-prescribed wheelchair has shown other health benefits such as prevention of orthopedic deformities and contractures, improvement in respiratory and digestive functions, and improvement in the head, trunk and arm control. The results of a study conducted in South Africa, where custom made wheelchairs were provided to two groups of pediatric users who did not show deviations from the spine at the beginning of the study, demonstrated that additional and appropriately provided postural support reduced the

development of postural complications to 0.4% compared to 34% of the group that did not receive additional postural support (WHO, 2015b).

The benefits of a wheelchair are not reduced only to health benefits. Maintaining health has socioeconomic implications since the quality of life increases and it is more feasible for the user to make use of education, employment, and social participation services. An appropriate wheelchair allows access to educational opportunities and finding a paid job, promoting economic inclusion and social mobility of people (Inter-American Development Bank [IDB], 2009). When this need is not met, people with disabilities are isolated and without access to the same opportunities as other members of their own community (WHO, 2008). In Latin America, between 70% and 80% of children with disabilities do not have access to education, only 5% finish secondary school, and 70% of adults with disabilities do not have a job (IDB, 2009). In addition, independent mobility and a better physical functioning can reduce dependence on other people (caregivers), so they can go to school or work, improving the quality of life and income of all family members (IDB, 2009; WHO, 2015a). In fact, in the study of Glumac, Pennington, Sweeney & Leavitt (2009), it was found that after the user had acquired the wheelchair, caregivers mentioned having less physical and emotional burden and having more freedom to participate in social roles.

According to the statistics of the World Health Organization (WHO), approximately 70 million people in the world need a wheelchair, that is, 1% of the world population (WHO, 2015b). However, only between 5 and 15% of these have access to one (WHO, 2015b), and the number of people who have access to an appropriate wheelchair is even lower (WHO, 2008). According to the data census of June 2017 provided by the National Council of Integral Attention to Persons with Disabilities of El Salvador, in this country, there are about 314,027 people with disabilities. This means that, in El Salvador, 31,402 people need a wheelchair, but only between 1,570 and 4,700 have access to it. That is, only a minority has access to wheelchairs, of which, very few have access to an appropriate one (WHO, 2008). The lack of access to appropriate wheelchairs can lead to people with disabilities having a lower quality of life and greater tendency to poverty due to barriers to access to education and employment (WHO, 2015b).

With the ratification of the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), the government of El Salvador acquired a moral and legal obligation to "ensure and promote the full exercise of all human rights and fundamental freedoms of people with disabilities"; plus, personal mobility is a human right (UN General Assembly, 2008). Explicitly, Article 20 of the UNCRPD establishes that the government of El Salvador must take effective measures so that people with disabilities enjoy mobility as independently as possible, in the form and at the time they wish, at an affordable cost. (UN General Assembly, 2007).

Providing the right wheelchair is not always easy. People with disabilities are part of a vulnerable group, with diverse needs and environmental and socioeconomic disadvantages (WHO, 2008). Although the benefits of an appropriate wheelchair are known, today there still are many organizations that distribute wheelchairs that, based on experiential information from people working in the field do not meet the minimum safety requirements nor do they satisfy the needs of end users, putting their health at risk and even their lives.

This study will help generate valuable information on the impact of two different models of provision of wheelchairs on the quality of life, health and other socioeconomic indicators of users. This information will be useful for governments and humanitarian organizations in low and middle-income countries to make better decisions and generate public policies and social programs regarding the provision of wheelchairs and services for people with disabilities. It is expected that these changes in public policies and programs will result in the provision of appropriate wheelchairs for those who need them and, in this way, promote their health, independence, and social integration.

Background

United Cerebral Palsy Wheels for Humanity

The organization United Cerebral Palsy Wheels for Humanity (UCPW) is an organization founded in 1996. The aim of this organization is to increase access to mobility by improving the quality of life of children and adults with physical disabilities in low-income countries. For UCPW, it is important that wheelchairs are provided taking into account the needs of people and also that they are trained in its use and maintenance to maximize the benefits and to avoid secondary medical problems. In addition, UCPW provides training to clinical staff so that appropriate wheelchair services can be provided (UCP Wheels for Humanity, n.d.). The presence of UCPW in El Salvador is due to the importance of satisfying the need for a provision of appropriate wheelchairs, which aims to eliminate barriers and create opportunities for the complete inclusion and participation of wheelchair users in society.

WHO Guidelines and Wheelchair Service Training Packages

In 2008, the WHO published Guidelines on the provision of manual wheelchairs in less-resourced settings as mentioned in the WHO document (EN version) also known as "the WHO 8 steps". The 8 steps establish the recommendations made by experts for governmental and non-governmental organizations to improve the provision of wheelchairs in their countries. That is, these services must consider the characteristics, the individual needs of users, and their environment, such as the design, quality and systems through which they are delivered to the user. According to the WHO, the 8 steps correspond to appointment and referral, assessment, prescription, funding and ordering, product preparation, fitting, user training, maintenance/repair and follow-up. The benefits of applying these guidelines are reflected in their health, quality of life, economy and the participation of wheelchair users in society.

Through the implementation of the 8 steps of the WHO, it is intended to ensure 1) that the user has been evaluated to identify their health needs, postural support, their social role, the characteristics of their environment and the activities they perform; 2) that the wheelchair has

been adjusted and prepared for the user before being delivered; 3) that the user and their family receive the necessary training to use the wheelchair in a functional and safe way, as well as to keep it in good condition; 4) that the services are continuous and intentional and that any subsequent needs will be identified.

For the implementation of the 8 steps, the WHO developed two Wheelchairs Service Training Packages (WSTP), Basic and Intermediate levels. These training packages are made to offer service providers the knowledge and skills necessary for the provision of wheelchairs to users with different postural support needs. For example, the Basic WSTP package focuses on services to users who can sit upright without the need for additional postural support, while the WSTP Intermediate focuses on users with more complex needs that require greater postural support to stay upright, comfortably and functionally. A third and fourth training package was developed for authorities, supervisors, managers, and providers of wheelchair service centers (WSTP for Managers and Stakeholders) in order to increase knowledge about the importance of services and the number of professionals trained to disseminate this knowledge among other health professionals (WHO, 2015a). WHO, the United States Agency for International Development (USAID) and several international organizations have recognized the potential impact of a wheelchair and the training packages of the WHO and work collaboratively to provide appropriate products and services in lower income countries. An example of these synergies are the ACCESS and CLASP projects described below.

The Accelerating Core Competencies for Effective Wheelchair Service and Support project (ACCESS)

The ACCESS project is a project funded by USAID implemented in Kenya, India, Romania, Nicaragua and El Salvador. The project seeks to strengthen the professional sector of wheelchair provision in these countries and ensure that everyone with mobility limitations, especially women and children, can access appropriate products through qualified service providers. The project was implemented in three and a half years and ended in June 2017.

The ACCESS project tries to address the problem of mass distribution of wheelchairs by humanitarian organizations; which, most of the time, distribute chairs without performing the evaluation of the user's needs and their environment, the appropriate adjustment or follow-up as described in the 8 steps of the WHO. In most low and middle-income countries, service providers are unaware of the WHO's 8 steps and are not trained in the provision of wheelchairs, increasing the number of users who have not enhanced their independence and personal mobility.

The three main objectives of ACCESS were: 1) to foster an enabling environment for the efficient management of wheelchair service and products through the participation of local and national stakeholders; 2) to expand the provision of wheelchair services in the five aforementioned countries by diversifying the range of available products and strengthening the management and service capacity of local organizations; and 3) to train wheelchair service personnel in the Basic and Intermediate Wheelchair Service Training Packages to increase the capacity of human resources to deliver quality wheelchair services in each country.

UCPW collaborated in the ACCESS project giving technical support to local organizations through training, equipment, consumables and continuous mentoring throughout its implementation. In El

Salvador, UCPW trained approximately 65 service providers at the Basic level and 39 in the Intermediate level. Currently, due to lack of access to appropriate and varied products, only 15 suppliers continue to provide wheelchairs following the 8 steps of the WHO.

Consolidating Logistics for Assistive Technology Supply & Provision (CLASP)

The provision of wheelchairs in low and middle-income countries is rapidly improving through sectoral investments in clinical training and advances in the quality and cost of appropriate wheelchairs for different environments. However, progress is imbalanced by the lack of access to these products. To date, this has been addressed mainly with mass production in countries with industrial manufacturing capacity. This has contributed to the improvement of the designs, higher quality and lower costs, but it has also promoted a system guided by the donors and not by the user with regard to the products and their selection.

CLASP is a social project developed by UCPW that addresses the current challenges faced by wheelchair service providers in less resource-rich environments, which include a limited variety of products, extensive delivery times and logistic burdens.

CLASP took advantage of the competences already developed in the area of provision and production of wheelchairs and involved professionals in logistics and supply chains to build a simplified provision system. In this way it was possible to consolidate products of several models and project inventories, making the order, shipping and importation of wheelchairs easier, faster and including a wider range of products. With this, the CLASP consolidation center and the business model were developed, which has allowed CLASP to: 1) donate wheelchairs financed by USAID to selected providers of CLASP, service providers that have committed themselves to ensuring that the wheelchairs that they receive are supplied through the appropriate services, following the standards and guidelines of the WHO; 2) donate appropriate wheelchairs financed by humanitarian organizations that historically have made large investments for the distribution of these; and 3) sale of wheelchairs to interested parties, including national or municipal governments, humanitarian organizations, wheelchair service provider organizations or regional assistive technology distributors.

CLASP is located in Shanghai, China and it consolidates products from more than six mobility product manufacturers of different types that meet the needs of different users (Motivation, Whirlwind, Jarik, GRIT, UCPW, INTCO), and it has more than fourteen suppliers of wheelchair services trained in accordance with the 8 steps of the WHO based in Jordan, India, Tanzania, Nicaragua, El Salvador, Brazil, Romania, Indonesia, Samoa, South Africa, Mexico and Thailand. CLASP beneficiaries include people with disabilities who receive a product through the CLASP provision system, wheelchair service providers who have a greater variety of affordable and quality products, and wheelchair manufacturers.

Justification

The Member States of the United Nations that signed and ratified the UNCRPD have a legal and moral obligation to comply with the responsibilities acquired under this international law. Promoting and facilitating the personal mobility of people with disabilities in the form and at the time they wish is one of the obligations acquired, and even more, a human right. Access to an appropriate wheelchair for those who need it is an indispensable factor in improving personal mobility and promoting the exercise of other human rights such as access to health and education.

Nowadays, there is not enough quality scientific evidence to conclusively justify the adoption of the WHO's recommendations for the provision of wheelchair services, as well as the investment in adequate products by governments of low and middle-income countries. It is necessary to generate quality information on the impact of different models and systems of the provision of wheelchairs to guide decision-making towards the interventions that have the greatest benefits and make the most efficient use of available resources.

Problem Statement

Many humanitarian organizations provide wheelchairs that, according to anecdotal data collected by people in the field, do not meet quality standards nor do they meet the needs of the end user, leading to dangerous and deadly complications, such as pressure ulcers. There is no scientific evidence on the negative consequences of mass distributions of poor quality donated wheelchairs and without related services in the quality of life of end users. Similarly, low- and middle-income governments, and humanitarian and disability organizations continue to make decisions and to buy products without objective data and without knowledge of the positive and negative consequences of their social policies and programs. The lack of information on the impact of different models of wheelchair provision in low and middle-income countries hampers decision making in this area. Based on this, we pose the following research questions.

What is the impact of wheelchair service provision following the WHO guidelines, in accordance with the WHO's recommendations, on the socioeconomic status, quality of life, health and social integration of wheelchair users?

What is the impact wheelchair service provision following the WHO guidelines in the caregiver's burden?

Can the use of information technologies improve the impact of regular maintenance on wheelchairs?

Research objectives and hypothesis

Objective 1: Determine the impact of the wheelchair service provision through the WHO 8 steps on the socioeconomic status, quality of life, health and social integration of wheelchair users.

Hypothesis 1.1: Users who receive wheelchairs provided through the WHO 8 steps will have a significant increase over baseline measurements in their socioeconomic status, quality of life, health status, and social integration.

Hypothesis 1.2: Users who receive wheelchairs supplied through the WHO 8 steps will have a significant reduction in the frequency and severity of secondary injuries such as pressure ulcers, cuts, bruises, pain and falls of the wheelchair compared to baseline measurements.

Hypothesis 1.3: Users supplied wheelchairs through the WHO 8 steps will have significantly few wheelchair breakdowns and related adverse events compared to baseline measurements for those who previously had wheelchairs.

Hypothesis 1.4: Users who receive wheelchairs supplied through the WHO 8 steps will have a significant increase in the levels of mobility (distance and speed) and ability to move in their wheelchair compared to baseline measurements for those who previously had wheelchairs.

Objective 2: Determine the impact of the provision of wheelchairs through the WHO 8 steps on the caregiver's burden.

Hypothesis 2.1: Caregivers of users who receive wheelchairs through the WHO 8 steps will have a significant reduction in the caregiver burden indicator compared to baseline measurements.

Hypothesis 2.2: Caregivers of users who receive wheelchairs through the WHO 8 steps will have a significant increase in the number of paid hours as a non-caregiver and in their levels of social participation, compared to baseline measurements.

Objective 3: Determine if the use of SMS maintenance reminders reduce wheelchair breakdowns and related consequences.

Hypothesis 3.1: Individuals who receive maintenance reminders via SMS will have significantly fewer wheelchair breakdowns and related associated adverse events compared to users who do not receive SMS reminders.

Theoretical Framework

The concepts and variables used in this research study are described below.

Wheelchair User: All people who use a wheelchair for mobility because their ability to walk is limited (WHO, 2008).

Wheelchair user's caregiver: The person who takes on the role of caregiver is usually a family member or a person who has been hired and who is in charge of the care of the wheelchair user.

Appropriate wheelchair: WHO establishes that an appropriate wheelchair is one that meets the needs of the user and their environment, it offers a good fit and postural support, it is safe, durable, available in the country, and can be obtained and maintain locally (WHO, 2008).

Inappropriate wheelchair: This type of wheelchair allows very little adjustment, so it cannot be configured to meet the physical and functional needs of the user. This chair contributes very little to the independence of the user, and sometimes it hinders it. In addition, it can contribute to the development of secondary diseases, such as pressure ulcers and orthopedic deformities. Generally, they are hospital wheelchairs that are used for a long period of time and in different environments, which are designed to be used for a short time and indoors (Armstrong, Reisinger & Smith, 2007).

Proper Wheelchair Provision:

For an appropriate provision of manual wheelchair services, the WHO recommends following the 8 steps (WHO, 2012) as described below:

Referral and Appointment: The person must receive an appointment or be directed to the place of care to receive wheelchair services. These wheelchair services can be provided by workers, governmental or non-governmental health and rehabilitation volunteers and they can be carried out at various levels such as community, district or regional. If there are potential wheelchair users, wheelchair services must be able to identify them and refer them to social and health services, and to school, work and community participation.

Assessment: This step gathers the information of each wheelchair user, their demographic characteristics, their health state, lifestyle, environment, and the wheelchair used at the time of the study. In addition, the user's measurements are taken, and the method of propulsion and transfer is considered.

Prescription (selection): Based on the information from the previous step, details of the wheelchair and cushion are indicated as size, type and other characteristics and corresponding modifications for each individual. The necessary use and maintenance training should be mentioned.

Funding and ordering: It refers to the importance of identifying the source of financing considering wheelchairs available in the service or provider.

Product (wheelchair) Preparation: Taking into account the available products and resources of the service, the trained personnel prepare, configure, assemble, and if necessary, make the corresponding modifications to the wheelchair and its components. Finally, it is verified that the wheelchair is safe, that it is ready to be used, and that it has all the parts working before the test with the user.

Fitting: The service personnel works together with the wheelchair user to verify that the wheelchair and its components are properly configured and fit properly.

User training: Consists of informing and training the wheelchair user and their family members in the handling, transfer, mobility skills, prevention and care of pressure ulcers, care of the cushion and the wheelchair, as well as actions to take in case of problems.

Maintenance, repair and follow-up: Consists of maintenance services and repair of technical problems that cannot be resolved by the user, and which are available within the community. It is important to follow up on the maintenance activities carried out in order to check the adjustment of the chair and provide more training and support. The monitoring is carried out according to the needs of the user and the available services. The maintenance and regular care of both the wheelchair and the cushion allow savings in repair costs, lengthen its life, and prevents secondary injuries to the user. In case the wheelchair is no longer appropriate, it is necessary to supply a new chair following the 8 steps again.

Wheelchair Distribution: Unlike the appropriate provision, there is the so-called wheelchair distribution, also known as the current standard-of-care (CSC). Under this concept, some organizations buy wheelchairs that have been manufactured for institutional and temporary use such as hospitals or airports. Usually, these are inexpensive, which allows the purchase of a large number of these products. Many organizations massively distribute new wheelchairs through donations. It is believed that these distribution mechanisms are effective because a large volume of chairs are delivered in a short period of time in places with a great need (Pearlman et al., 2008; Toro, Eke & Pearlman, 2016). However, since wheelchairs are massively distributed, neither the needs of the user nor those of the environment are taken into account, resulting in the abandonment of the product, at best. These wheelchairs are usually heavy, difficult to maneuver, not very adjustable, not very durable, they do not include a cushion to prevent pressure ulcers, and their maintenance is complicated due to the lack of availability of spare parts and necessary resources (Pearlman et al., 2008). In this study, the distribution of wheelchairs through the current standard-of-care refers to the delivery or mass distribution of wheelchairs without following the 8 steps of the WHO.

Measured Variables

Socioeconomic Indicators

Socioeconomic indicators are reference measures that take into account the age, gender, marital status, educational level, employment status and socioeconomic status of the people:

Poverty Probability Index in El Salvador (PPI): This study uses the PPI to measure the socioeconomic level of the participants. The PPI is described later.

Quality of Life: The quality of life as defined by the WHO, is "the perception of each person about their place in life according to the context and the value system in which they live and the relationship with their goals, expectations, standards and concerns" (WHO, 2014). Therefore, quality of life is related to aspects of physical and psychological health, social relationships and the environment of people. In this study, the WHOQOL-BREF quality of life assessment instrument is used to measure this indicator.

Health: The physical health of wheelchair users is related to pain, fractures, injuries, and secondary conditions, due to the use of a wheelchair. A questionnaire previously developed by the Massachusetts Institute of Technology-Comprehensive Initiative on Technology Evaluation (MIT-CITE) is used for the pilot study and is described below.

Social Integration: Social integration refers to the frequency of interaction and the initiation of social relationships that determine social competence and skill, support, and interpersonal characteristics (Whiteneck et al., 1992, Haring & Breen, 1992). For the measurement of this variable, the social integration section of the Craig Handicap Assessment and Reporting Technique (CHART) instrument, described later, will be used in this study.

Wheelchair skills: Wheelchair skills refers to maneuvers performed independently by the user in different environments (Kirby et al., 2016). For example, take turns in the place, climb steep slopes, descend slopes while doing a wheelie, among others (Keeler, Kirby, Parker, McLean & Hayden, 2018). The instrument for measuring this variable is the WST-Q skills questionnaire, described later.

Wheelchair maintenance: Wheelchair maintenance refers to inspection tasks and actions performed on the wheelchair and its components. These tasks must be carried out frequently and require knowledge in order to be completed (Toro et al., 2017). For this reason, the Wheelchair Maintenance Questionnaire WMT-Q, mentioned below, was selected.

Adverse events caused by wheelchair breakdowns: Adverse events are the consequences for users due to technical failures of the wheelchair. Technical failures can be broken front wheels, fractures in the frame, loose positioning brackets, worn or broken components, either the seat, backrest, or cushion; among others. Adverse events are situations that users have had to go through due to breakdowns, such as being stranded somewhere, missing school or work, missing medical appointments, injury due to breakdown, etc. The instrument of Breakdowns and Adverse Consequences has been selected and it is described in Data Collection Instruments in this document.

Wheelchair mobility levels: This variable refers to the distance and speed with which users travel in their wheelchairs. Distance is defined as the journey traveled in the wheelchair, and speed as the ratio of distance and time that the wheelchair travels. Since this variable implies the mobility of the user, sensors called Data-Loggers (DL) are required for the measurement of this variable described later in Data collection instruments.

Caregiver burden: The caregiver's burden refers to the subjective experience of the caregiver's responsibilities and how these affect the different areas of their life, that is, in their family, free time and social activities (Zarit, 2016). For the measurement of this variable the Zarit caregiver's burden questionnaire detailed below is used.

Materials and Methodology

Study design

An intra-subject longitudinal study design will be used, that is, the data before and after the wheelchair service provision will be compared at various points in time (2 months before, at the time of delivery, 3 and 6 months after the delivery). The impact of the provision will be evaluated according to the 8 steps of the WHO in the quality of life, health, socioeconomic status, social integration, and mobility of users, as well as the level of their caregiver's burden.

The indicators will be measured through personal interviews, telephone calls, and mobility sensors, known as Data-Loggers (DLs). In addition, text messages with reminders of wheelchair maintenance activities will be sent. Service providers will be evaluated at the start of the study to measure their knowledge of the 8 steps of the WHO.

Sampling method

A sampling strategy for consecutive cases will be used for the selection of participants for ethical reasons. For the study branch of maintenance reminders by text messages, two blocks will be analyzed and assigned randomly. The first block consists of the comparison of two groups, participants who have a wheelchair at the beginning of the study and for participants who do not have it. The second block consists of the comparison by the type of wheelchair that the participants have received in the study. Attempts will be made to recruit all caregivers of participating wheelchair users who meet the inclusion criteria.

Inclusion and exclusion criteria

Participating wheelchair users

Wheelchair users may participate in this study if:

They are adults 18 years and older

They require the use of a wheelchair as a primary means of personal mobility

They are on the waiting list to receive a new basic-level wheelchair

They have the cognitive and verbal ability to answer questions related to the study, or failing that, they have a caregiver who can answer the questions on their behalf

They have a cell phone line and can receive text messages from any telephone company (or a proxy with a cell phone)

They want to receive maintenance reminders twice a week through text messages voluntarily

They wish to participate in the study and have signed the informed consent

Those users who require additional postural support to remain upright in the wheelchair (intermediate-level services) cannot participate in this study.

Participating caregivers of wheelchairs users

Caregivers will be included in this study if they:

They are adults 18 years or older

They are the main caregiver of the participating wheelchair user

Sample size

In this study, a maximum of 300 adults who live in El Salvador and who are on the waiting list to receive a new wheelchair by any of the institutions or organizations participating in this study will be invited. Only those users whose positioning needs are at the basic level according to the criteria established by the WHO will be included. That is, wheelchair users that can sit upright without the need for additional postural support.

People who are on the waiting list and who go to the participating institutions or organizations will be invited to participate voluntarily in the study and will be informed about the maintenance reminders twice a week through text messages. Given that all participants must have cell phone service, the allocation will be randomized by type of wheelchair and based on whether or not they have a wheelchair at the beginning of the study. The caregivers of participating wheelchair users who require assistance will also be invited in order to obtain a maximum of 300 participating caregivers.

Study Procedures

Recruitment of participants

Under no circumstance will it be allowed to initiate study activities without having obtained the informed consent of the user and their caregiver for their participation in the study. The delivery of the wheelchair and the services related will not be conditioned to the participation of the user in the study.

Wheelchair users

All wheelchair users who participate in this study will be recruited from the waiting list of the participating institutions. All institutions have rehabilitation professionals, physical and occupational therapists, who have been previously trained in the 8 steps of the WHO. Participating wheelchair users will be informed about the study through the service providers of the institutions. This information will be provided along with a study brochure (See Appendix A) at the time of scheduling the appointment for care, that is, before the day of assessment and prescription of the wheelchair. The service provider will indicate that the user's participation is totally voluntary and

that their decision will not affect in any way the quality of the services and the delivery of the new wheelchair. In other words, the delivery and related services are not conditioned to their participation in the study. In case the user is interested in participating, they must notify the service provider. The provider will notify an associate researcher so that they can attend the day of the assessment and prescription service of the wheelchair and thus carry out the process of obtaining the informed consent. The associate researcher will provide all the information regarding the study and resolve all doubts and concerns of the user. If the user has more doubts about the study, they will be able to consult them with the researcher at that moment and throughout the study.

Caregivers of users participating in the study

The recruitment of the caregivers will be conditioned by the fact that the person in their charge is a participant of the study and that the caregiver wishes to participate voluntarily. As for the participants, under no circumstances will it be allowed to start study activities without having obtained the informed consent of the caregiver to participate in the study. Caregivers will be informed about the study through the service providers of participating institutions in which the wheelchair user has been recruited. In case the caregiver is interested in participating, they should notify the service provider who will notify an associated researcher so that the latter can proceed to explain the study procedures and obtain informed consent to participate.

The caregivers will be recruited on the same day as the wheelchair users, that is, the day of the assessment and prescription of the wheelchair. A time of approximately two months for the recruitment of users of wheelchairs and their caregivers has been considered.

Participating institutions

The participants of this study will be recruited from the following institutions or organizations:

FUNTER Merliot City

FUNTER Sonsonate

FUNTER San Vicente

Physical Medicine and Rehabilitation Unit of the Salvadoran Social Security Institute

Polyclinic Hospital Planes de Renderos -ISSS

Medical Unit 15 de Septiembre -ISSS

Medical Unit Ilopango -ISSS

Santa Ana's Hospital -ISSS

Usulután's Hospital -ISSS

Sonsonate's Regional Hospital -ISSS

Polyclinic Hospital Zacamil -ISSS

Regional Hospital San Miguel -ISSS

El Salvador's UCPW -ISSS

ISWP Basic Knowledge Test

All providers of wheelchair services from the participating institutions will take the basic knowledge test developed by the ISWP (International Society of Wheelchair Professionals), only once at the beginning of the study, and prior to the Wheelchair assessment and prescription service. The objective of this examination is to evaluate and record the level of knowledge of service providers. The qualification obtained in this exam will not affect the participation of the service provider in the project. The online platform through which the test is performed will request the following demographic information from each service provider before answering the test:

Full name

Postal code, city, state and country of residence

Email

Year of birth

Gender

Native language and languages spoken

Years of experience providing wheelchair services

Place where they received training in wheelchair services

Education, certifications or current licenses

Population age group to which they provide services

Affiliation associations

Employment status, place of work, and number of working hours per week

Reason for taking the exam and material used for training, if applicable

The demographic information obtained at the beginning of the test will be used solely for statistical purposes and to determine future offers of online training programs and will only be shared publicly as a group without identifying any individual service provider.

Wheelchair User Interviews

Four personal interviews will be conducted with wheelchair users and their caregivers in the service provision centers. Only in specific cases, will users be interviewed at home or at a point near their home. The personal interviews that will be conducted are the following:

Initial Baseline Questionnaire ([Appendix B](#)) which will be carried out on the same day as the assessment and prescription of the wheelchair, two months before the delivery of the wheelchair
Initial Wheelchair Delivery Questionnaire ([Appendix C](#)) which will be carried out at the time of delivery of the wheelchair (maximum two months after the evaluation)

3-Month Follow up Questionnaire ([Appendix D](#))

6- Month End Line Questionnaire ([Appendix E](#))

Personal interviews will be used to collect demographic information from participants, health, wheelchair use, quality of life, socioeconomic status, social integration, and wheelchair skills. The components of these questionnaires are described later in the data collection tools section.

The interviewer will read all the questions on the questionnaires as they are on the electronic tablet and, in case the participant does not understand the meaning of any question, the interviewer will explain without guiding the response and will ensure that the participant understands the meaning of the question. The participant may refrain from answering any question that seems inappropriate or that they do not want to answer.

The interviews will take approximately 45 to 60 minutes to complete. All the answers of the participants will be registered in electronic tablets previously configured with the questionnaire through the application KoBoToolbox. Once the interview is completed, the interviewer will write the important notes and complete a printed form with their observations (See [Appendix H](#)).

The information gathered in the personal interviews will be recorded, stored and handled as detailed in the sections on data management and storage below. Researchers will organize visits to the corresponding health centers according to appointments of services scheduled for users in the participating institutions so that the interviews are conducted on the same day of the service in a coordinated manner.

Caregiver Interviews

Caregivers of wheelchair users who require assistance to perform their activities of daily living will be interviewed in person with the same frequency and on the same days as the participating users. To interview the caregivers, the Caregiver Burden Questionnaire (Appendix F) will be used. Their answers will be recorded on electronic tablets.

Monthly Phone Follow-up

Wheelchair users (or their caregiver) will receive a monthly follow-up call for 6 months after receiving the wheelchair and excluding the months in which personal interviews are conducted (3 and 6 months). The first phone call will be one month after receiving the new wheelchair. In this call, information will be obtained about any damage to the wheelchair and its consequences for the user and/or caregiver (See [Appendix H](#)). The answers to the questions asked during these calls will be recorded on an electronic tablet in the same way as in the personal interviews. Monthly follow-up information by phone call will be documented and stored as detailed in the [document](#).

Installation of Data-Loggers (DLs)

A representative sample of the activity levels of the users will be obtained through sensors or "Data-Loggers" that will be installed in the spokes of one of the rear wheels of the wheelchair. The Data-Loggers will be installed three times for participants who have a wheelchair at the time of recruitment, and twice for those who get their wheelchair for the first time. That is, for

participants who have a wheelchair at the time of recruitment, the data-logger will be installed in the wheelchair they use at that time and will remain installed for two weeks. Later, when these participants receive their new chair, a data-logger will be installed in the new equipment for data collection for two weeks. Three months after receiving the new wheelchair, data-loggers will be installed in the spokes of the wheels of all participants again for two weeks for data collection.

The installation of the data-loggers will be carried out during the visits of the participants to the health centers of the participating institutions. The researchers will take a photograph of the data-logger once installed and of each of the 3 installations to make sure it has been installed correctly.

After two weeks of being installed, the data-loggers will be removed from the participants' wheelchair. To carry out this activity, this study has considered the hiring of personnel with motorcycles that can travel to the homes of the participants or to a meeting point to remove the data-logger from the wheelchair. The hired personnel mobilized on a motorcycle will remove the data-logger and deliver it to the researchers so that they are the only ones who have access to the data. Wheelchair users and their caregivers will be instructed by researchers on how to remove the data-logger from their wheelchair. In addition, they will be given printed instructions on how to remove the sensor ([Appendix W](#)), a screwdriver, and a cardboard box so that they can remove the sensor and store it safely. There is no risk of damaging the wheel spokes of the wheelchair when removing the sensor. Each time the researchers install, or receive a data-logger, they will have to verify that the procedure has been carried out correctly using the Data-Logger's Checklist ([Appendix Q](#)).

Maintenance reminders

Participants in this study who have agreed to participate voluntarily in the maintenance reminder study branch will receive reminders twice a week through text messages or "SMS". We want to explore the usefulness of text messages to promote the care and proper functioning of the wheelchair. The maintenance reminders will be sent according to the message schedule indicated in [Appendix I](#), and the messages to be included are detailed in [Appendix J](#). The messages sent, and the platform used to send the messages will be made by an associate researcher of the University of Pittsburgh. If at any time the participating users would like to stop receiving the reminders by text messages, they may indicate this to the researcher so that the latter may notify the associate researcher of the University of Pittsburgh and be removed from the subscription list. All study procedures will have to be recorded in the protocol checklist ([Appendix O](#)).

Data collection instruments

Questionnaire for personal interviews

In order to collect information on the impact of the provision of wheelchairs in the different aspects of users' lives (health, socioeconomic status, social integration, etc.), questionnaires have been selected to cover the topics relevant for this study and which will be administered in person or via telephone during the interviews with the participants. In some cases, certain questions have been eliminated or adapted to ensure that they are appropriate to the social and cultural context of the El Salvador participants. All participants will be given the option to complete in-person interviews via telephone if travel arrangements are inconvenient or too expensive.

The 4 questionnaires that are part of the personal interviews of wheelchair users are:

Initial Baseline Questionnaire ([Appendix B](#))

Initial Wheelchair Delivery Questionnaire ([Appendix C](#))

3-Month Follow up Questionnaire ([Appendix D](#))

6- Month End Line Questionnaire ([Appendix E](#))

The tools that are part of these questionnaires are indicated below.

ISWP Minimum Uniform Dataset (MUD)

The International Society of Wheelchair Professionals (ISWP) developed a questionnaire called ISWP Minimum Uniform Dataset (ISWP-MUD), to be used by wheelchair service providers during the delivery or service with customers. This questionnaire considers the acquisition of the wheelchair or its replacement. ISWP-MUD allows us to obtain demographic information of the client such as age, gender, educational level, working status, the technology used to mobilize, propulsion method, assistance required in both indoor and outdoor spaces and means of transport used. For this study, the complete version of this questionnaire was selected, which consists of 36 questions, and requires between 7 and 10 minutes to be completed. The short version of this instrument (26 questions) has been used in pilot studies in Kenya between 2016 and 2017 (International Society of Wheelchair Professionals [ISWP], n.d.a).

Questionnaire for the Measurement of Social Integration Craig Handicap Assessment and Reporting Technique (CHART)

The Craig Handicap Assessment and Reporting Technique (CHART) questionnaire was developed by Whiteneck et al. (1992). It is based on the domains of the WHO for the assessment of orientation, physical independence, mobility, occupation, social integration and economic sufficiency of people with disabilities. For this study, only the social integration domain of CHART was selected, which refers to the measurement of the ability of people with disabilities to participate and maintain social relationships. This domain considers factors such as the people living in their home, partner relationships, the number of relatives, business associates and friends with whom frequent oral or written contact is maintained and the number of conversations with strangers that the person initiates.

Wheelchairs Service Questionnaire

Accelovate is a global program dedicated to increasing the availability and use of innovative technology for low-income countries. In 2015, Accelovate conducted a study that analyzes wheelchair services received by users in Kenya and the Philippines. For this, a questionnaire was

developed that contains a module on the wheelchair service in which the supply is evaluated in relation to the evaluation, adjustment, user training, maintenance, repair and follow-up. That is, through this questionnaire it is possible to obtain information about the services granted. Therefore, questions from this questionnaire have been adapted and translated into Spanish to be used at the beginning of this study and at the time of delivery of the wheelchair.

Wheelchair Skills Test Questionnaire (WST-Q)

The Wheelchair Skills Test Questionnaire, (WST-Q), allows assessing the capacity, confidence and frequency with which the wheelchair user performs a series of activities safely in their wheelchair. For example, assess the user's ability to operate the wheelchair parts, propel the chair long distances, raise and lower ramps and stairs, lift the front wheels to avoid obstacles, make transfers to and from the wheelchair, turn, among others. The WST-Q can be self-administered or completed in the form of an interview with the help of the caregiver, by telephone, or by mail, so it does not require equipment or specialized space to carry it out. This instrument consists of 34 questions and takes about ten minutes to be administered (Kirby et al., 2016). The WST-Q is available in Spanish for the use of participants and data collectors in El Salvador.

Wheelchair Maintenance Training Questionnaire (WMT-Q)

The Wheelchair Maintenance Training Questionnaire, WMT-Q, is dedicated to health professionals and users of manual and power wheelchairs. This questionnaire allows us to obtain information about the participant's knowledge about the maintenance that must be performed regularly to the wheelchair (Toro et al., 2017). It should be noted that for this study only the version for manual wheelchair users has been considered. WMT-Q has 20 main questions with logic related to 20 additional questions in case of an affirmative answer.

Breakdowns and Adverse Consequences Questionnaire (BAC-Q)

The Breakdowns and Adverse Consequences Questionnaire (BAC-Q) will allow obtaining information about the failures that may occur in the wheelchairs during the study. BAC-Q allows knowing the failures in the tires, front wheels, the wheelchair frame, elements of postural support, seat, backrest, cushion, and it gives the opportunity to indicate another type of failure if necessary. By means of this questionnaire it is possible to know the person who carried out the repair and the consequences in the users due to wheelchair breakdowns (McClure et al., 2009). For example, being stranded at home or away from home, injuries due to failure, lack of school attendance, work, medical appointments, or other.

Poverty Probability Index (PPI) in El Salvador

The Poverty Probability Index (PPI) measures the level of poverty in which participants live and their changes over time. In other words, it determines if the people that make up a household are below the poverty line of reference of the PPI. The version for El Salvador is based on censuses and local data. The PPI was created by Mark Schreiner of Microfinance Risk Management in 2010 and is available in Spanish. This consists of ten multiple-choice questions about the characteristics of the home and its assets. The time required for the administration of this survey is between five and ten minutes (PPI, n.d.).

WHO Quality of Life Questionnaire (WHOQOL-BREF)

WHO developed a questionnaire called WHOQOL-BREF to measure the quality of life of people. Its design is suitable to be used in different cultural environments with research objectives, policy making, health practices and auditing. WHOQOL-BREF is the reduced version of WHOQOL-100 and allows a complete evaluation when analyzing four fundamental domains, such as: physical, psychological, social relations and environment. It is designed in such a way that it can be answered by the participant with or without assistance. According to the information provided by the WHO, this tool has been shown to have good discriminating validity, content and reliability. In addition, the WHO indicates that this material is being tested in the field and that the sensitivity to change is being analyzed at the moment (WHO, 2014).

The WHOQOL-BREF consists of 26 questions, but a question related to sexual activity was eliminated, because it was considered culturally inappropriate. Questions regarding transportation and the environment were also eliminated to avoid repetition in other questionnaires.

MIT Health Questionnaire

The questions corresponding to this section of the questionnaire were developed by the Massachusetts Institute of Technology - Comprehensive Initiative on Technology Evaluation (MIT-CITE) for the pilot phase of this study. It was developed in order to determine the reasons, consequences, and medical attention received for injuries related to the use of the wheelchair such as falls during transfers, falls during maneuvering, injuries to the shoulders, elbows, wrists, hands and back. This section consists of 25 questions that were based and inspired by the pilot phase that took place in Indonesia, and in other tools that have addressed similar issues such as the health section corresponding to module 5 of the Accelovate study in 2015.

The Zarit Caregiver Burden Questionnaire (ZBI)

The questionnaire that will be used in personal interviews with caregivers is the Zarit Caregiver Burden Questionnaire or better known as ZBI (Zarit Burden Interview), which consists of 22 questions that evaluate the burden of caregivers of people with senile dementia and people with disabilities. The ZBI assesses the caregiver's burden taking into account aspects of the caregiver's life such as family, free time and social activities (Zarit, 2016). This questionnaire can be self-administered, has high content validity, high internal consistency, and great confidence of repetition (Ankri, Andrieu, Beaufils, Grand, & Henrard, 2005). The ZBI is available in Spanish, so it can be used in El Salvador as an instrument to measure caregiver burden. (See Appendix F)

Phone Follow-Up Questionnaire

The questionnaire that will be used during the telephone follow-up of the participants is intended to know the user's satisfaction, the failures or repairs made, adverse consequences related to failures in the chair, and the inadvertent development of pressure ulcers. This telephone call will last approximately 10 minutes and will be carried out by local researchers at the University of El Salvador. (See Appendix G)

Data Loggers

For this study, robust and waterproof sensors were developed, known as data-loggers (see

Data-logger information). The Data-logger is a device that is installed in the spokes of the rear wheel of the wheelchair and that measures the time of use and the number of turns that the wheel gives. Therefore, with the data obtained it is possible to calculate the distance and speed of the user in the wheelchair. The data-loggers have an SD memory card, where the collected data will be stored for later transfer to a secure computer and uploaded to the secure server of the University of Pittsburgh, as mentioned in Data Management and Storage.

Additional Tools

For ethical reasons and to ensure that the study procedures are carried out properly, this research study includes wheelchair providers who have been previously trained in the 8 steps recommended by the WHO. Therefore, to assess the level of knowledge of the providers and be able to associate it with the results obtained, they must perform The Basic Wheelchair Service Knowledge Test, developed by ISWP.

ISWP Basic Level Knowledge Test

The ISWP Basic Exam developed by ISWP is based on the Basic Level Wheelchair Service Training Package (WSTPb) developed by the WHO. This test is intended to measure the knowledge of wheelchair service providers consists of 75 multiple-choice questions and covers domains of evaluation, prescription, fitting, production, user training, process and monitoring, maintenance and repair. This exam is available in Spanish and can be done online on the ISWP platform (ISWP, n.d.b). This questionnaire will serve as an instrument to measure the level of knowledge of the service providers involved in this study. Providers are not required to pass the exam, but everyone is expected to pass the exam.

Data documentation

The information collected will be recorded in forms in printed and digital format as described below.

Forms in printed form:

The following is a list of all the forms that will be used with each participant and that are attached at the end of this document:

WUV Informed Consent Forms (See Appendix K)

WUV Informed Consent Forms for Participants Who Cannot Read or Write (Appendix K.1)

Informed Consent Form for Caregivers ([Appendix L](#))

Informed Consent Form for Caregivers Who Cannot Read or Write ([Appendix L.1](#))

Documentation of Informed Consent ([Appendix M](#))

WUV Inclusion/Exclusion Criteria ([Appendix N](#))

Protocol Checklist ([Appendix O](#))

WUV Adverse Event Protocol Deviation Form ([Appendix P](#))

Data Logger Verification Checklist ([Appendix Q](#))

In addition, the training of investigators and data collectors in the field will be documented in printed format through the following forms, as well as training certificates:

Data Collector Training Sign in Sheet ([Appendix R](#))

Trainer Observation Checklist ([Appendix S](#))

Forms in digital format

All the questionnaires will be administered in digital format through the application KoBoToolbox installed in tablets given to each of the researchers. KoBoToolbox is a free set of tools that allows the implementation of questionnaires and the collection of data in the field. KoBoToolbox was developed by The Harvard Humanitarian Initiative for use in complex environments, including humanitarian emergency locations. This application is intended for mobile devices, whether electronic tablets, smartphones, or computers, and can be used with or without an Internet connection.

This data collection tool has been chosen because:

It decreases the probability of error by the researcher when entering the answers since the application allows to configure the type of question/answer (open, closed), response options (categories, ranges, etc.), and the format of the answer (numeric, date, number of digits, text, etc.)

The application can be used in offline mode without the need of an Internet connection or specialized technical knowledge. In this way, all responses are stored locally on the device and synchronized on the secure server once you have access to a secure data transmission network. In addition, it allows the direct export of data in a spreadsheet

The data is automatically stored in the desired format without the need for the researcher to modify or process them, thus decreasing the probability of making mistakes

It allows the control of access to information, that is, only the authorized persons will have access to the data entered in the questionnaires, ensuring the privacy and confidentiality of these; and

Once the interview files are synchronized on the KoBoToolbox server, a research associate at the University of Pittsburgh will be responsible for reviewing the data to ensure its integrity and quality, integrate them into a database and analyze them.

List of forms in KoBoToolbox:

Initial Baseline Questionnaires (See Appendix B)

Initial Wheelchair Delivery Questionnaire (See Appendix C)

3- Month Follow Up Questionnaire (See Appendix D)

6- Month End Line Questionnaires (See Appendix E)

Caregiver Burden Questionnaire (See Appendix F)

Follow-Up Phone Script Questionnaire Electronic spreadsheets(See Appendix G)

All spreadsheets will be stored on a password protected computer and will be maintained on a secure server at the University of Pittsburgh.

List of spreadsheets:



WUV Data Management Spreadsheet (See [Appendix T](#))

WUV DL Registry (See [Appendix U](#))

WUV Study Participant Contact Information (See [Appendix V](#))

Schedule of activities with wheelchair users

Below are the activities that will be carried out in the study from recruitment to the end of the study. The study contains activities that are carried out in person and by telephone, as shown in Table 1. Activity Schedule with Wheelchair Users.

Activities in person

Recruitment

Baseline Questionnaire

Installation of DL at the time of recruitment

Follow-up questionnaire at the time of wheelchair delivery

Installation of DL in new wheelchairs for two weeks

Follow-up questionnaire at three months (optional by telephone)

Installation of DL in new wheelchairs for two weeks

End of study questionnaire at 6 months (optional by telephone)

Telephone follow-up questionnaire at months 1, 2, 4, and 5. (by telephone)

The participant have a waiting period of two months to receive their new wheelchair after the day of the evaluation and prescription made by the service provider in order to prepare the product according to the needs of the user and have enough basic information to be able to identify changes in the indicators due to the provision of a wheelchair through the 8 steps of the WHO. Therefore, the telephone follow-up questionnaire is done the first month after receiving the new wheelchair and then monthly as indicated above.

Table 1. Activity Schedule with Wheelchair Users

Activity	1 month	1.5 month	2 month	2.5 month	3 month	3.5 month	4 month	5 month	5.5 month	6 month	6.5 month	7 month	8 month	8.5 month	9 month	10 month	11 month
Recruitment	X																
Baseline questionnaire	X																
Follow-up questionnaire at the time of delivery of the wheelchair					X												
Follow-up questionnaire by phone call-month 1							X										
Follow-up questionnaire by phone call-month 2								X									
Follow-up questionnaire at three months										X							
Follow-up questionnaire by phone call-month 4												X					
Follow-up questionnaire by phone call-month 5													X				
End of study questionnaire																X	
Data Logger Installation		X*				X**				X							
Data Logger Deinstallation			X*				X**				X						

*Installation/Deinstallation of Data Loggers for those users who have a wheelchair at the time of recruitment

** Installation/Deinstallation of Data Loggers in new wheelchairs at the moment of delivery

Schedule of activities with caregivers

The activities with the caregivers consist of carrying out the corresponding questionnaires at the beginning of the study, at the time of delivery of the new chair, at 3 months and at the end of the study as indicated in Table 2.

Table 2. Schedule of Activities with Caregivers

Activity	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month	10 month	11 month
Recruitment		X									
Caregiver questionnaire at the moment of the evaluating the participating wheelchair users		X									
Caregiver questionnaire at the time of delivery of the new wheelchair to the participating wheelchair users			X								
Caregiver questionnaire three months after the delivery of the new wheelchair to the participant						X					
Caregiver questionnaire six months after the delivery of the new wheelchair to the patient									X		

Data Management and Storage

No data will be collected until the both institutions the University of El Salvador and the IRB (Institutional Review Board) by the University of Pittsburgh approve the study. All data from personal interviews with users and their caregivers, as well as telephone call interviews, will be collected using electronic tablets. Once the interview or call has been completed, the information will be stored locally on the tablet and sent to a secure server in KoBoToolbox when there is access to the Internet and a secure network. Study files will be removed from the tablets periodically, once the data is completely verified and on the servers. The files containing identifiable information will be stored in the Pitt Box secure server at the University of Pittsburgh in a separate folder with restricted access.

The text files generated by the Data-Loggers will be downloaded and deleted from the sensor memory card. The photographs of the sensors installed wheelchairs, will be downloaded from the electronic tablets and removed from them. Both the text files and photographs will be stored in the researchers' computer in a folder with a password then uploaded in Pitt Box.

All printed forms will be scanned and uploaded to PittBox. The files containing identifiable information will be stored in a separate folder and with restricted access. Researchers at the University of Pittsburgh will update the WUV Data Management Spreadsheet (Appendix T) to track participants and ensure that all information is complete. The physical copy of the participants' informed consents will be stored in a locked cabinet for a minimum of seven years. Access to both physical and digital documents will be restricted and only the Principal Investigator and the associated research staff will have access to them. Each user account for PittBox and KoBoToolbox is password protected. All study data will be separated from identifiable information. These will be stored in a separate electronic spreadsheet that will be created as the data is

received and then uploaded to the secure server at the University of Pittsburgh. In all reports, we will refer to the participant with categorical names such as wheelchair user. Other researchers may want to see this data. Thus, we will ask participant's permission to share this de-identified information, so that they can review and use the data, but will not be able to identify the participant.

Statistical Methods

Descriptive statistics will be used to report the demographic and health information of the participants at the beginning of the study. For continuous variables, measures of central tendency (mean and median) and variability (standard deviation) will be reported. In addition, a graphic exploration of the distribution of the sample will be made. For categorical variables, the frequency and percentages of the total sample will be reported by the wheelchair group.

As mentioned above, all the main hypotheses aim to detect a significant intra-subject longitudinal change. Detailed graphical explorations will be carried out for each result over time, both for the total sample and for each participant. In order to test all hypotheses, including continuous variables, ANOVA will be carried out with repeated measures, such as, for example, Hypothesis 1.1, quality of life values. In the case of counting or binary variables, such as Hypothesis 1.2: number of falls, pressure ulcers, etc; 1.3: number of failures and/or adverse events in the wheelchair, logistic or longitudinal Poisson regression will be performed. The total number of failures and adverse events of wheelchairs recorded during the study period will be described for the total sample and per participant.

A secondary analysis will be performed comparing two groups according to the measurements over time. The first group is formed by participants who report having a wheelchair at the beginning of the study and the second group corresponds to those who report not having a wheelchair at the beginning. For continuous variables, such as quality of life, or economic participation, ANOVA of mixed effects will be carried out by group for the inter-subject variables and by the point of time of data collection for the intrasubject variable. Interaction between groups (participants who have a wheelchair versus those who do not have a wheelchair at the beginning of the study) and time (beginning, follow-up and end of the study) would be of greater interest given that those participants who have a wheelchair at the beginning of the study are expected to have better results than those that did not. That is, their results would increase significantly after receiving services following the 8-steps recommended by the WHO in conjunction with the new wheelchair. For this secondary analysis, an adequate power (≥ 0.8) is expected to significantly detect a small effect size for the interaction time (partial $\eta^2 = 0.01$), even if there is a small sample number of participants with a wheelchair at the beginning of the study ($n = 162$). In other words, in the event that about half of the desired number of participants is recruited, although this situation is not expected and being extremely conservative, only about 80 participants who have a wheelchair at the beginning will be needed (G * Power 3.1.9.2).

Adverse Events and Protocol Deviations

Investigators should email the coordinating center within 10 working days of any unanticipated problems or non-compliance that occurred during conducting the study. The site should provide the following information:

Describe the unanticipated problem which occurred during the conduct of the research (include subject ID, chronology of events, persons involved, etc.)

Explain the reason(s) this unanticipated problem occurred

Indicate whether the described unanticipated problem involves risk to human subjects or other (for each described problem, indicate the risk to each individual subject or to the study population in general)

Describe steps which have been taken to resolve the problem and procedures implemented to avoid future occurrences

Ethical considerations

In order to respect the confidentiality and dignity of the participants before, during and after the study, including data collection, the following ethical considerations will apply: Each person has the power to participate voluntarily in the study, as well as to leave at any time. Participants who decide to participate in the study should read the document "Informed Consent", which describes the study before starting the investigation. This document confirms that all confidential, private, sensitive and identifying information to the participant will be protected and stored in the University of El Salvador in a locked cabinet. In case participants present difficulties in reading informed consent, the document will be read and explained in a way that ensures that users and their caregivers understand the study procedures. Doubts or questions that wheelchair users or their caregivers have will be answered. The study will respect the realization of the activities in the Health Centers where the research will be carried out. The disturbance caused by the activities of the researchers will be minimal. Participants are not required to participate in the study under any circumstances in order to receive a wheelchair. That is, people who choose not to participate in the study will be assessed, receive the corresponding service, be prescribed and be given the appropriate wheelchair according to their needs without any difference to the people who choose to participate in the study. The people who provide the wheelchair services for the study have been properly trained in the 8 steps of the WHO. That is to say, the personnel that will attend the patients are qualified to provide the adequate services in the supply of wheelchairs. Health services will be given regardless of whether people choose to participate or not in the study. The physical documents will be kept in a locked cabinet for a minimum of seven years. Access to physical and digital documents is restricted to the Principal Investigator and the associated research staff. The personal information of each participant will be stored on a password protected or protected computer through the network. Local researchers will be trained in the responsible and ethical conduct of research with human subjects, as well as in the study procedures. The cultural aspects have been taken into account according to the context of El Salvador, so that

questions that could be offensive or culturally inappropriate have been removed. The study procedures will not be initiated without the prior authorization of the National Committee of Ethics in Health Research.

Ethical considerations corresponding to the stage of analysis and interpretation of data

All researchers at the University of El Salvador will be certified in the protection of human subjects. Permission will be requested to carry out the research in the participating institutions through agreements signed between the parties involved in it.

Informed Consents

Since there are two types of participants, two different informed consents are required: Participant Informed Consent and the Caregiver Consent.

Wheelchair users - will be recruited as the main participant. Sensitive and identification data will be collected through a fully documented process. This document will be duly stored and protected by the data collectors of the University of El Salvador.

Caregivers of wheelchair users- who require a caregiver will be recruited to provide information about their levels of effort as caregivers and about the wheelchair users who cannot provide it independently, where they will act as representatives. The informed consent form of caregivers is separate from the informed consent form of wheelchair users. This document will be duly stored and protected by the data collectors of the University of El Salvador.

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Appendices

- A. Study Brochure
- B. Initial Baseline Questionnaires
- C. Initial Wheelchair Delivery Questionnaire
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- H. WUV Observational Sheet
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- T. WUV Data Management Spreadsheet
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