Multicenter Implementation of Orthogeriatrics and the Fracture Liaison Service for Elderly Hip Fractures: An evidence-based framework for a sustainable digital health registry

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I. Synopsis

Fragility hip fractures in the elderly impose a heavy clinical and economic burden on both patient and society. To begin addressing this under-recognized problem, the combined Orthogeriatric Fragility Fracture Management (OFFM) and the Fracture Liaison Service (FLS) of the University of the Philippines Manila - Philippine General Hospital (UP-PGH) was established in October of 2017[1]. Utilizing a team-based coordinated multidisciplinary approach in managing elderly hip fractures, including its secondary prevention, early results in UP-PGH showed significantly improved patient outcomes and cost effectiveness, with an average savings of 20,000 pesos per treatment of each elderly charity patient with a hip fracture. In the process of documenting these improvements, we were also able to establish a quality in-hospital database to continuously support and audit our clinical services for fragility hip fracture care.

With the collateral effects of the COVID-19 pandemic wherein many elderly people were unable to continue their regular bone strengthening activities due to lockdowns, we anticipate a far greater number of fragility fractures to occur in our country in addition to the expected increase in numbers prior to the pandemic. This study aims to expand OFFM and FLS across hospitals in the country, describe the outcomes over a two-year period (January 2022 to December 2023), and produce an electronic data collection framework based on key clinical standards that will be the basis for a sustainable national hip registry.

II. Introduction

Osteoporosis, an often asymptomatic but debilitating disease, has been labelled as the "silent killer" for decades [2]. However, given the inevitable and dramatic rise in the world's ageing population, osteoporosis is now raising alarms all over the global health landscape. The annual incidence rate of osteoporotic fractures, otherwise known as fragility fractures, in women is now greater than the combined incidence rates of heart attack, stroke and breast cancer [2]. Corollary to this problem, local data from the Philippine General Hospital has estimated the annual financial burden to be a staggering Php 1,094,048,363.00 or US $22,595,007.79 for patients with acute fragility hip fractures alone[3]. According to the International Osteoporosis Foundation's (IOF) 2019 Compendium on Osteoporosis, "In 2010 the number of individuals aged 50 years and over at high risk of osteoporotic fracture worldwide was estimated at 158 million and this is set to double by 2040."[4] These fragility fractures commonly occur at the hip, shoulder, ankle, spine and wrist joints with debilitating sequelae.

International literature estimates that across fragility fractures there is a hospitalization rate of 93% for hip fractures, 36% for humeral fractures, 31% for ankle fractures, 28% for vertebral fractures and 23% for wrist fractures [5]. Vertebral fractures are the most common osteoporotic fractures worldwide, which occur in 30-50% of people beyond the age of 50 [5,6]. Majority of these fractures are undetected and even fewer are hospitalized. These fractures, even if asymptomatic, are linked with poor outcomes such as persistent back pain, physical impairment and a higher risk of subsequent fractures. Wrist fractures are the most common fractures seen in perimenopausal females[5]. The risk of getting a hip or vertebral fracture after a wrist fracture is doubled. Humeral fractures represent the 3rd most common non-vertebral type of fracture, following wrist and hip fractures [5,6]. The presence of a humeral fracture increases the risk of getting a hip fracture by 5 times [5]. Likewise, sustaining foot and ankle fractures also double the risk of getting a hip fracture[5].

Among fragility fractures, those that occur in the hip remain the leading cause of disability and death around the world. Almost 1 in 4 elderly patients following a hip fracture will die within one year after the fracture, half of all patients will sustain long term disabilities, and another quarter will require long term nursing care [7,8]. A recent study conducted by the Asian Federation of Osteoporosis Societies (AFOS) reported that there will be a 2.28-fold increase in the number of Osteoporotic Hip Fractures in the Asian region from 1,124,060 in 2018 to 2,563,488 in 2050[6]. Parallel to that is the projected increase in the financial burden of fragility hip fracture management from 9.5 billion United States dollars (USD) in 2018 to 15 billion USD in the year 2050[9]. The cost per hip fracture is estimated to be over US$ 2,000 (over Php 110,000)[8]. In the United States alone in 2005, osteoporosis-related fractures cost its healthcare system approximately US$19 billion. By modest projections, these costs would amount to about US$25.3 billion in 2025[8]. These glaring statistics are already placing an enormous burden on healthcare systems, especially in low to middle income (LMIC) countries like the Philippines. The latest data from our National Health Insurance System shows a total of 17,875 fractures from 2007-2012 in those aged 50 years old and above. The IOF hip fracture incidence map shows that Philippine hip fracture prevalence is estimated at 93/100,000 per year[10].

Several countries have now adopted an interdisciplinary approach in the treatment, rehabilitation and secondary prevention of fragility fractures, with the goal of improving patient outcomes and curbing its economic effects using a coordinated effort. The accepted standard of care for fragility hip fractures is a multidisciplinary model known as Orthogeriatrics which aims to provide

a comprehensive approach encompassing urgent surgery, early mobilization, optimal rehabilitation, secondary fracture prevention, and shorter hospital stay to maximize recovery and minimize perioperative morbidity and mortality [12, 13, 14, 15, 16, 17].

Orthogeriatrics is defined as "medical care for older patients with orthopaedic disorders that is provided collaboratively by orthopaedic services and aged care or rehabilitation services.[18]" Its primary goal is to ensure immediate fracture treatment within 48-72 hours from the time of injury which includes: comprehensive geriatric assessment, medical optimization, treatment of comorbidities, acute surgery, management of post-operative complications, and subsequent falls prevention[18,19]. In the last 50 years, It has already resulted in demonstrable improvements worldwide with regards to the care of elderly patients with fragility fractures as well as being more cost effective than the previously accepted standard of care [19,20].

Orthogeriatrics was only recently introduced to the Philippine medical setting on October 2017 at the UP-PGH when the Department of Orthopedics launched the combined Orthogeriatric Fragility Fracture Management (OFFM) and Fracture Liaison Service (FLS). While Orthogeriatrics provides acute, excellent and multidisciplinary care in the setting of fragility fractures, the FLS closes the osteoporotic treatment gap by identifying, investigating and subsequently treating osteoporosis among those presenting with hip fractures, including those with symptomatic non-hip, non-vertebral fragility fractures, which constitute the majority of fracture sites[19]. This combined treatment model was conducted in partnership with the Departments of Anesthesiology, Internal Medicine, Family and Community Medicine, and Rehabilitation Medicine.

Anesthesiologists and internists work together with the orthopedic surgeon in providing early risk assessment, clearance, and surgery for elderly patients with hip fractures. In addition, the anesthesiologist, as well as pain specialists, provide adequate pre-op and post-operative pain control to allow these patients to mobilize earlier, and this further prevents morbidity from prolonged immobilization. Our partners from Rehabilitation Medicine provide each patient with pre-operative conditioning, and post-operative bedside exercises and gait retraining, focusing on falls prevention. Medicine specialists, along with Family and Community Medicine physicians, ensure that each patient is screened and treated for osteoporosis, with the necessary laboratory exams and DXA scan (if available), maintenance medications, and lifestyle modifications. During the outpatient follow-ups and evaluation, a Comprehensive Geriatric Assessment (CGA) tool is used by Geriatricians, from both

the Internal Medicine and Family Medicine Services. The CGA is the most comprehensively researched model for the delivery of healthcare to the elderly population, focusing not only on medical concerns but also functional impairments, environmental and social issues of an individual.

This Orthogeriatric team works in concert with the FLS. The FLS is a coordinator-based unit which ensures that each patient is evaluated for fracture risk assessment and is managed for osteoporosis and secondary fracture prevention even before the patient has been discharged. The FLS coordinator is tasked to identify each eligible patient upon admission and documenting their hospital stay. Its essential role is continued even after discharge by monitoring the compliance of each patient to the necessary medications, instructions, exercises, and follow-up consultations, whereby calling patients is performed routinely to remind them of their follow-up dates. As coordinator, the FLS sets the pace of the team and implements the patient pathway. This vital contribution has proven not only to be work-efficient but also cost-efficient, with increased savings for elderly hip fractures by as much as $30,849-1,498,961 USD/lifetime [21].

Developing Orthogeriatrics and FLS will be of urgent need mainly because of the Philippines' steadily growing and ageing elderly population. Filipino citizens aged 70 years old and above have been projected to increase by 372%, from 2.8 million to 13.4 million by the year 2050. By the year 2050, Filipino life expectancy is also predicted to improve from 72 to 80 years[22]. The geriatric population will have multiple problems unique to their age group, emphasizing the fact that they are not just "older adults". Among these frailties include decreased muscle mass and strength, poorer response time and decreased bone mass. These altogether lead to a propensity for fractures even from low-energy impact injuries, such as falling from a standing height[7].

Looking at the initial results upon implementing the combined OFFM and FLS in the Philippine General Hospital[1], a decrease in the interval of patient admission-to-surgery from 13.42 to 8.31 days and length of hospital stay from 21.48 to 15.47 days were observed. There was a resulting 62% decrease in the time-to-surgery and a 28% decrease in the length of hospital stay[1]. While this demonstrates improvement in key outcomes, it is still far from ideal. National data shows that a mere 25 to 50% of fragility hip fractures are treated surgically[10]. Thus, continuous improvement of the clinical pathway adapted to our setting is needed to respond to the global call to action to improve the care of people with fragility fractures [23].

The framework of this study involves expanding the evaluation and treatment approach of elderly patients with fragility hip fractures using the combined Orthogeriatric and FLS model by setting up similar models in other hospitals with the goal of furthering orthogeriatric care nationwide (Figure 1).

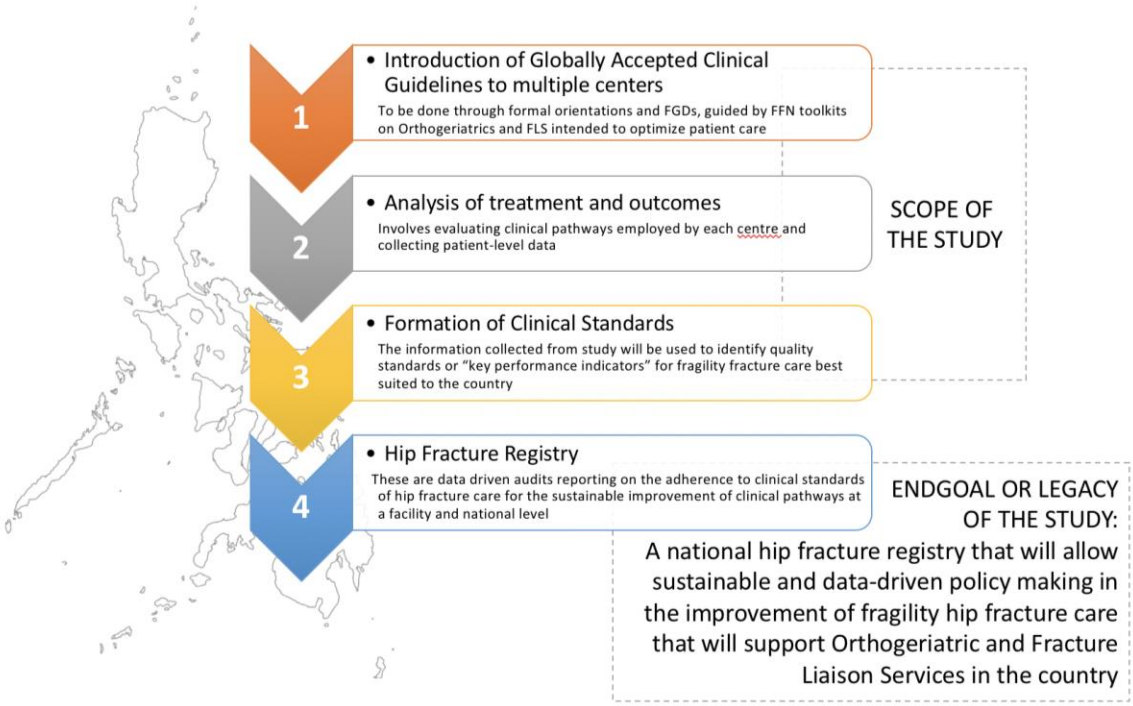


Figure 1. Framework of the study.

This comprehensive strategy will contribute to the optimal care of the elderly fracture patient from both the perspective of the patient and the health care provider while eventually mitigating direct and indirect costs from osteoporotic fractures. The key performance indicators that will be determined in this study will be prerequisite to the establishment of a clinically relevant and sustainable multicenter hip fracture registry. This registry will allow continuous feedback to hospitals, translating to continuous improvements in the quality of their health service by allowing them to measure their performance based on clinical standards and subsequently use this data to build on improving fragility fracture care for patients.

III. Significance of the study

As we enter the Decade of Healthy Ageing (2021-2030), as declared by the World Health Organization and the United Nations, it is high time that focus be given to the most dreaded complication of osteoporosis, that is fragility hip fractures in the elderly. In order for the country to keep abreast with the rest of the world regarding their management, the improvement of fragility hip fracture care should be based on proven and cost-effective models of care such as Orthogeriatrics and the Fracture Liaison Service. This study will expand these proven models of care to major hospitals in the country with the hope of delivering efficient and ideal patient management at the lowest possible cost. By measuring the clinical outcomes of patients undergoing current pathways of care, we will be able to determine the key performance indicators needed to improve services. This will be the necessary precursor to a future national fragility hip fracture registry. Unlike previous attempts in establishing a hip registry in which the focus is just on statistical data gathering, this project will obtain quality and relevant clinical outcome data which will generate a sustainable hip fracture registry that can be a tool for continuously improving health service delivery.

IV. Objectives

Primary Objectives:

1. To describe the clinical, treatment, and post-treatment characteristics of geriatric patients with fragility hip fractures.

2. To measure the following outcomes in geriatric patients with fragility hip fractures

Primary:

a. Quality of life

b. Functional recovery

c. Mortality rate

d. Pre- and post-operative complications

Secondary:

a. Follow-up rate

b. Compliance to bone protection medications

3. To determine significant clinical, treatment and post-treatment factors, to be known as key performance indicators, associated with the outcomes to be studied.

4. To generate an electronic data collection framework that will include key performance indicators for use in a future sustainable national hip registry.

Secondary Objectives:

1. To develop OFFM and FLS models of care to major hospitals nationwide.

2. To describe current practices and challenges in the implementation of a Combined OFFM and FLS for elderly fragility hip fractures among participating hospitals.

V. Study Methodology

This will be a prospective cohort study that aims to describe the characteristics and outcomes of geriatric patients with fragility hip fractures treated in participating hospitals, as well as to analyze and determine significant factors associated with those outcomes. Because we want to expand the evaluation and treatment approach of elderly patients with fragility hip fractures using the combined Orthogeriatric and FLS model by setting up similar models in other hospitals, the objective of this study is also to describe current pathways of care and the challenges in implementing these models as experienced by those hospitals. Another objective would be to recommend a data collection form that will include key performance indicators for use in a clinically relevant and sustainable national hip registry in the future. The study duration will be 24 months.

A. Study Population

Inclusion Criteria

All geriatric patients aged 60 years old and above who were managed by the combined OFFM and FLS in the different participating hospitals from the time period of January 2022 to June 2023 with fragility hip fractures regardless of the time from injury, will be included in the study. This will include all patients admitted during the time period, as well as patients initially seen at the outpatient clinic but not admitted. Fragility hip fractures in this study will be defined as any fracture of the hip or proximal femur in a patient aged 60 years or older after minor trauma (ie. fall from standing or sitting height). Hip fractures include intracapsular (femoral head and femoral neck), intertrochanteric (extracapsular, between the greater and lesser trochanters), and subtrochanteric (from lesser trochanter to 5 cm distal to it) fractures. For patients with prior hospital admissions for the same hip fracture, only the data entry from the most recent admission in which definitive treatment was given will be recorded. This pertains to instances where patients who were admitted but sent home without definitive treatment (i.e. due to COVID, unavailability of implants/OR schedule, concurrent medical illness etc.) are re-admitted again for definitive treatment. Patients without the ability to give consent will still be included in the study as long as a legalized authorized representative (LAR) will sign the LAR form on the patient's behalf.

Exclusion Criteria

Patients with multiple fractures, pathologic fractures, and those without consent for participation in the study will be excluded. Those who are unable to complete the 120-day follow-up in absence of demise, for example those having palliative care only, will also be excluded. Hip fractures secondary to bone metastasis and primary bone tumors will also be excluded. All reasons for exclusion will be properly recorded.

B. Sample Size Calculation

Non-probability consecutive sampling will be used per representative site wherein all consecutive eligible subjects treated in each hospital will be enrolled until the target number of patients recruited is reached. **We have estimated a target of 1000 patients based on the rate of patients from a similar multicenter pilot study of fragility hip fractures during the COVID quarantine period ("Improving the Multidisciplinary Orthogeriatric Care of Fragility Hip Fracture**

Patients During the COVID-19 Pandemic: A Multi-center Experience from a Country with an Emerging Economy; SJREB-2020-32.") also conducted by the research team with data collection spanning 6 months across several hospitals. Around 13-15 patients were enrolled (including dropouts) in that shorter time period with less participating hospitals involved. Given that there is four times the data collection period in this current study and 3 additional hospitals with easing of quarantine restrictions, we estimated around 1000 patients for this study.

C. Study Procedure

The study shall be conducted as follows:

1. Recruitment of Hospital Centers

The selection of hospitals shall be based on the following requirements:

- The hospital is an accredited Philippine Board of Orthopedic (PBO) training institution, a hospital under the Department of Health (DOH) or a hospital authorized by the Department of Health Bureau of Licensing and Regulation, capable of delivering a coordinated multidisciplinary care for elderly patients with hip fractures based on their existing manpower and resources, and is willing to be oriented about the principles of Orthogeriatrics and the Fracture Liaison Service.
- The hospital must provide a point person who will act as the center's orthogeriatric/fracture liaison officer if he or she has not yet been designated such a role already.
- The hospital must provide a Consultant Research Supervisor or site lead investigator who will oversee the research project throughout its course, and who will coordinate with Central Research Data managers. The site lead investigator must at least be a practicing medical consultant or a clinical faculty of the participating hospital/institution.

The research group will contact and recruit those hospitals fulfilling the above requirements.

2. Orientation of Participating Hospitals

a. Introduction of Study

The research group shall conduct an orientation of the study with each participating Hospital, with emphasis on stressing the importance of the combined OFFM and FLS multidisciplinary model, and to address the challenges confronting each participating institution on how to implement it given their existing manpower and system. This will be carried out through Focused Group Discussions (FGDs), in the form of online teleconference or face to face meetings, whichever is more applicable, which will be carried out prior to the actual data collection.

b. Provision and Distribution of OFFM and FLS Toolkit composed of:

Patient Data Forms:

i. *Health-related Quality of Life Score EuroQol (EQ-5D–5L)* to be collected at baseline (retrospective preinjury) and 120 days. The EQ-5D-5L is a validated, patient-reported outcome measure widely used in many countries. This is a generic health-related quality of life measure consisting of 5 dimensions each with a five-level answer possibility. Each combination of answers can be converted into a nation-specific health utility score. **The EQ-5D-5L, which comes in both English and Tagalog versions, will be self-administered with the supervision of a member of the research team.**

ii. *Minimum Common Dataset*

The minimum common dataset (MCD) developed by the Fragility Fracture Network Global will be adapted and appropriately modified by the research group for use as the data collection form. The participating hospitals, however, may still use additional forms unique to their existing record system, these additional data however will not be included in the study. The minimum common data set will include the following:

(a) Clinical characteristics - age, sex, pre-fracture residence, pre-fracture mobility, mental capacity, co-morbidities, pre-fracture bone medications, fracture type, history of fragility fracture

(b) Treatment characteristics - time to consultation and attributed delays, type of treatment (conservative vs surgical vs none), time to surgery and attributed delays, type of surgery performed, type of anesthesia, intra-operative blood loss, pre- and post-operative pain treatment, involvement of multidisciplinary team, administration of a comprehensive geriatric assessment (CGA), pre- and post-operative rehabilitation, immediate post-operative mobility, DVT prophylaxis, bone protection medication,

(c) Post-treatment resources - residence type, home modifications, frequency of therapy received, and type of caregiver.

Clinical Toolkits:

iii. *Progress Assessment Form*

This is a descriptive evaluation form with tools adapted from the 2nd edition Orthogeriatrics (2021) textbook to allow the participating hospital to narrate their current practices for hip fractures in the elderly, their experience in implementing an OFFM and FLS, as well as the challenges/problems which might be encountered. A follow-up form will be given periodically via a secure online survey every 3 months to monitor their progress.

iv. *FFN Orthogeriatric Clinical Toolkit*

The orthogeriatric clinical toolkit for geriatric patients with fragility fractures is a set of updated learning materials/ guidelines from the FFN Global that will be provided for reference.

v. *FLS Clinical Practice Standards*

These are clinical standards developed by the Osteoporosis Liaison Service, Fragility Fracture Network - Japan and the Japan Osteoporosis Society with the goal of promoting evidence-based care based on institutional experiences, international publications and clinical guidelines. It is a highly practical and adaptable reference that can guide participating hospitals in their own FLS development. See appendix for detailed material.

3. Setting up of Data Management System

a. Physical Setup

Each participating hospital must have an available password-protected computer (desktop or laptop) and/or tablet, with access to the internet, to which a secure data management website (Research Data Capture or REDCAP) will be accessed. A detailed description of this database developed by Vanderbilt University may be seen in the Appendix. The main server will be securely hosted by the implementing agency and licensed REDCAP collaborator, the University of the Philippines - Manila, in coordination with the UP Information Management System at no cost to the research since REDCAP is a free and secure database software . A clinical IT manager, who will also be a member of the project staff, will oversee the project's database design, functions, troubleshooting and data extraction.

b. Training of Personnel

A research assistant will work closely with the participating hospital to assist in the training of involved personnel, data collection and management. **Target period for initial training of personnel will be on the last week of April 2022.**

c. Data Entry

Input of data into the REDCAP database system by the designated properly trained personnel coming from each participating hospital.

4. Implementation of the OFFM and FLS

A coordinated multi-disciplinary team approach will be implemented for all orthopedic geriatric patients with fragility hip fractures. The multidisciplinary team will be ideally composed of members from the following departments: Orthopedics, Internal Medicine, Rehabilitation Medicine, Anesthesiology, and if available, Geriatric Medicine, Nuclear Medicine, and Family and Community Medicine. However, the composition of the orthogeriatric multidisciplinary team of the participating hospital will depend on the hospital's own existing health care manpower, as long as coordination among the different subspecialties will be followed.

Upon presentation, the clinical pathway for geriatric patients with fragility hip fractures will be activated (sample pathway shown in Appendix A.). The patients will be screened and an initial assessment will be done by an orthopedic resident, or an equivalent health care personnel. Necessary blood work and radiographs will be ordered from the initial encounter to further classify the fracture type and to identify baseline parameters. Pain assessment and management, as well as delirium assessment will be immediately rendered at the emergency room. Temporary stabilization and the necessary medications will be administered, if needed. Immediate referrals to the concerned sub-specialties will be done either at the emergency room (ER) for patients received in the ER, or at the ward for direct ward admissions. Each patient will be seen by the FLS coordinator in-charge of collecting demographic data, documenting details regarding the patient's admission and follow-up using the data collection forms, and coordinating these follow-up consultations. Patient consent will be obtained, whereby patient information and details of the hospital stay will be continuously recorded. The Orthogeriatric/FLS Coordinator will follow the patient's hospital course and follow-up, making sure that there is coordination among the different co-managing subspecialties right from the start in terms of urgent OR scheduling, identification of comorbidities, including the patient's financial status.

The co-managing services will then provide information for surgical and anesthetic planning, with a unified goal of performing fragility fracture surgery within the earliest elective operation day, ideally within 48-72 hours from the time of admission to the hospital, as well as for post-op care and discharge planning. If urgent surgical care cannot be carried out, the reason for the delay will be documented. Each patient will be evaluated for pre-operative surgical risk-stratification. Laboratory and radio-imaging will be carried out, and DXA scan (if available) will also be done while the patient is still in the hospital. Osteoporosis education, including the importance of pharmacological and non-pharmacological means of addressing osteoporosis, home rehabilitation strengthening programs, falls prevention, and caregiver education will be offered to each patient. Once discharged, all patients will be advised to follow-up at the outpatient clinic, or will be contacted via phone call or other online consultation platform if the physical follow-up is not feasible. Information regarding ambulation status, completion of the CGA, and compliance to anti-osteoporosis meds will be

recorded. Likewise, compliance to the rehabilitation program, whether in an inpatient rehabilitation center, community rehabilitation center or a home-based rehabilitation program, will be assessed for each patient.

In addition, all patients will be checked for any perioperative morbidity such as surgical site infection and implant failure, and any secondary fractures will be documented. Follow-up dates are to be scheduled as follows: 2 weeks, 1 month, 2 months, 4 months, 6 months, 9 months, and 12 months post-surgery (or post-admission, for those admitted but did not undergo any surgery). Patient follow-ups will be conducted either via the traditional face to face clinic consults in FLS clinics, or via phone call and other online consultation platforms (for patients who will have difficulty returning to the FLS clinic for follow-up), intended to increase patient compliance to follow-ups. Patients who will be lost to follow up will be contacted by a member from the FLS (the FLS coordinator) through telephone, and with the aid of a script (Appendix D), the patients will be reminded of their check-ups and asked regarding their ambulation status, compliance to medications and exercises. All information from the data collection forms will be encoded into the hip fracture database. For private patients enrolled by participating hospitals or in those without a designated FLS clinic yet, the participating attending physician should alert their designated research coordinator regarding the follow-up schedule of the patient so that they may also be present to collect the data.

5. Evaluation of participating hospital's progress in establishing/improving their pathways

The Progress Form will be given to the participating hospital at the beginning of the study. This will allow the participating hospital to narrate their current practices for hip fractures in the elderly, their experience in implementing an OFFM and FLS, and the challenges faced. The progress form and FGD will be given periodically every 4 months to monitor their progress throughout the course of the study.

6. Data Collection

Data will be collected at baseline during the patient's index admission or consult using the data forms mentioned above. A fracture liaison officer and a consultant supervisor will oversee the operations and compliance to the pathways. Patients will again be contacted on the 120-day post-injury follow-up to determine the same outcome information. All forms will be

entered into a single database which can be extracted for data analysis. Monthly monitoring of data quality per institution will be done by the research management team.

VI. Data Management and Analysis

Data from the REDCAP database will be extracted and reviewed. Standard descriptive statistics will be employed. Categorical variables are to be expressed in terms of frequency (percentages) and continuous variables as median (range), mean and standard deviations. The average time between date of admission and date of surgery, as well as the average total length of hospital stay will be computed. All outcomes will be presented with summary statistics and comparisons reported together with 95% confidence intervals and all statistical tests will be at the 5% two-sided significance rate. A Cox regression model will be used to determine factors associated with outcomes of quality of life, functional recovery and mortality. Progress assessment forms will be summarized descriptively to provide an in-depth review of the current OFFM and FLS pathways and challenges experienced by each institution.

VII. Quality assurance, risks and benefits and ethical issues

There are no foreseeable risks for this study, and this will not compromise the quality of care of the patients, but rather has the potential to be improved. The target beneficiaries are current and future practitioners of Orthogeriatrics, patients, nurses, allied medical practitioners, caregivers and hospitals wherein the promotion of a Multidisciplinary Orthogeriatric Care and FLS will deliver a better, cost effective, quality of care and develop a more holistic approach to patient management.

Throughout the course of the study, patient information will be kept private. Patients will be asked to participate in the study whereby a written consent is secured. Consent forms will be translated to local dialects if requested by the REB of participating local hospitals. It will be explained to patients that they may leave the study at any time. This will not in any way diminish the quality of care they receive in this hospital, instead there will be a big potential for improvement. They may also refuse to answer any questions and still remain in the study. **Informed consent will be valid until the end of the study.** The choice of surgery and pharmacological interventions will be left at the discretion of the attending physicians. In the event that a hospital withdraws, is removed from the study, or chooses to terminate the recruitment of patients, only patients who have already completed their 120 day-data will be included for analysis. The transfer of data per institution will be covered by a

memorandum of agreement and shall be compliant with existing Philippine laws and regulations. Personal patient information will only be known to the participating lead-site investigators. The research management team will only have access to de-identified data. The lead coordinator and project team will be constantly monitoring for any data breaches and will follow protocol as prescribed by the Data Privacy Act should there be any reported breach or violation. All data input and access will be through the secure REDCAP Database system with user-based privileges that will be set by the REDCAP Project Manager in conjunction with the Head of the Research Project. The research management team will only have access to de-identified data. The lead coordinator and research project team will be constantly monitoring for any data breaches and will follow protocol as prescribed by the Data Privacy Act should there be any reported breach or violation. Please see attached appendix of DATA LOGISTICS MANUAL for a more detailed description for the process of entering and accessing digital files on REDCAP. De-identified data will be extracted into a statistical software database accessible only to the research project team.

VIII. Financial and resource use (Line-Item Budget)

This is a study conducted by the University of the Philippines Manila - Department of Orthopedics and the Philippine General Hospital - Orthogeriatric and Fracture Liaison Service , in cooperation with the Fragility Fracture Network (FFN)-Philippines, the Philippine Orthopedic Association Orthogeriatric and Osteoporosis Working Group, the Healthy Ageing Unit under the DOH - DPCB, the UPM NIH – ASTRO (Advanced Studies and Research in Orthopedics) Working Group and Institute of Aging, and the Osteoporosis Society of the Philippines Incorporated (OSPFI). Funding for the study will be sought, primarily to cover the costs and stipends of the research assistants, as well as the necessary systems management support needed for data gathering for each participating hospital. The study will not provide for diagnostic tests, implants, medicines of the patients.

IX. Timetable

2022									2023		
APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC	JAN	FEB	MAR
Start of data collection Baseline Progress Form	Continuous data collection			1st point of Feedback Focused group discussions	Continuous data collection			2nd point of Feedback Focused group discussions	Continuous data collection		

2023									2024			
APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR
3rd point of Feedback Focused group discussions	Continuous data collection				End of follow-up period; end of study	Continuous data collection Completion of follow-up/data entries				Data Analysis Final manuscript composition		

X. References

1. Reyes PVSJ, Tabu IA. Fragility Hip Fractures in a Team-Based Multidisciplinary Orthogeriatric Care Setting with a Fracture Liaison Service: Patient's Profile and Early Outcomes (*8th Fragility Fracture Network Poster Presentation August 28-30 2019 Oxford University Oxford England)*

2. Jahan F (2015) Osteoporosis: A Silent Killer. J Women's Health Care 4: 260. doi:10.4172/2167-0420.1000260

3. Cortez KA, Lai JGL, Tabu IA. Economic burden and the effects of early vs. delayed hospitalization on the treatment cost of patients with acute fragility hip fractures under the UPM-PGH Orthogeriatric Multidisciplinary Fracture Management Model and Fracture Liaison Service. 2020. Philippine General Hospital.

4. Cooper C. and Ferrari S. (2019). IOF Compendium of Osteoporosis. 2nd edition. http://share.iofbonehealth.org/WOD/Compendium/2019-IOF-Compendium-of-Osteoporosis-PRESS.pdf

5. Tarantino ,U., Capone, A., Planta, M. et al. The incidence of hip, forearm, humeral, ankle, and vertebral fragility fractures in Italy: results from a 3 year multicenter study. Arthritis Res Ther 12, R226 (2010). https://doi.org/10.1186/ar3213

6. Falaschi P, Marsh D. Orthogeriatrics: The management of older patients with fragility fractures. https://doi.org/10.1007/978-3-030-48126-1

7. National Clinical Guideline Centre (UK). Osteoporosis: Fragility Fracture Risk: Osteoporosis: Assessing the Risk of Fragility Fracture. London: Royal College of Physicians (UK); 2012 Aug. (NICE Clinical Guidelines, No. 146.) 1, Introduction.Available from: https://www.ncbi.nlm.nih.gov/books/NBK115326/

8. Noordin S, Allana S, Masri BA, Establishing a hospital based fracture liaison service to prevent secondary insufficiency fractures, International Journal of Surgery (2017), doi:10.1016/j.ijsu.2017.09.010.

9. Cheung, C.-L., Ang, S. B., Chadha, M., Chow, E. S.-L., Chung, Y.-S., Hew, F. L., … Fujiwara, S. (2018). An updated hip fracture projection in Asia: The Asian Federation of Osteoporosis Societies study. Osteoporosis and Sarcopenia, 4(1), 16–21. doi:10.1016/j.afos.2018.03.003

10.. The international osteoporosis foundation (2013). The asia pacific regional audit: epidemiology, costs and burden of osteoporosis in 2013. International osteoporosis foundation, Switzerland.

11. Kanis JA, Oden A, Johnell O, Jonsson B, De LC, Dawson A. The burden of osteoporotic fractures: a method for setting intervention thresholds. Osteoporos Int. 2001;12(5):417–427.

12. S. Sabharwal, H. Wilson (2015). Orthogeriatrics in the management of frail older patients with a fragility fracture. International osteoporosis foundation and national osteoporosis foundation. Doi: 10.1007/s00198-015-3166-2

13. The British Orthopedic Association (2007). The care of patients with fragility fracture. The british orthopedic association, London.

14. Patel, N. K., Sarraf, K. M., Joseph, S., Lee, C., & Middleton, F. R. (2013). Implementing the national hip fracture database: An audit of care. Injury,44(12), 1934-1939. doi:10.1016/j.injury.2013.04.012

15. Ellanti, P., Cushen, B., Galbraith, A., Brent, L., Hurson, C., & Ahern, E. (2014). Improving hip fracture care in ireland: A preliminary report of the Irish Hip Fracture Database. Journal of Osteoporosis,2014, 1-7. doi:10.1155/2014/656357

16. Ho, W. W., Dai, D. L., Liu, K. W., Chow, K. M., Lau, E., Woo, J., & Leung, K. S. (2009). To investigate the effect and cost-effectiveness of implementing an orthogeriatric intervention for elderly patients with acute hip fracture: The experience in Hong Kong. Journal of the American geriatrics society,57(11), 2153-2154. doi:10.1111/j.1532-5415.2009.02529.x

17. Hawley, S., Javaid, M. K., Prieto-Alhambra, D., Lippett, J., Sheard, S., Arden, N. K., Judge, A. (2016). Clinical effectiveness of orthogeriatric and fracture liaison service models of care for hip fracture patients: population-based longitudinal study. Age and ageing,45(2), 236-242. doi:10.1093/ageing/afv204

18. Australian and New Zealand Society for Geriatric Medicine (2010). Orthogeriatric care revised 2010.

19. Mitchell P, Akesson K, Chandran M, et al. Implementation of models of care for secondary osteoporotic fracture prevention and orthogeriatric models of care for osteoporotic hip fracture. Best Pract Res Clin Rheumatol. 2016;30:536–558. doi:10.1016/j.berh.2016.09.008

20. Tarazona-Santabalbina F.J., Belenguer-Varea Á., Rovira E., Cuesta-Peredó D. Orthogeriatric care: improving patient outcomes. *Clin Interv Aging*. 2016;11:843-56. Published 2016 Jun 24. doi:10.2147/CIA.S72436

21. Wu, CH., Kao, IJ., Hung, WC. et al. Economic impact and cost-effectiveness of fracture liaison services: a systematic review of the literature. Osteoporos Int (2018) 29: 1227. https://doi.org/10.1007/s00198-018-4411-2

22. Highlights of the Philippine population 2015 census of population. Taken from https://psa.gov.ph/content/highlights-philippine-population-2015-census-population

23. Dreinhofer K.E., Mitchell P.J., Begue T., Cooper C. et al (2018). A global call to action to improve the care of people with fragility fractures. Injury, Int. J. Care 49: 1393- 1397

24. Oliver, D; Britton, M; Seed, P et al (1997). Development & evaluation of evidence based risk assessment tool (STRATIFY) to predict which elderly inpatients will fall: case control & cohort studies, British Medical Journal 315: 1049-1053

25. Saini, A. K., Dawe, E., Thompson, S. M., & Rosson, J. W. (2017). Vitamin D and Calcium Supplementation in Elderly Patients Suffering Fragility Fractures; The Road not Taken. The open orthopaedics journal, 11, 1230-1235. doi:10.2174/1874325001711011230

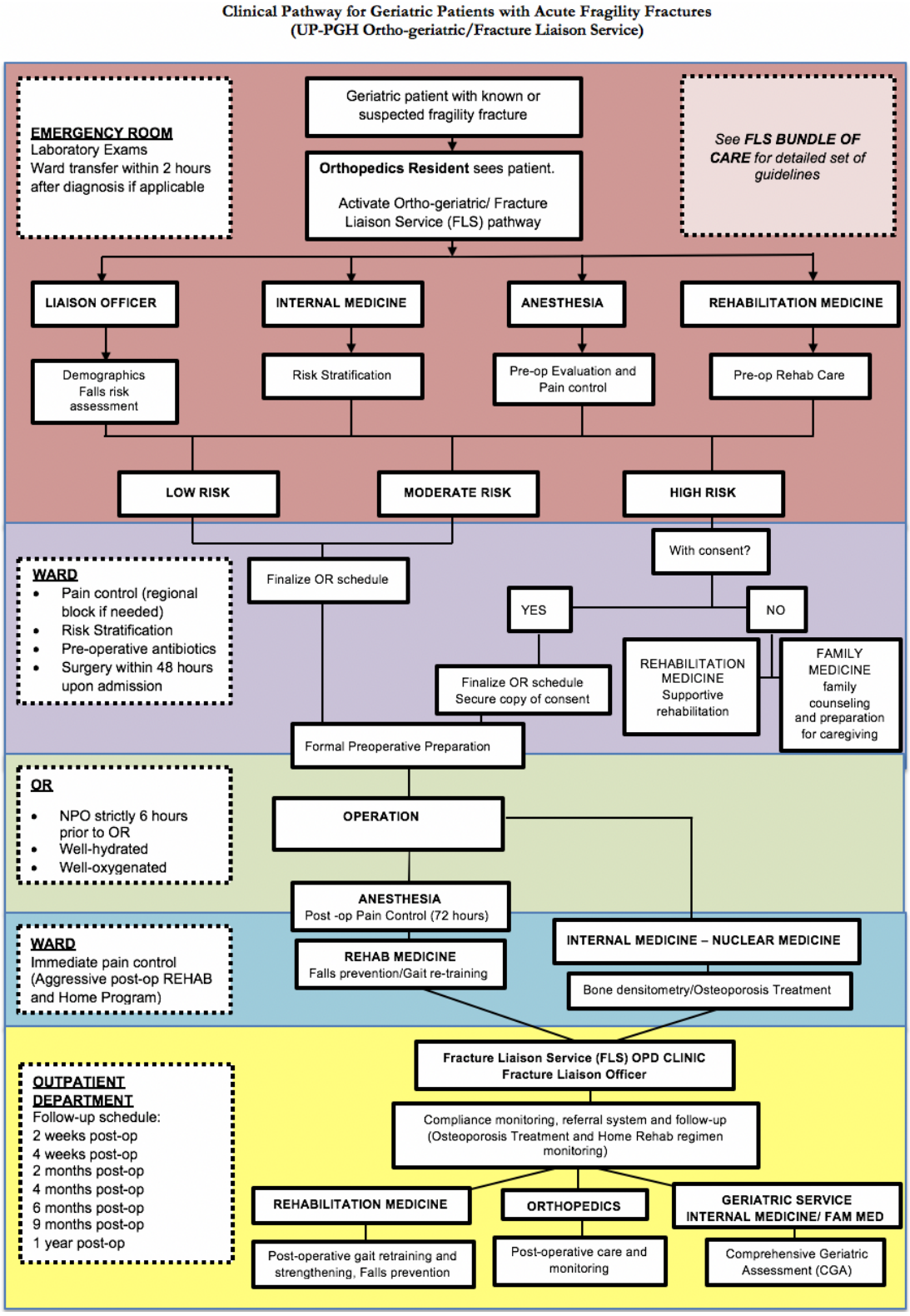
26. Compston, J., Cooper, A., Cooper, C., Gittoes, N., Gregson, C., Harvey, N., Hope, S., Kanis, J. A., McCloskey, E. V., Poole, K., Reid, D. M., Selby, P., Thompson, F., Thurston, A., Vine, N., National Osteoporosis Guideline Group (NOGG) (2017). UK clinical guideline for the prevention and treatment of osteoporosis. Archives of osteoporosis, 12(1), 43.

27. Ong T., Sahota O. (2021). Establishing an Orthogeriatric Service. In: Falaschi P., Marsh D. (eds) Orthogeriatrics. Practical Issues in Geriatrics. Springer, Cham. https://doi.org/10.1007/978-3-030-48126-1_5

28. Arai, H. et al (2019). Clinical Standards for Fracture Liaison Services in Japan. 2nd edition. FLS Clinical Standards Working Group, Japan Osteoporosis Society, NPO Fragility Fracture Network Japan.

XI. Appendices

Appendix A. Sample Clinical Pathway for Geriatric Patients with Fragility Hip Fractures



Appendix B. Assent and Informed Consent.

INFORMED CONSENT FORM

This Informed Consent Form is written for patients seen at the (NAME OF PARTICIPATING HOSPITAL) who are invited to participate in our study. Consent will be obtained by the acting fracture liaison service member.

Principal Investigator:
Co-Investigator:
Fracture liaison service member:

You are invited to participate in this study because you have a fragility hip fracture or fracture secondary to osteoporosis. This interview for informed consent will last for 15 minutes.

In order for you to decide whether you would like to be a part of this research study, you must understand what you have to do, as well as the possible risks and benefits of being part of this study. This form will give you detailed information on the research. Someone will also talk to you about the research and answer any questions you may have. Once you understand the study, if you would like to participate in it, you will be asked to sign the consent form. **Informed consent will be valid until the end of study.** Allow yourself to have as much time as you would like to make your decision. Feel free to discuss this with your family, friends, and doctor.

WHY IS THIS RESEARCH BEING DONE?

The number of patients ages 60 years old and above with fragility hip fractures is rising due to the increasing rates of osteoporosis, falls and muscle weakness. Most of these patients are not given the complete treatment needed, and most have various illnesses aside from the fracture. In other countries, particularly in the United Kingdom, they implement what is called a "joint care model" in which elderly patients with fragility fractures are seen by a multidisciplinary team, including physicians from Orthopedics, Adult Medicine (Geriatricians), Anesthesiology, Cardiology, Endocrinology, Rheumatology, Rehabilitation Medicine, Psychologist and Family Medicine. Aside from the fracture, special attention is given to the patient's other illnesses such as heart disease, osteoporosis, muscle weakness, poor eye-sight, poor balance etc. Having a holistic treatment that quickly identifies and addresses the other systemic illnesses can help shorten the time to operation and decrease the risk of inpatient morbidity and mortality. Patients are also given adequate pain control and an excellent rehabilitation program that can shorten hospital stay.

WHAT IS THE PURPOSE OF THIS STUDY?

This study is a research that aims to describe the profile of patients in the (NAME OF PARTICIPATING INSTITUTION) ages 60 years old and above with fragility fractures being managed by a multidisciplinary team. A database of orthopedic geriatric patients with fragility fractures will be formed with information that can be monitored and used for further improvements in fragility fracture care.

WHAT ARE FRAGILITY FRACTURES, ORTHOGERIATRICS, and FLS?

Fragility Fractures are breaks in the bone caused by simple falls and slips from standing height without the need of any excessive force or traumatic force. Usually, the injury is experienced by elderly patients with brittle bone caused by osteoporosis.

Orthogeriatrics is a proven model of care for patients with fragility fractures, already being used by many countries in the care of elderly patients. It involves a focused and coordinated system of care for elderly patients with fractures, not only focused on the fracture itself, but also on the other medical aspects confronting the patient, including adequate pain control, immediate management of the fracture without unnecessary delay, immediate rehabilitation/recovery, falls prevention and avoiding the occurrence of another fractures by treating the osteoporosis.

Fracture Liaison Service (FLS) is a coordinator-based, secondary fracture prevention service implemented by health care systems for the treatment of osteoporotic patients.

PATIENT FOLLOW-UPS (EITHER FACE TO FACE OR TELEMEDICINE): HOW WILL THE ONLINE CONSULT/FOLLOW-UP BE CONDUCTED AND WHAT WILL HAPPEN IF THIS IS INACCESSIBLE?

If you opt to use the online consultations for your follow-ups, a separate consent, that of the Philippine Medical Association Consent Form for Telemedicine Consultation, will be asked from you or your authorized representative in compliance to the Joint Memorandum Circular 2020-0001 of the Department of Health (DOH) and the National Privacy Commission (NPC) on the use of telemedicine in the COVID-19 response. If you cannot access the internet, or you find it more convenient to have the traditional face to face follow-up, this is still the preferred form of follow-up within the existing protocols of the hospital taking care of you. **Follow-up physical visits are part of the regular and standard process of surveillance of post-operative patients. All follow-up visits at participating sites, therefore, follow regular health safety protocols already practiced by these hospitals.**

WHAT WILL I HAVE TO DO IF I TAKE PART IN THE STUDY?

If you wish to take part in the study, we will ask you and your doctor information, your injury, and other illnesses you have aside from the fracture, as well as your ability to function prior to the injury. Other necessary information will be retrieved from your medical chart, including your date of admission, time to operation, and details on the injury. During your hospital stay and follow-up at the outpatient clinics, you will be closely monitored by your physicians and the fracture liaison service to document your illness, rehabilitation and recovery.

WHAT ARE THE POSSIBLE RISKS?

There are no known risks involved. This study will not diminish the quality of care that you will receive in any way.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

This study has no target population size. All patients 60 years old and above with fragility fractures admitted and followed-up with consent to participate, will be included in the study.

WHAT ARE THE POSSIBLE BENEFITS FOR ME AND FOR SOCIETY?

There are no foreseeable risks for this study, and this will not compromise the quality of care of the patients, but rather has the potential to be improved upon. The potential benefits of the study are:

a. For the patient

i. Quality and multi-disciplinary standard of care including prevention of secondary fractures

ii. Patient, family and care-giver education about the disease

b. For future fragility fracture patients, allied medical professionals and hospitals

i. Workforce development of physicians, nurses, and allied medical professionals capable of delivering quality coordinated standard of care anchored on the principles of Orthogeriatrics.

ii. Promotion of Multidisciplinary Orthogeriatric Care and Fracture Liaison Service for adoption by other hospitals

iii. More cost-effective pathway of care for both the immediate management of the fragility hip fracture and follow-up care, including prevention of secondary fractures

c. For the society

i. Decreasing the burden of osteoporosis and fragility hip fractures

ii. Help establish a standard of care for patients with fragility hip fractures, which is in line with the Universal Health Care program of the country.

Also, your participation may contribute to future improvements in the treatment and management of elderly patients with hip fractures. There will be no compensation or incentive in participating in this study as these procedures are involved as standard of care.

IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

You must understand that you can choose not to participate in the research. If you do not wish to take part in the study, we will respect your decision and it will not affect your care and treatment.

WHAT INFORMATION WILL BE KEPT PRIVATE?

Your information and details as a patient will not be shared with anyone except with your consent or as the law requires. Your personal information will be removed, including your name, address, phone number, and doctor's name, and replaced with a number. We will have a list linking this number to your name in a protected area. The data without your personal information will be kept in a locked office.

The study monitor, auditor, the Institution's Ethics Review Panel and the regulatory authorities will be given direct access to the medical records of patients for verification purposes (if necessary). All other information will remain confidential.

CAN PARTICIPATION IN THE STUDY END EARLY?

If you choose to participate in this study, you may leave the study at any time. This will not change the quality of care you receive in this hospital. You may also refuse to answer any questions and still remain in the study. Your study doctor may also remove you from this research if needed.

CONSENT STATEMENT

Signature of research participant

I have read the information thoroughly. I had the opportunity to ask questions, and all of them were answered to my satisfaction. I agree to take part in the study. I also understand that I will be receiving a signed copy of this form.

_____
Name of Participant

_____
Signature of Participant and Date:

Consent form administered and explained in person by:

_____
Name and Title

_____
Signature

Date:

Signature of Investigator:

In my judgment, the participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this study.

_____
Signature of Investigator
Date:

If you have any problems, questions or concerns, feel free to contact us through this number:

Site Lead Investigator: Bernardino Alpuerto II, MD
Department of Orthopedics Philippine General Hospital
Mobile: +639167292475

UPMREB Panel
Address: Rm. 126, National Institutes of Health Bldg.
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Ermita 1000 Manila
Email: upmreb@post.upm.edu.ph
Tel: +63 2 5264346

Name of Chair, Single Joint Review Board (SJREB)
Contact number of SJREB Chair

Consent to Take Part in this Research Study and Authorization to Disclose Health Information by the Patient/Subject's Legal Authorized Representative For the Research Study entitled: Multicenter Implementation of Orthogeriatrics and the Fracture Liaison Service for Elderly Hip Fractures: An evidence-based framework for a sustainable digital health registry

_____
Name of Patient

_____ _____
Name of Authorized Representative Relation to Patient

The Research Study and consent form have been explained to the patient and legal authorized representative.
By signing this form, you are indicating that you have answered the questions on behalf of the subject/patient and agreed to take part in this research study and has legally authorized to consent to the patient's participation. You have also agreed to let the (hospital/participating institution)_____ to use and share the patient's information as explained in the consent. If you do not agree to the collection, use and sharing of the patient/subject's information, the patient can not participate in the study.

Witness
By signing this form, you are indicating that the information in the Informed Consent Form as well as any additional information, conveyed by the person obtaining consent was presented to the Legal authorized representative and patient in a language preferred by and understandable to the legal authorized representative or the subject/patient.

_____
Name and Signature of Witness/Interpreter

Date signed:_____

Site Lead Investigator: Bernardino Alpuerto II, MD
Department of Orthopedics Philippine General Hospital
Mobile: +639167292475

UPMREB Panel
Address: Rm. 126, National Institutes of Health Bldg.
University of the Philippines Manila
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Tel: +63 2 5264346

Name of Chair, Single Joint Review Board (SJREB)
Contact number of SJREB Chair

KASULATAN NG PAHINTULOT (INFORMED CONSENT FORM)

Kayo po ay inaanyayahang sumali sa pag-aaral na ito dahil mayroon po kayong bali sa marupok ninyong mga buto. Ang inyong pahintulot ay kukunin ng isang miyembro ng fracture liaison service. Ang pakikipanayam na ito ay tatagal ng 15 na minuto.

Pangalan ng pangunahing may-akda:
Pangalan ng kasangguning may-akda:
Pangalan ng miyembro ng fracture liaison service:

Upang makapagdesisyon kayo kung nais ninyong maging bahagi ng pag-aaral na ito, dapat maunawaan ninyo ang mga kailangan gawin, mga posibleng panganib, at mga benepisyo kapag kayo ay sumali. Ang dokumentong ito ay naglalaman ng impormasyon tungkol sa pag-aaral na ito. Kakausapin kayo ng isang miyembro/kawani tungkol dito at sasagutin niya ang lahat ng mga katanungan ninyo.
Pagkatapos maipaliwanag sa inyo at sa sandaling maunawaan na ninyo ang pag-aaral, maaari na kayong magdesisyon kung nais ba ninyong sumali. Kayo ay pipirma sa isang salaysay ng pahintulot o "consent form." **Ang pahintulot na ito ay balido lamang hanggang sa katapusan nitong pag-aaral.** Hindi kailangan madaliin ang desisyon ninyo. Maaaring ninyo itong talakayin kasama ang inyong mga kaibigan, pamilya, o inyong doktor.

Bakit ginagawa ang pananaliksik na ito?

Dumadami ang mga pasyenteng nasa edad 60 na taong gulang pataas na nagkakaroon ng bali dahil sa paghihina ng mga buto dala ng sakit na "osteoporosis", sa madalas na pagka-dulas, sa panghihina ng kalamnan, sa pagkawala ng balanse, at iba pa. Karamihan sa mga pasyenteng ito ay hindi nabibigyan ng kumpletong gamutan at madalas ay meron pa silang iba't-ibang mga karamdaman bukod pa sa bali. Sa ibang mga bansa, katulad ng Inglatera, ang pag-aalaga sa mga matatandang may bali ay hindi lang ginagawa ng isang doctor, bagkus ang pasyente ay inaalagaan ng isang buong grupo ng doctor o isang "multidisciplinary team." Ang mga doktor na kasama sa grupo ay espesyalista sa Orthopedics, Adult Medicine, Anesthesiology, Cardiology, Endocrinology, Rheumatology, Family Medicine, Rehabilitation Medicine, at marami pa. Maliban sa nabaling buto, nabibigyang pansin din ang ibang mga sakit ng mga pasyente katulad ng sakit sa puso, "osteoporosis," pang-lalabo ng mga mata, panghihina ng mga kalamnan, at madalas na pagkadulas. Sa ganitong paraan ng pag-aalaga, nabibigyan ng pansin ang buong pangangatawan ng pasyente kaya't napapabilis ang iskedyul ng operasyon at nababawasan ang panganib ng mga kumplikasyon at pagkamatay ng pasyente. Nabibigyan din ng nararapat na gamot para sa kirot at magaling na programa ng rehabilitasyon para mapabilis ang pag-galing ng pasyente at makauwi kaagad mula sa ospital.

Ano ang mga layunin ng pag-aaral na ito?

Ang pag-aaral na ito ay isang pagsusuri kung saan ilalarawan ang mga pasyenteng may edad 60 pataas na may bali dahil sa marupok na buto na hindi lalampas ng isang buwan mula sa pagka-aksidente; at sumangguni sa Ospital para gamutin ang bali at naaalagaan ng isang "grupo ng manggagamot." Layunin din ng pag-aaral na magkaroon ng isang "database" na maaaring gamitin upang matutukan ang gamutan ng isang matandang nagkaroon ng bali para mapaganda at mapabuti ang buong pag-aalaga sa kanila.

Ano ang ibig sabihin ng Fragility Fracture, at Orthogeriatrics?

Ang kahulugan ng **Fragility Fracture** ay ang pagkabali ng buto ng mga matandang pasyente na sanhi ng pagkadulas o pagkahulog mula sa pagkakatayo na hindi nangangailangan ng malakas na puwersa o matinding aksidente. Ang pinsala na ito ay nangyayari sapagkat marupok na ang mga buto ng matatanda dahil sa sakit na "**osteoporosis**."

Ang **Orthogeriatrics** ay isang napatunayang konsepto ng paraan ng pag-aalaga sa isang matandang nabalian ng buto na ginagamit na ng maraming bansa sa mundo. Ito ay kinabibilangan ng nakatutok at organisadong pag-aalaga sa mga matatandang pasyente, na hindi lamang nakatuon sa mismong bali ng buto; bagkus pati narin sa iba't ibang problemang medical ng pasyente katulad ng nararapat kontrol sa sakit, mabilisang pag-schedule ng operasyon ng nabaling buto, kaagad na rehabilitasyon, mapigilian na maulit ang pagkabagsak at aksidente, at magamot ang "osteoporosis."

Ang **Fracture Liaison Service (FLS)** ay isang modelo ng pag-aalaga ng isang pasyenteng nabalian ng buto sanhi ng osteoporosis kung saan may isang taga-pangasiwa na tumututok para maiwasan muli na mabalian ng buto ang isang pasyente. Hindi nagtatapos ang pag-aalaga ng pasyente sa ospital. Kasama ang pagtutok sa pasyente hanggang sa siya ay makauwi na sa kanyang tahanan at mga susunod na pag-konsulta.

Follow-up/Konsulta ng Pasyente (Maaring tradisyunal na harapang pag-konsulta o "Telemedicine/online"): Paano gaganapin ang online follow-up at ano ang mangyayari kung hindi ka makasali dito?

Kung ang pinili ninyo ay "online consult" bilang pamamaraan ng inyong follow-up, kailangan ninyong punan ang isa pang hiwalay na pahintulot. Ito ay ang "Philippine Medical Association Consent Form for Telemedicine Consultation." Kailangan ninyo o ng inyong awtorisadong kinatawan na sagutan ang "form" na ito bilang pagtugon sa "Joint Memorandum Circular 2020-0001 ng Department of Health (DOH)" at ng "National Privacy Commission (NPC)" sa paggamit ng "telemedicine" ngayong panahon ng COVID-19. Kung wala po kayong paraan ng pag-access sa "online" na konsultasyon at kung sa palagay ninyo ay mas madali ang tradisyunal na harap-harapang follow-up, maaari ninyo parin itong gawin at ito pa din ang mas kaaya-ayang paraan ng pagkonsulta. Kailangan lamang na magpapa-schedule ayon sa protokol ng ospital na nag-aalaga po sa inyo. **Ang follow-up ay bahagi ng regular na proseso ng pagsubaybay sa ating mga pasyente pagkatapos ma-operahan. Lahat ng mga ospital na bahagi ng pag-aaral na ito ay sumusunod at sumasang-ayon sa mga health and safety standards lalo na sa pisikal na pagfollow-up ng mga pasyente.**

Ano ang mga kailangan kong gawin kung ako ay pumayag na maging bahagi ng pag-aaral na ito?

Kung kayo ay sumali sa pag- aaral, kayo at ang inyong doctor ay tatanungin namin tungkol sa mga pangyayari at detalye ng inyong aksidente at pati narin tungkol sa ibang mga sakit ninyo maliban sa bali sa buto. Kailangan din naming malaman ang inyong kapasidad/abilidad sa paglalakad bago kayo naaksidente. Kukunin din namin ang ibang mga impormasyon sa inyong "medical charts", katulad ng mga detalye sa pagpasok sa ospital, gaano kabilis naoperahan, at mga iba pang detalye sa aksidente. Habang kayo ay nananatili pa sa ospital at hanggang sa pag-follow-up ninyo sa klinika, babantayan kayo ng inyong mga doktor at ng fracture liaison service upang madokumento ang mga detalye ng inyong sakit at paggaling pati narin rehabilitasyon.

Ano ang mga posibleng panganib kung kayo ay sumali?

Walang mga panganib na kaakibat sa pag-aaral. Hindi makakabawas sa kaledad ng serbisyo ng paggamot na inyong matatanggap kung kayo ay lalahok sa pagaaral na ito.

Gaano karaming mga tao ang dapat kasama sa pag-aaral na ito?

Ang pagaaral na ito ay walang eksaktong bilang ng mga tao na dapat kasali. Lahat ng mga pasyente na may edad na 60 pataas na nabalian dahil sa marupok na buto ay maaring sumali basta't sila ay pumayag at nagbigay ng pahintulot sa pagsali sa pag-aaral.

Ano ang mga posibleng benepisyo ng pag-aaral para sa inyo at para sa lipunan?

Ang inyong pagsali sa pagsusuring ito ay maaring makatulong sa kinabukasan at sa pagpapabuti ng pag-alaga sa mga matatandang pasyenteng may bali. Walang kabayaran o insentibo sa paglahok sa pag-aaral na ito sapagkat ang mga gawaing ito ay ang kasalukuyang pamantayan ng pangangalaga.

Ang mga sumusunod ay iba pang posibleng benepisyo na maaring makamtan kapag kayo ay sumali sa pag-aaral:

1. Benepisyo para sa pasyente
    i. Agarang pagpayo at pagsangguni sa nararapat na espesyalistang doktor kung sakaling may matuklasang ibang kundisyong medikal maliban sa bali sa buto.
    ii. Dagdag na kaalaman at edukasyon para sa pasyente, mga ka-pamilya, at taga-pangalaga ng pasyente tungkol sa gamutan ng mga matatandang may bali sa buto.
2. Para sa iba pang matandang mababalian ng buto at para sa mga ospital
    ii. Ang tuluyang pagpapalaganap at pagtanggap ng konsepto ng Orthogeriatrics at Fracture Liaison Service sa iba't ibang Ospital bilang mainam at subok na paraan ng pangangalaga sa mga matatandang nabalian ng buto.
2. Para sa Komunidad at bansa
    i. Maaring mapababa ang bilang ng mga matandang nababalian ng balakang dahil sa osteoporosis
    ii. Makatulong na makalikha ng pamantayan ng pangangalaga para sa mga pasyenteng nabalian ng balakang na naayon sa adhikain ng "Universal Health Care" na programa ng bansa.

Kung hindi ko nais makilahok sa pag-aaral, may iba pa bang pagpipilian?

Importanteng maintindihan po ninyo na hindi po kayo pinipilit na sumali sa pag-aaral na ito. Nasa inyo po ang desisyon kung nais niyo po bang sumali o hindi. Kapag hindi po kayo sumali, rerespetuhin po namin ang inyong desisyon at hindi ito makakaapekto sa paggamot ng inyong karamdaman.

Anong mga impormasyon ang mananatiling pribado?

Ang inyong mga pribadong impormasyon o detalye bilang pasyente ay hindi ibinabahagi maliban nalang kung may pahintulot mula sa inyo o iniutos ng batas. Tatanggalin po namin ang mga personal na impormasyon tulad ng inyong pangalan, address, numero ng telepono, pati na rin po ang pangalan ng inyong doktor. Papalitan po ito ng isang numero na kaugnay ng inyong pangalan na itatago sa protektadong lugar. Ang mga datos na walang personal na impormasyon ay itatago sa nakakandadong opisina. Ang mga sumusunod lamang na tao ang magkakaroon ng direktang "access" sa inyong medical records: study monitor, auditor, Ethics Review Panel, at regulatory authorities. Ang kanilang "access" ay limitado lamang sa mga beripikasyon na proseso. Lahat ng iba pang impormasyon tungkol sa inyo ay mananatiling pribado o kumpidensyal.

Maari pa bang bawiin ang pagsali kapag ang pag-aaral ay nasimulan na?

Opo. Maaari ninyo pong bawiin ang inyong desisyon sa pagsali sa kahit anong pagkakataon habang kayo ay nasa pag-aaral. Ang desisyon na ito ay hindi makakaapekto sa kalidad ng gamutan na inyong matatanggap sa ospital. Maaari ninyo rin pong tanggihan ang pagsagot ng anumang mga katanungan na hindi niyo po nais sagutin at mananatili pa rin na kasali sa pag -aaral. Ang mananaliksik na doktor ay maaari rin mismong tanggalin kayo sa pag-aaral na ito kung kinakailangan po.

SALAYSAY NG PAHINTULOT

LAGDA NG TAONG MAKAKASAMA SA PAG-AARAL

Nabasa ko ng mabuti ang lahat ng impormasyon. Binigyan po ako ng pagkakataon na makapagtanong, at lahat ng aking mga katanungan ay nasagot ng maayos at kaayaya. Pumapayag ako na lumahok sa pag-aaral. Naiintindihan ko na ako ay makakatanggap ng kopya ng kasulatang ito.

_____
Pangalan ng Kalahok

_____
Lagda ng kalahok

Petsa:

Kasulatan ng Pahintulot ay ipinaliwanag at pinangasiwaan ng personal ni:

_____

Pangalan at katungkulan

_____
Lagda
Petsa:

Lagda ng Manunuri:

Sa aking pananaw, ang kalahok ay kusang-loob at may buong kaalaman na nagbibigay ng pahintulot at may legal na kapasidad na magbigay ng kasulatan ng pahintulot na sumali sa pag-aaral na ito.

_____
Lagda ng Manunuri
Petsa:

Kung magkaproblema o may katanungan tungkol sa pag-aaral, maaaring kontakin ang number sa ibaba:

Site Lead Investigator: Bernardino Alpuerto II, MD
Department of Orthopedics Philippine General Hospital
Mobile: +639167292475

UPMREB Panel
Address: Rm. 126, National Institutes of Health Bldg.
University of the Philippines Manila
547 Pedro Gil St.
Ermita 1000 Manila
Email: upmreb@post.upm.edu.ph
Tel: +63 2 5264346

Chair, Single Joint Review Board (SJREB)
Contact number:

Pahintulot to ng isang Legal na Kumakatawan ng pasyente upang mapasama ang pasyente sa pagsusuri na pinamagatang:

_____

Pangalan ng Pasyente

_____ _____

Pangalan at Pirma ng Legal na Kumakatawan sa Pasyente Relasyon sa Pasyente

Ang Buod ng Pagsusuri at Salaysay ng Pahintulot as lubusang naipaliwanag sa Legal na Kumakatawan sa pasyente

Sa pamamagitan ng pag pirma sa dokumentong ito, iyong pinatunayan na nasagot ang lahat ng katanungan hinggil sa pagsusuri, at ikaw ay pumapayag na mapasama ang pasyente sa pagsusuri bilang legal na kumakatawan ng pasyente. Pinapahintulutan mo din an Ospital (Pangalan ng Ospital)_____ na gamitin at ipamahagi ang impormasyon ukol sa pasyente sa ilalim ng mga pamantayan na binggit sa salaysay ng pahintulot, at kung hindi ka pumpayag sa mga pamantayang ito, ay hindi maaring makasali and pasyente sa pagsusuri.

Saksi

Sa pamamagitan ng iyong pag lagda sa dokumenton ito, iyong pinatunayan na ikaw ay naging saksi na lubos na naunawaan ng Legal na Kumakatawan sa pasyente , and mga katanungan at impormasyon hinggil sa pagsusuri na ipinaliwanag ng mga kinatwan ng pagsusuri sa kumakatawan sa pasyente.

_____

Lagda ng saksi

Petsa ng pag lagda:_____

Kung magkaproblema o may katanungan tungkol sa pag-aaral, maaaring kontakin ang number sa ibaba:

Site Lead Investigator: Bernardino Alpuerto II, MD
Department of Orthopedics Philippine General Hospital
Mobile: +639167292475

UPMREB Panel
Address: Rm. 126, National Institutes of Health Bldg.
University of the Philippines Manila
547 Pedro Gil St.
Ermita 1000 Manila
Email: upmreb@post.upm.edu.ph
Tel: +63 2 5264346

Chair, Single Joint Review Board (SJREB)
Contact number:

Appendix C-1. EQ-5D-5L English Version

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

TAKING CARE OF YOURSELF

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, household chores, family or leisure activities)*

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

PAIN / DISCOMFORT

I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

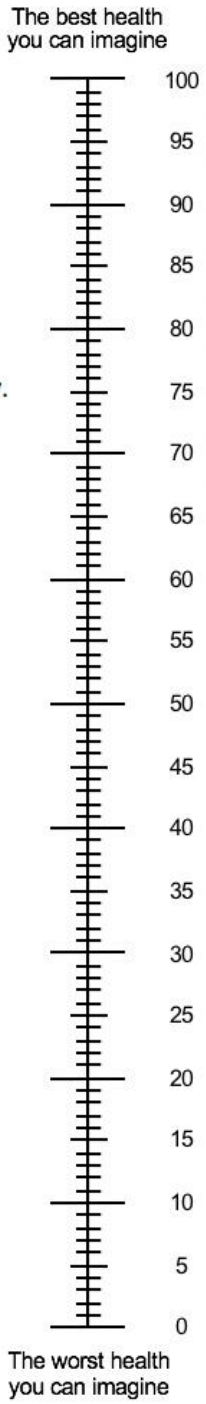
ANXIETY / DEPRESSION

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

2

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Appendix C-2. EQ-5D-5L Tagalog Version

Sa ilalim ng bawat paksa, paki-tsek ang ISANG kahon na pinakamagandang maglalarawan sa iyong kalusugan sa ARAW NA ITO.

PAGGALAW O PAGKILOS

- Wala akong problema sa paglalakad-lakad ❑
- May bahagya akong mga problema sa paglalakad-lakad ❑
- Medyo may mga problema ako sa paglalakad-lakad ❑
- May mga matindi akong problema sa paglalakad-lakad ❑
- Hindi ako nakakapaglakad-lakad ❑

PANGANGALAGA SA SARILI

- Wala akong problema sa paliligo o pagsusuot ng damit ❑
- May mga bahagya akong problema sa paliligo o pagsusuot ng damit ❑
- Medyo may mga problema ako sa paliligo o pagsusuot ng damit ❑
- May mga matitindi akong problema sa paliligo o pagsusuot ng damit ❑
- Hindi ko kaya ang paliligo o pagsusuot ng damit ❑

MGA KARANIWANG GAWAIN *(hal.: mga aktibidad sa trabaho, pag-aaral, gawain sa bahay, pamilya o libangan)*

- Wala akong problema sa paggawa ng aking mga karaniwang gawain ❑
- May mga bahagya akong problema sa paggawa ng aking mga karaniwang gawain ❑
- Medyo may mga problema ako sa paggawa ng aking mga karaniwang gawain ❑
- May matitindi akong mga problema sa paggawa ng aking mga karaniwang gawain ❑
- Hindi ko kayang gawin ang aking mga karaniwang gawain ❑

PISIKAL NA SAKIT O KIROT / PAGIGING DI-KOMPORTABLE

- Wala akong nararamdamang pisikal na sakit o kirot o pagiging di-komportable ❑
- May nararamdaman akong bahagyang pisikal na sakit o kirot o pagiging di-komportable ❑
- Medyo may nararamdaman akong sakit o kirot o pagiging di-komportable ❑
- May nararamdaman akong matinding sakit o kirot o pagiging di-komportable ❑
- May nararamdaman akong labis na sakit o kirot o pagiging di-komportable ❑

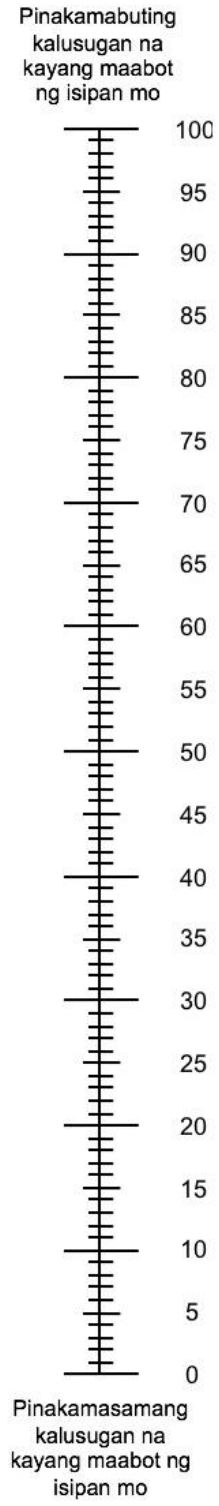
PAGKABAHALA / PAGKALUMBAY

- Hindi ako nababahala o nalulumbay ❑
- Ako ay bahagyang nababahala o nalulumbay ❑
- Ako ay medyo nababahala o nalulumbay ❑
- Ako ay masyadong nababahala o nalulumbay ❑
- Ako ay labis na nababahala o nalulumbay ❑

2

- Gusto naming malaman kung gaano kabuti o kasamâ ang iyong kalusugan sa ARAW NA ITO.
- Ang iskalang ito ay nalagyan ng numero simula 0 hanggang 100.
- Ang 100 ay nangangahulugan ng pinakamabuting kalusugan na iyong maiisip.
  Ang 0 ay nangangahulugan ng pinakamasamang kalusugan na iyong maiisip.
- Markahan ng X ang iskala upang ipakita ang katayuan ng iyong kalusugan sa ARAW NA ITO.
- Ngayon, pakisulat sa kahon sa ibaba ang numerong iyong minarkahan sa iskala.

ANG IYONG KALUSUGAN SA ARAW NA ITO = ☐



Appendix D. Minimum Common Dataset for Hip Fractures

#	Variable / Field Name	Field Label *Field Note*	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: **Patient Enrollment and Demographics** (patient_enrollment_and_demographics)			Collapse
1	patient_id	Patient Study ID	text
2	last_name	Last Name	text, Required, Identifier
3	first_name	First Name	text, Required, Identifier
4	gender	Gender	radio, Required 1, Male 2, Female Custom alignment: RH
5	dob	Date of birth	text (date_mdy), Required Custom alignment: RH
6	age	Age	calc Calculation: rounddown(datediff([dob], [date_enrolled],"y","mdy")) Custom alignment: RH
7	contact_number	Contact Details	text, Identifier
8	address	Address	text, Identifier
9	with_informed_consent	With informed consent?	radio, Required 1, Yes 2, No Custom alignment: RH
10	uploaded_consent Show the field ONLY if: [with_informed_consent] = '1'	Please upload proof of consent here *May be jpeg, pdf or word file*	file, Identifier Custom alignment: RH
11	date_enrolled	Date Enrolled *Date enrolled refers to date consent was signed*	text (date_mdy), Required
12	patient_enrollment_and_demographics_complete	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **Injury Details** (injury_details)			Collapse
13	date_of_injury	Date & Time of injury *If cannot recall exact date and time please provide an estimate*	text (datetime_mdy), Required Custom alignment: RH
14	pre_fracture_residence	Pre-fracture Residence	radio, Required 1, Home 2, Institution 3, Acute care clinic 4, Hospital 5, Unknown

15	pre_fracture_mobility	Pre-Fracture Mobility	radio, Required 1 Freely mobile without aids 2 Mobile outdoors with one aid 3 Mobile outdoors with two aids or frame 4 Mobile outdoors but wheelchair dependent 5 Some indoor mobility but never goes outside without help 6 No functional mobility 7 Unknown
16	abbreviated_mental_test_sc	Abbreviated Mental Test Score *This is a rapid assessment test for dementia in the elderly*	text (integer, Min: 0, Max: 10), Required
17	view_amts_ref	Click below to download or view AMTS reference	descriptive
18	side_of_fracture	Side of Fracture	radio, Required 1 Left 2 Right Custom alignment: RH
19	pathologic_fracture	Pathologic Fracture? *A fragility fracture in this study is defined as non-pathologic. Those with pathologic fractures may be entered into the record but will not be included in the final statistical analysis*	radio, Required 1 No 2 Atypical fracture 3 Secondary to malignancy/metastasis 4 Unknown
20	fracture_type	Fracture Type	radio, Required 1 Intracapsular UNdisplaced 2 Intracapsular displaced 3 Intertrochanteric 4 Subtrochanteric 5 Other
21	pre_fracture_bone_med	Has the patient been on bone protection medication prior to the fracture?	radio, Required 1 Yes 2 No Custom alignment: RH
22	pre_fracture_coag_med	Has the patient been on any anti-coagulation therapy in the past 7 days?	radio, Required 1 Yes 2 No Custom alignment: RH
23	type_of_anticoag Show the field ONLY if: [pre_fracture_coag_med] = '1'	What type of anti-coagulation therapy has the patient been on?	radio 1 Aspirin / Clopidogrel 2 DOACs (Direct Oral Anti-coagulants, i.e. Dabigatran, Rivaroxaban) 3 Warfarin 4 Heparin 5 Others
24	click_here_to_view_the_lat	Click below to view the latest AOTrauma recommendations regarding patients on anti-thrombotic therapy	descriptive
25	covid_symptoms	Does the patient have any COVID-19 or flu-like symptoms?	radio, Required 1 Yes 2 No Custom alignment: RH

26	date_time_of_admission	Date & Time of Admission *Refers to either ER admission or Direct Ward admission, whichever is the earliest official date*	text (datetime_mdy), Required
27	delay_in_consult	Time of injury-to-admission (hours): *Delay is defined as consult done > 24 hours after injury*	calc, Required Calculation: rounddown(datediff([date_time_of_admission], [date_of_injury],"h","mdy")) Custom alignment: RH
28	reason_delay_consult Show the field ONLY if: [delay_in_consult] >= 24	What was the primary reason for the delay in admission?	radio, Required 1 Delay in prior acute care or inter-hospital coordination 2 Transportation issues going to hospital 3 Financial issues going to hospital 4 Patient chose alternative treatments prior 5 Fear of contracting sickness at hospital or in public 6 Patient or relatives did not think suspect an urgent injury 7 Unknown 8 Others
29	click_below_for	Section Header: *The following section contains other helpful references in the Orthogeriatric Management of the patient* AOTrauma Pain Management	descriptive
30	pre_conditioning_rehabilit	Pre-conditioning Rehabilitation	descriptive
31	injury_details_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Labs / Imaging** (labs_imaging)			Collapse
32	rt_pcr_test_result	Section Header: *SARS-COV-2 Tests* RT PCR Test result	radio, Required 1 Positive 2 Negative 3 Pending 4 Not done Custom alignment: LH
33	rapid_antibody_test	Rapid antibody test	radio, Required 1 Positive 2 Negative 3 Not done Custom alignment: LH
34	chest_radiograph_result	Section Header: *Chest Imaging* Chest Radiograph result	radio, Required 1 Normal 2 Abnormal Custom alignment: LH
35	describe_results_of_chest Show the field ONLY if: [chest_radiograph_result] = '2'	Describe results of chest radiograph here	notes Custom alignment: LH

36	chest_ct_scan_result	Chest CT scan result	radio, Required 1 Normal 2 Abnormal 3 Not done Custom alignment: LH
37	describe_results_of_ct_sca Show the field ONLY if: [chest_ct_scan_result] = '2'	Describe results of CT scan here	notes Custom alignment: LH
38	hgb	Section Header: *Complete Blood Count (CBC) Results* Hemoglobin (g/L) *Reference range: 135-180*	text (number) Custom alignment: LV
39	hct	Hematocrit *Reference range: 0.40-0.54*	text (number) Custom alignment: LV
40	plt	Platelets (x10^9 / L) *Reference range: 150-450*	text (number) Custom alignment: LV
41	neutro	Neutrophils *Reference range: 0.50-0.70*	text (number, Min: 0.01, Max: 0.99) Custom alignment: LV
42	lympho	Lymphocytes *Reference range: 0.20-0.50*	text (number, Min: 0.01, Max: 0.99) Custom alignment: LV
43	labs_imaging_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Treatment** (treatment)			Collapse
44	asa_grade	ASA Grade *Confirm with anesthesiologist if unsure*	dropdown, Required 1 I = Normal healthy individual 2 II = Mild systemic disease that does not limit activity 3 III = Severe systemic disease that limits activity but is not incapacitating 4 IV = Incapacitating systemic disease which is constantly life-threatening 5 V = Moribund-not expected to survive 24 hrs with or without surgery 6 Unknown
45	definitive_treatment	Definitive treatment given to patient	dropdown (autocomplete), Required 1 Conservative (no operation performed) 2 Cannulated screws 3 Sliding hip screw 4 IM nail 5 PHA 6 THA 7 Other surgery

46	reason_no_surgery Show the field ONLY if: [definitive_treatment] = '1'	Indicate primary reason patient did not undergo surgery	radio, Required 1 Patient did not consent 2 Patient could not afford surgery 3 No medical/cardio-pulmonary clearance 4 Treatment of choice by surgeon 5 Implant availability 6 Lack of hospital resources 7 Unknown 8 Others
47	date_of_surgery Show the field ONLY if: [definitive_treatment] = '2' or [definitive_treatment] = '3' or [definitive_treatment] = '4' or [definitive_treatment] = '5' or [definitive_treatment] = '6' or [definitive_treatment] = '7'	Section Header: *Surgery Details* Date & Time of Primary Surgery	text (datetime_mdy), Required
48	time_surgery_to_admission Show the field ONLY if: [definitive_treatment] = '2' or [definitive_treatment] = '3' or [definitive_treatment] = '4' or [definitive_treatment] = '5' or [definitive_treatment] = '6' or [definitive_treatment] = '7'	Time to surgery from admission (hours)	calc Calculation: rounddown(datediff([date_time_of_admission],[date_of_surgery],"h","mdy"))
49	reason_delay_surgery Show the field ONLY if: [time_surgery_to_admission]> 72	Indicate the primary reason for delay in surgery (this question appears if the time from admission to surgery > 72 hours)	radio, Required 1 Patient indecision 2 Patient/relatives could not afford surgery 3 Implant availability 4 Lack of hospital resources (scheduling, OR theatre, understaffing etc.) 5 SARS-COV-2 testing-related issues 6 Delayed CP clearance 7 Unknown 8 Others
50	type_of_anesthesia Show the field ONLY if: [definitive_treatment] = '2' or [definitive_treatment] = '3' or [definitive_treatment] = '4' or [definitive_treatment] = '5' or [definitive_treatment] = '6' or [definitive_treatment] = '7'	Type of Anesthesia	radio, Required 1 General 2 Spinal 3 Other Regional
51	duration_of_surgery Show the field ONLY if: [definitive_treatment] = '2' or [definitive_treatment] = '3' or [definitive_treatment] = '4' or [definitive_treatment] = '5' or [definitive_treatment] = '6' or [definitive_treatment] = '7'	Duration of surgery (hours) *refers to total anesthesia time*	text (number, Min: 0), Required

52	estimated_blood_loss_ml Show the field ONLY if: [definitive_treatment] = '2' or [definitive_treatment] = '3' or [definitive_treatment] = '4' or [definitive_treatment] = '5' or [definitive_treatment] = '6' or [definitive_treatment] = '7'	Estimated Blood Loss (mL)	text (number, Min: 0), Required
53	pre_op_pain_assessment	Section Header: *Multi-disciplinary Care* Pain assessment and management done by *Pain scores should preferably be by NRS; or VAS/FRS for patients with cognitive impairment*	checkbox, Required 1 pre_op_pain_assessment___1 Pain specialist or Anesthesiologist 2 pre_op_pain_assessment___2 Palliative Med physician 3 pre_op_pain_assessment___3 Orthopedic surgeon 4 pre_op_pain_assessment___4 Family Med physician 5 pre_op_pain_assessment___5 Internal Med physician
54	rehab_assessment_done	Rehab assessment done	radio, Required 1 Pre-operatively 2 Post-operatively 3 Not seen by Rehab during admission
55	physician_geriatrician_inv	Physician/Geriatrician involvement during admission	radio, Required 1 Internist (includes pulmo, IDS, CVS, Adult Med, Endo) 2 Geriatrician 3 Internist and Geriatrician 4 None
56	reference_delirium	Section Header: *This next section displays references and tools helpful in Multidisciplinary Orthogeriatric Management* Delirium	descriptive
57	reference_ga	Geriatric Assessment	descriptive
58	printable_cga_form	Printable CGA form	descriptive
59	reference_osteoporosis	Osteoporosis Management and Treatment	descriptive
60	reference_complications	How to avoid common hip fracture complications	descriptive
61	treatment_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Post-treatment and Disposition** (posttreatment_and_disposition) Collapse			
62	cga_admission	Was a 10-minute Comprehensive Geriatric Assessment (CGA) given during course of admission?	radio, Required 1 Yes 2 No Custom alignment: RH
63	postop_mobilization Show the field ONLY if: [definitive_treatment] = '2' or [definitive_treatment] = '3' or [definitive_treatment] = '4' or [definitive_treatment] = '5' or [definitive_treatment] = '6' or [definitive_treatment] = '7'	Describe patient's mobility on first post-operative day	radio, Required 1 Unable to do any bedside mobilization 2 Able to do sitting mobilization 3 Able to do (partial weightbearing) standing 4 Able to do (full weightbearing) standing 5 Able to do (partial weightbearing) ambulation 6 Able to do (full weightbearing) ambulation

64	pressure_ulcer	Does the patient have pressure ulcers?	radio, Required 1 Pre-admission 2 During admission 3 None Custom alignment: RH
65	dvt_prophylaxis_given	Type of DVT prophylaxis given during admission	radio, Required 0 None 1 Aspirin / Clopidogrel 2 DOACs (Direct Oral Anti-coagulants, i.e. Dabigatran, Rivaroxaban) 3 Warfarin 4 Heparin 5 Low-molecular weight heparin 6 Others
66	bone_meds_admission	Was bone protection medication given during course of admission? *Bone protection medication refers specifically to anti-osteoporosis medication*	radio, Required 1 Yes 2 No Custom alignment: RH
67	bone_meds_discharge	Was bone protection medication recommended prior to discharge from orthopedic care?	radio, Required 1 Yes 2 No Custom alignment: RH
68	patient_clinical_status	Final Disposition	dropdown, Required 1 Discharged for home 2 Transfer to Rehab ward 3 Transfer to Medical ward 4 Transfer to other hospital 5 Home against medical advice 6 Dead 7 Unknown
69	circum_death Show the field ONLY if: [patient_clinical_status] = '6'	What were the circumstances surrounding patient's death?	dropdown, Required 1 Died before surgery 2 Died intra-operatively 3 Died from post-operative complications 4 Died post-op from unrelated or unknown complications
70	date_of_disposition	Date & Time of Disposition	text (datetime_mdy), Required
71	length_of_stay_days	Length of Stay (days) *Refers to no. of days from admission to discharge*	calc Calculation: rounddown(datediff([date_time_of_admission], [date_of_disposition], "d","mdy"))
72	posttreatment_and_disposition_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Follow-up Form** (followup_form)			Collapse

73	date_of_follow_up	Section Header: *PREVIOUS RECORD SUMMARY: Patient Name: [admission_arm_1][last_name], [admission_arm_1][first_name] Age/Sex: [admission_arm_1][age]y.o. / [admission_arm_1][gender] Date of Admission: [admission_arm_1][date_time_of_admission] Date of Injury: [admission_arm_1][date_of_injury] Fracture: [admission_arm_1][fracture_type] Treatment: [admission_arm_1][definitive_treatment] Date of surgery: [admission_arm_1][date_of_surgery] Mobility day after treatment: [admission_arm_1][postop_mobilization] Seen by rehab during admission: [admission_arm_1][rehab_assessment_done] Bone protection meds recommended prior to discharge: [admission_arm_1][bone_meds_discharge] 10-minute CGA done during admission: [admission_arm_1][cga_admission] Disposition after treatment: [admission_arm_1][patient_clinical_status] Date of Discharge: [admission_arm_1][date_of_disposition]* Date of follow-up	text (date_mdy), Required
74	latest_residence	Latest residence or location?	radio, Required 1 Home 2 Institutional care 3 Rehab Ward 4 Hospital
75	primary_mobility	Describe primary mobility achieved by patient	radio, Required 1 Freely mobile without aids 2 Mobile outdoors with one aid 3 Mobile outdoors with two aids or frame 4 Mobile outdoors but wheelchair dependent 5 Some indoor mobility but never goes outside without help 6 No functional mobility (i.e. bedridden) 7 Unknown
76	click_below_to_view_the_ti	Click below to view the Timed "Up and Go" test (an objective measurement for strength, balance and posture recovery)	descriptive
77	compliant_to_rehab	Was patient compliant to a rehabilitation program?	radio, Required 1 Yes 2 No 3 Not advised Custom alignment: RH
78	compliant_bone_meds	Was patient compliant with bone protection medication?	radio, Required 1 Yes 2 No 3 Not prescribed prior Custom alignment: RH
79	complications_present	Since last seen, did the patient develop any complications?	radio, Required 1 Yes 2 No Custom alignment: RH

80	complications_type Show the field ONLY if: [complications_present] = '1'	Indicate which complication(s) the patient developed	checkbox, Required 1 complications_type___1 Surgical site infection 2 complications_type___2 Implant failure 3 complications_type___3 Hip dislocation 4 complications_type___4 Contractures 5 complications_type___5 Pressure ulcers 6 complications_type___6 Hospital-acquired infection (pneumonia, catheter-related, UTI,etc.) 7 complications_type___7 Others
81	specify_type_of_complicati Show the field ONLY if: [complications_type(7)] = '1'	Specify type of complication if not listed in the above choices:	text
82	readmitted	Since last seen, has the patient been re-admitted for the hip related problem? *If patient has not been discharged from hospital at this point, select "No"*	radio, Required 1 Yes 2 No Custom alignment: RH
83	date_of_re_admission Show the field ONLY if: [readmitted] = '1'	Indicate date of re-admission	text (date_mdy)
84	reoperation Show the field ONLY if: [readmitted] = '1'	What operation was performed on re-admission?	radio, Required 1 None 2 Hip reduction 3 Washout or debridement 4 Implant removal 5 Revision of components 6 Conversion to THA 7 Girdlestone / Excision arthroplasty 8 Periprosthetic fracture fixation 9 Other
85	date_of_re_operation Show the field ONLY if: [reoperation] = '2' or [reoperation] = '3' or [reoperation] = '4' or [reoperation] = '5' or [reoperation] = '6' or [reoperation] = '7' or [reoperation] = '8' or [reoperation] = '9'	Indicate date of re-operation	text (date_mdy)
86	latest_clinical_status	Latest clinical status	radio, Required 1 Alive 2 Alive with complications 5 Died of disease or treatment-related complications 6 Died of unrelated complications 7 Died of unknown cause
87	date_of_death Show the field ONLY if: [latest_clinical_status] = '5' or [latest_clinical_status] = '6' or [latest_clinical_status] = '7'	Date of death:	text (date_mdy), Required

88	ffup_method	How was this follow-up conducted?	radio, Required 1 Teleconsult / teleplatforms 2 Physical follow-up Custom alignment: RH
89	what_type_of_telemed_platf Show the field ONLY if: [ffup_method] = '1'	What type of telemed platform was used?	radio, Required 1 Telephone call 2 Online messenger applications 3 Video call 4 Others
90	followup_form_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete

Appendix E. Telephone script for phone interview

ENGLISH

Good morning/afternoon!

This is *(name of FLS member)* from the (NAME OF PARTICIPATING HOSPITAL). On behalf of the fracture liaison service, I am calling to check-up on the patients that were lost to follow-up, with you being one of them. We noticed that it has been a while since our last encounter with you. Would it be okay for me to ask a few questions regarding your condition via phone call?

If patient gives verbal consent:

I would just like to ask how you've been.

Are you able to walk? (*If yes)* Are you walking using assistive devices or are you able to walk independently?
Is there any pain while walking?

(If no) Are you able to move around with a wheelchair?

Have you been taking your calcium, vitamin D supplements, and anti-osteoporosis medications?
Have you been doing any rehab exercises at home or in a community rehab center?

How is the wound? Any redness or discharge coming from the wound?

Any new injuries or fractures since the hospital admission?

Thank you for this information and for taking time to have this conversation with me. We really hope you can come by for your next check-up with us so we can see how you are doing and better instruct you on your recovery.

If patient does not give verbal consent:

I understand and respect your decision to opt out of this phone call interview. Thank you for your time, and we hope to see you back at the clinic for your follow-up check-up.

FILIPINO

Magandang umaga/hapon!

Ako po si *(pangalan ng miyembro ng FLS)* galing sa (PANGALAN NG OSPITAL)ure liaison service, tumatawag po ako para kamustahin ang mga pasyente naming hindi na nakakapag-follow-up, at kayo po ay kasama sa mga taong ito. Napansin po namin na matagal na namin kayong hindi nakikita. Maaari po ba akong magtanong sa telepono ng iilang mga tanong tungkol sa inyong kondisyon?

Kung pumayag:

Gusto ko pong malaman kung kamusta na po kayo.

Nakakalakad na po ba kayo? *(Kung oo)* Gumagamit ba kayo ng tungkod o saklay, o nakakalakad na po ba kayo nang walang tulong? May masakit po ba habang kayo'y naglalakad?
(Kung hindi) Nakakagalaw po ba kayo gamit ng wheelchair?

Naiinom niyo po ba yung calcium, vitamin D at gamot para sa osteoporosis?
Nakakapagehersisyo po ba kayo o nakakapunta po ba kayo sa isang rehab center malapit sa inyo?

Kamusta na po yung sugat? May pamumula o katas po ba na lumalabas sa sugat?

May mga bago po ba kayong pinsala or bali mula nung na-admit kayo?

Maraming salamat po sa lahat ng impormasyon na ibinigay ninyo kayo'y nagbahagi ng oras upang makapag-usap tayo. Umaasa po kaming makakarating po kayo sa susunod ninyong check-up upang makita namin ang inyong kalagayan at mas mapag-usapan natin ang inyong paggaling.

Kung hindi pumayag:

Naiintindihan ko po at iginagalang ko ang inyong desisyon na hindi ituloy ang ating pag-uusap. Maraming salamat po, at umaasa po kaming magkikita po tayo sa susunod ninyong follow-up.

Appendix F. Progress form for participating hospitals to be given every 4 months

Progress Form

*Principles and tools are taken from the Orthogeriatric textbook (2nd edition)

Period covered: Jan 2022 – June 2022 (q6 months)
Lead Site/ Co-site investigator:
Hospital:

ORTHOGERIATRIC COMPONENT

1. What is my hospital's current clinical pathway for elderly patients presenting with acute hip fracture?

An orthogeriatric service needs to consider the entire journey of the patient with a hip fracture, from their presentation to the Emergency Department all the way through to their rehabilitation and recovery. Hence, an important initial step to understand the local hip fracture pathway and how the future orthogeriatric service can be delivered locally is by performing a mapping exercise. The mapping exercise has to be a detailed assessment of each phase of care during the patients' hospital journey from what happens in the Emergency Department, pre-operatively, during the operation, after the operation and rehabilitation period.

In each phase, the mapping exercise needs to specify what the treatment goals are (principles of care) and how these goals can be delivered (explicit care delivered):

CURRENT PATHWAY IN YOUR HOSPITAL:

Phase of Care	Treatment Goals / Principle of Care	Please state exact care that is usually delivered:
Emergency Department		
Pre-op Phase		
Operative Phase		
Post-op Phase		
Rehabilitation		

- A detailed example of this may be found in Chapter 5 (Table 5.1) of the orthogeriatric textbook (2nd edition) on establishing an orthogeriatric service.

2. Who is currently in my core multidisciplinary team?

Many healthcare professionals with different discipline backgrounds have important contributions to make to high-quality care for older patients with hip fractures. Mapping the pathway allows identification of these key members of the inter-professional multidisciplinary team (MDT).

Kindly check which of these members you already have on your MDT:

- ❑ Orthopaedic surgeon
- ❑ Physician with expertise in older people, frailty, trauma and bone health (e.g., orthogeriatrician)
- ❑ Anaesthetist
- ❑ Nurse
- ❑ Physiotherapist
- ❑ Occupational therapist
- ❑ Others (please specify):

Remember: This is not an exhaustive list as many successful services are supported by other health professionals such as social workers, clinical pharmacists, dieticians, fracture liaison services and radiology. The key to efficient multidisciplinary working has to be coordination and communication between the various team members.

3. What are my current resources and how can I maximize these to drive change within the hospital?

The "Seven S" model is a way of thinking holistically about the resources required to drive change within the organization to achieve the components of optimal hip fracture care. Please review and comment on these resources with help from the guide questions below:

Resource	Description	Assessment
Staff	are the right staff members in place to facilitate the introduction of the new orthogeriatric service? Are fewer staff required? Consider appropriate recruitment methods if needed.	
Skills	Do the staff have the necessary expertise? Do they require more training?	
Structure	Does the existing organizational structure lend itself to supporting acute fracture care? (e.g. allowing prompt surgeries, referrals)	

Shared values	do all parties involved truly believe in the improvement of care processes? Management, ward, theatre staff, and surgeons all need to back the venture, and this will only happen if all parties are involved in the whole process from its conception to its execution	
Style of management	Is the current management style appropriate to oversee this? The orthogeriatric service needs to be driven predominantly by the core MDT with management as willing co-partners; a management autocracy here is not appropriate	
Strategy	Are the steps in place to facilitate change? All staff providing hip fracture care need to know about the patient pathway; patients need to be informed about new services, and ward staff have to change existing care protocols to make them more specific.	
Systems	This encompasses all aspects from information technology to patient support.	

ORTHOGERIATRICS SWOT Analysis:

This allows the organisation to concentrate on internal factors (strengths and weaknesses of the existing service) and external factors (opportunities and threats that the new service provides). This gives a very clear global view of the situation and often reveals

issues that were previously not considered. Both analyses rely on the steering group brainstorming, which circumvents the bias of a single proponent.

Strengths	Weaknesses
Guide questions: • What kind of policy influence do you have? • Where have you had most success? • What engagement skills or expertise do you have? • Do you have relationships with other actors in the hospital that may help the service/program? • What capacity do you have? • Are you involved in projects or initiatives you could leverage? • What local data are available?	Guide questions: • What kinds of challenges have you or your alliance faced when trying to establish orthogeriatrics? • What skills or expertise is lacking? • What capacity do you lack? • What areas would others see as your weaknesses?
Opportunities	Threats
Guide questions: • Does the policy space present any opportunities you can take advantage of? • Are there other groups working towards your goal? • Are there potential sources of advice you can pursue? • How can you turn your strengths into opportunities?	Guide questions: • Are there any threats that could impact your ability to achieve your goal? • Are there any groups working against your goal? • What threats do your weaknesses expose?

FRACTURE LIAISON SERVICE (FLS) COMPONENT

The FLS model is a coordinator-based, secondary fracture prevention service which is implemented by a healthcare system in order to ensure that those patients presenting with a fragility fracture are identified as osteoporotic and at risk of falls, and thus managed as such.

1. What is the current status of my hospital's Fracture Liaison Service?
For each FLS criteria or benchmark kindly check in which phase your hospital/service is currently in (for detailed description of each benchmark, refer to next page):

Benchmark criteria	Preparatory	Level 1	Level 2	Level 3
1. Patient identification	❑ Not available yet	❑ Patient ID'd, not tracked	❑ Patients ID'd, are tracked	❑ Patients ID'd, tracked and independent review
2. Patient evaluation	❑ Not available yet	❑ 50% assessed	❑ 70% assessed	❑ 90% assessed
3. Post-fracture assessment timing	❑ Not available yet	❑ Within 13-16 weeks	❑ Within 9-12 weeks	❑ Within 8 weeks
4. Vertebral Fracture (VF) ID	❑ Not available yet	❑ Known VF assessed	❑ Routinely assesses for VF	❑ Radiologists identify VF
5. Assessment Guidelines	❑ Not available yet	❑ Local	❑ Regional	❑ National
6. Secondary Causes of Osteoporosis	❑ Not available yet	❑ 50% of patients screened	❑ 70% of patients screened	❑ 90% of patients screened
7. Falls Prevention Services	❑ Not available yet	❑ 50% of patients evaluated	❑ 70% of patients evaluated	❑ 90% of patients evaluated
8. Multifaceted assessment	❑ Not available yet	❑ 50% of patients screened	❑ 70% of patients screened	❑ 90% of patients screened
9. Medication Initiation	❑ Not available yet	❑ 50% of patients initiated	❑ 70% of patients initiated	❑ 90% of patients initiated
10. Medication Review	❑ Not available yet	❑ 50% of patients assessed	❑ 70% of patients assessed	❑ 90% of patients assessed
11. Communication Strategy	❑ Not available yet	❑ Communicates to doctor	❑ Communicates to the doctor with 50% criteria*	❑ Communicates to the doctor with 90% criteria*
12. Long-term Management	❑ Not available yet	❑ 1 year follow-up		❑ 6 month follow-up & 1 year follow-up
13. Database	❑ Not available yet	❑ Local	❑ Regional	❑ National

*Criteria: FRAX, DXA, Vertebral DXA/x-ray, primary risk factors, secondary risk factors, falls risk, current medications, medication compliance, follow-up plan, lifestyle risk-factors, time since last fracture.

Description of each benchmark:

1. Patient identification—patients with fragility fractures may be identified (level 1), tracked through the health system and may be independently reviewed by the FLS (level 2 and 3).

2. Patient evaluation—assesses the percentage of patients with a fragilty fracture who have been evaluated for the risk of future fracture via a clinical prediction tool (FRAX®) or assessment of bone mineral density.

3. Post-fracture assessment timing—assesses how quickly patients with fragility fractures are assessed with a formal fracture risk assessment by the FLS in
weeks since the fracture.

4. Vertebral fracture identification—despite being the most common fragility fracture many vertebral fractures are identified by chance (e.g. as incidental
findings in radiological investigations) due to variation in clinical presentation.
To achieve the highest level of practice in this criterion it is necessary to liaise with radiology to ensure that they identify and report vertebral fractures and provide a coherent pathway for these patients to access the FLS.

5. Assessment guidelines—evaluates whether the practice of the FLS is aligned to local, national or international guidance for the assessment of fragility fractures.

6. Secondary causes of osteoporosis—assesses the percentage of patients with fragility fractures who are screened for secondary causes of osteoporosis.

7. Falls prevention services—concerns the percentage of patients evaluated for referral to a falls service.

8. Multifaceted assessment—addresses the assessment (and management) of lifestyle factors which may underlie the fracture.

9. Medication initiation—includes the percentage of patients who were eligible for treatment receiving anti-osteoporosis medication.

10. Medication review—includes the percentage of patients who are on anti-osteoporosis medication who have their compliance assessed and in whom alternative medications are considered.

11. Communication strategy—assesses the quality of communication between the FLS and doctors in primary and secondary care including whether the following items are communicated; FRAX® scores, DXA outcomes, vertebral imaging, primary and secondary risk factors for fracture, falls risk, current medication and compliance, follow-up plan, lifestyle risk-factors and time since last fracture.

12. Long-term management—assesses whether medication compliance and tolerance
are assessed at 6 months and 1 year after commencement.

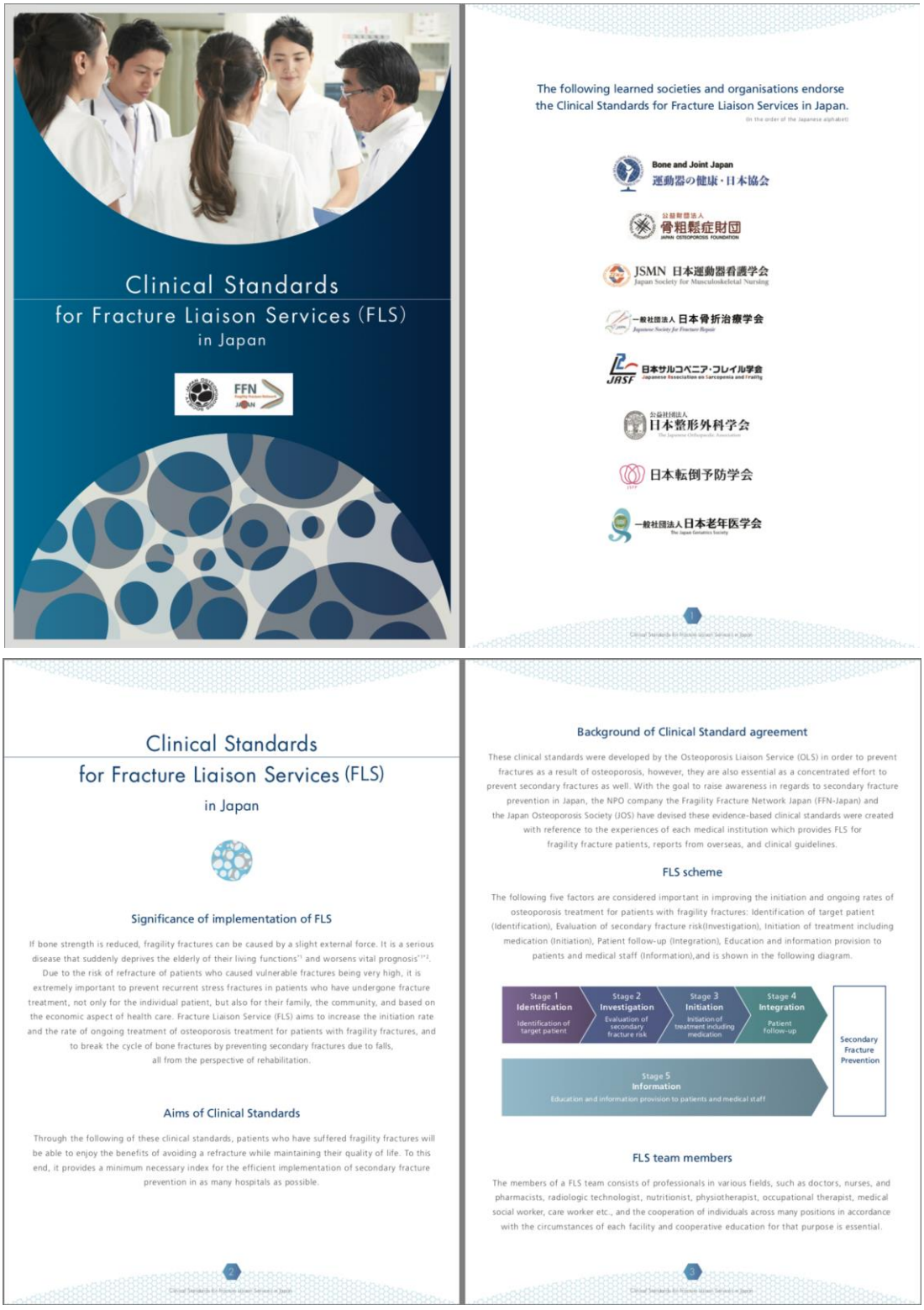
13. Database—refers to whether the FLS contributes to a database for fragility fractures at a local, regional or national level.

FLS SWOT Analysis:

This allows the organisation to concentrate on internal factors (strengths and weaknesses of the existing service) and external factors (opportunities and threats that the new service provides). This gives a very clear global view of the situation and often reveals issues that were previously not considered. Both analyses rely on the steering group brainstorming, which circumvents the bias of a single proponent.

Strengths	Weaknesses
Guide questions: • What kind of policy influence do you have? • Where have you had most success? • What engagement skills or expertise do you have? • Do you have relationships with other actors in the hospital that may help the service/program? • What capacity do you have? • Are you involved in projects or initiatives you could leverage? • What local data are available?	Guide questions: • What kinds of challenges have you or your alliance faced when trying to establish the FLS? • What skills or expertise is lacking? • What capacity do you lack? • What areas would others see as your weaknesses?
Opportunities	**Threats**
Guide questions: • Does the policy space present any opportunities you can take advantage of? • Are there other groups working towards your goal? • Are there potential sources of advice you can pursue? • How can you turn your strengths into opportunities?	Guide questions: • Are there any threats that could impact your ability to achieve your goal? • Are there any groups working against your goal? • What threats do your weaknesses expose?

Appendix G. FLS Clinical Practice Standards



Clinical Standards
for Fracture Liaison Services (FLS)
in Japan

FFN

The following learned societies and organisations endorse
the Clinical Standards for Fracture Liaison Services in Japan.
(in the order of the Japanese alphabet)

Bone and Joint Japan
運動器の健康・日本協会

骨粗鬆症財団
JAPAN OSTEOPOROSIS FOUNDATION

JSMN 日本運動器看護学会
Japan Society for Musculoskeletal Nursing

一般社団法人 日本骨折治療学会
Japanese Society for Fracture Repair

日本サルコペニア・フレイル学会
Japanese Association on Sarcopenia and Frailty

公益社団法人
日本整形外科学会
The Japanese Orthopaedic Association

日本転倒予防学会

一般社団法人日本老年医学会
The Japan Geriatrics Society

1

Clinical Standards
for Fracture Liaison Services (FLS)
in Japan

Significance of implementation of FLS

If bone strength is reduced, fragility fractures can be caused by a slight external force. It is a serious disease that suddenly deprives the elderly of their living functions[*1] and worsens vital prognosis[*2]. Due to the risk of refracture of patients who caused vulnerable fractures being very high, it is extremely important to prevent recurrent stress fractures in patients who have undergone fracture treatment, not only for the individual patient, but also for their family, the community, and based on the economic aspect of health care. Fracture Liaison Service (FLS) aims to increase the initiation rate and the rate of ongoing treatment of osteoporosis treatment for patients with fragility fractures, and to break the cycle of bone fractures by preventing secondary fractures due to falls, all from the perspective of rehabilitation.

Aims of Clinical Standards

Through the following of these clinical standards, patients who have suffered fragility fractures will be able to enjoy the benefits of avoiding a refracture while maintaining their quality of life. To this end, it provides a minimum necessary index for the efficient implementation of secondary fracture prevention in as many hospitals as possible.

2

Background of Clinical Standard agreement

These clinical standards were developed by the Osteoporosis Liaison Service (OLS) in order to prevent fractures as a result of osteoporosis, however, they are also essential as a concentrated effort to prevent secondary fractures as well. With the goal to raise awareness in regards to secondary fracture prevention in Japan, the NPO company the Fragility Fracture Network Japan (FFN-Japan) and the Japan Osteoporosis Society (JOS) have devised these evidence-based clinical standards were created with reference to the experiences of each medical institution which provides FLS for fragility fracture patients, reports from overseas, and clinical guidelines.

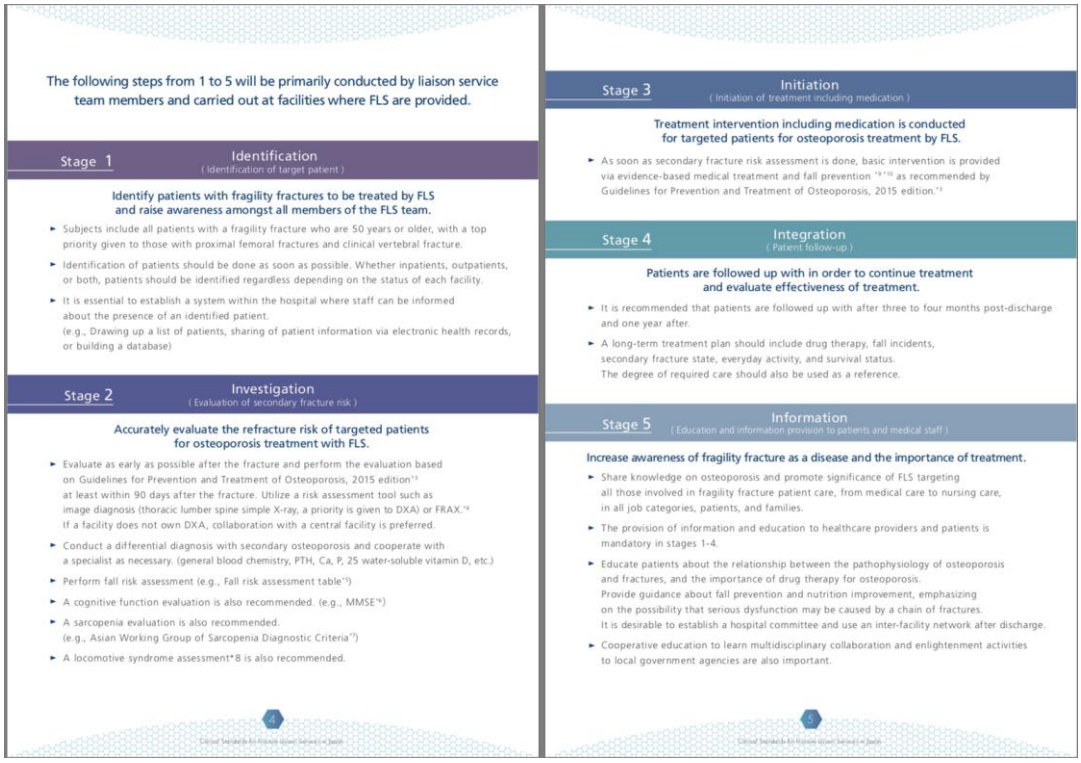
FLS scheme

The following five factors are considered important in improving the initiation and ongoing rates of osteoporosis treatment for patients with fragility fractures: Identification of target patient (Identification), Evaluation of secondary fracture risk(Investigation), Initiation of treatment including medication (Initiation), Patient follow-up (Integration), Education and information provision to patients and medical staff (Information),and is shown in the following diagram.

FLS team members

The members of a FLS team consists of professionals in various fields, such as doctors, nurses, and pharmacists, radiologic technologist, nutritionist, physiotherapist, occupational therapist, medical social worker, care worker etc., and the cooperation of individuals across many positions in accordance with the circumstances of each facility and cooperative education for that purpose is essential.

3



The following steps from 1 to 5 will be primarily conducted by liaison service team members and carried out at facilities where FLS are provided.

Stage 1 Identification
(Identification of target patient)

Identify patients with fragility fractures to be treated by FLS and raise awareness amongst all members of the FLS team.

- Subjects include all patients with a fragility fracture who are 50 years or older, with a top priority given to those with proximal femoral fractures and clinical vertebral fracture.
- Identification of patients should be done as soon as possible. Whether inpatients, outpatients, or both, patients should be identified regardless depending on the status of each facility.
- It is essential to establish a system within the hospital where staff can be informed about the presence of an identified patient.
  (e.g., Drawing up a list of patients, sharing of patient information via electronic health records, or building a database)

Stage 2 Investigation
(Evaluation of secondary fracture risk)

Accurately evaluate the refracture risk of targeted patients for osteoporosis treatment with FLS.

- Evaluate as early as possible after the fracture and perform the evaluation based on Guidelines for Prevention and Treatment of Osteoporosis, 2015 edition[*3] at least within 90 days after the fracture. Utilize a risk assessment tool such as image diagnosis (thoracic lumber spine simple X-ray, a priority is given to DXA) or FRAX.[*4] If a facility does not own DXA, collaboration with a central facility is preferred.
- Conduct a differential diagnosis with secondary osteoporosis and cooperate with a specialist as necessary. (general blood chemistry, PTH, Ca, P, 25 water-soluble vitamin D, etc.)
- Perform fall risk assessment (e.g., Fall risk assessment table[*5])
- A cognitive function evaluation is also recommended. (e.g., MMSE[*6])
- A sarcopenia evaluation is also recommended.
  (e.g., Asian Working Group of Sarcopenia Diagnostic Criteria[*7])
- A locomotive syndrome assessment*8 is also recommended.

4

Stage 3 Initiation
(Initiation of treatment including medication)

Treatment intervention including medication is conducted for targeted patients for osteoporosis treatment by FLS.

- As soon as secondary fracture risk assessment is done, basic intervention is provided via evidence-based medical treatment and fall prevention [*9 *10] as recommended by Guidelines for Prevention and Treatment of Osteoporosis, 2015 edition.[*3]

Stage 4 Integration
(Patient follow-up)

Patients are followed up with in order to continue treatment and evaluate effectiveness of treatment.

- It is recommended that patients are followed up with after three to four months post-discharge and one year after.
- A long-term treatment plan should include drug therapy, fall incidents, secondary fracture state, everyday activity, and survival status. The degree of required care should also be used as a reference.

Stage 5 Information
(Education and information provision to patients and medical staff)

Increase awareness of fragility fracture as a disease and the importance of treatment.

- Share knowledge on osteoporosis and promote significance of FLS targeting all those involved in fragility fracture patient care, from medical care to nursing care, in all job categories, patients, and families.
- The provision of information and education to healthcare providers and patients is mandatory in stages 1-4.
- Educate patients about the relationship between the pathophysiology of osteoporosis and fractures, and the importance of drug therapy for osteoporosis. Provide guidance about fall prevention and nutrition improvement, emphasizing on the possibility that serious dysfunction may be caused by a chain of fractures. It is desirable to establish a hospital committee and use an inter-facility network after discharge.
- Cooperative education to learn multidisciplinary collaboration and enlightenment activities to local government agencies are also important.

5

〈 AWGS Diagnostic Criteria 〉

Chen LK, et al. J Am Med Dir Assoc 2014; 15: 95-101.
©2014 American Medical Directors Association, Inc. with permission from Elsevier.

〈 Measuring Grip Strength & Walking Speed 〉

Grip Strength

Measure both the right and left sides two times each and use the largest values. We do not require a specific machine to measure grip strength, however we do recommend using the JAMAR hand dynamometer. Start with the patient seated and their upper arms bent at the elbow at a 90-degree angle near the center of their torso. Generally, it is recommended that the examiner hold the dynamometer in a manner so that the patient does not feel the weight of it. However, this test can also be administered with the patient standing with their arms extended.

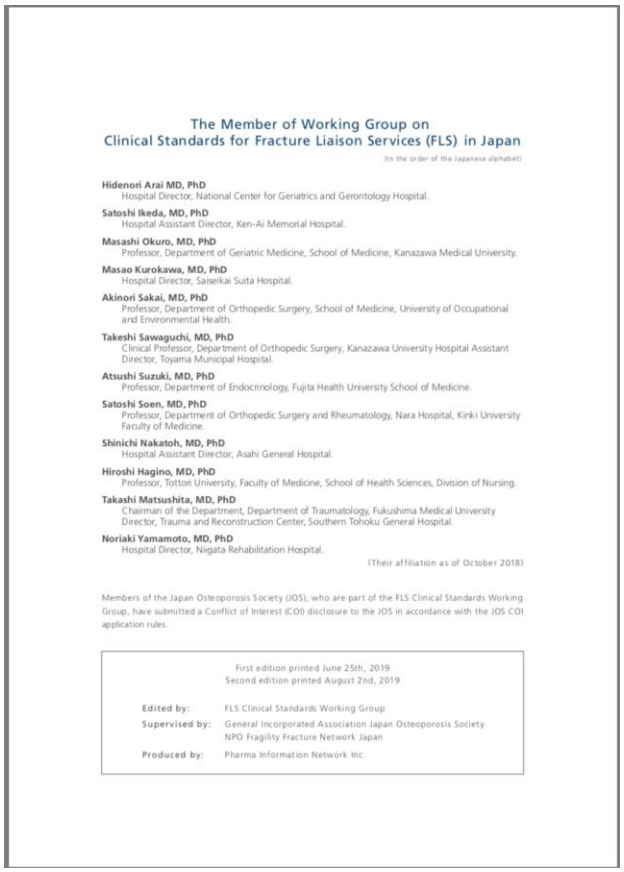
Walking Speed

Excluding acceleration and deceleration, it is recommended that the patient' s average walking speed be evaluated as they walk more than 4 m. In other words, find a 6 m or longer space that the patient can walk. Next, have the patient walk from the 0 m mark to the 6 m mark. Measure the amount of time it takes to travel from the 1 m mark to the 5 m mark. This measurement should only be taken once.

Sarcopenia Diagnostic Guidelines (2017 Edition)

8

	Stage1 Identification	Stage2 Investigation	Stage3 Initiation	Stage4 Integration	Stage5 Information
What	Identification of target patients	Evaluation of secondary fracture risk	Initiation of treatment including medication	Patient follow-up	Education and information provision to patients and medical staff
	Identify patients with fragility fractures to be treated by FLS and raise awareness amongst all members of the liaison service team.	Accurately evaluate the refracture risk of targeted patients for osteoporosis treatment with FLS	Treatment intervention including medication is conducted for targeted patients for osteoporosis treatment by FLS	Patients are followed up with in order to continue treatment and evaluate effectiveness of treatment.	Increase awareness of fragility fracture as a disease and the importance of treatment.
Who	FLS team				
Where	Facilities implementing FLS				
Whom	Subjects include all patients with a fragility fracture who are 50 years or older, with a top priority given to those with proximal femoral fractures and clinical vertebral fracture.				To target all of the job, and patients and their families involved in fragility fracture patients to care from it.
When	Identification of patients should be done as soon as possible. Whether inpatients, outpatients, or both, patients should be identified regardless depending on the status of each facility.	Evaluated as soon as possible after the fracture, evaluated within at least 90 days after the fracture.	Carried out immediately after the end of secondary fracture risk.	It is recommended that patients are followed up with after three to four months post-discharge and one year after.	The provision of information and education to healthcare providers and patients is mandatory in stages 1-4.
How	It is essential to establish a system within the hospital where staff can be informed about the presence of an identified patient. (e.g., Drawing up a list of patients, sharing of patient information via electronic health records, or building a database)	Utilize a risk assessment tool such as image diagnosis (thoracic lumber spine simple X-ray, a priority is given to DXA) or FRAX.*4 If a facility does not own DXA, collaboration with a central facility is preferred. Conduct a differential diagnosis with secondary osteoporosis and cooperate with a specialist as necessary. Perform fall risk assessment.*5 A cognitive function evaluation*6 and A sarcopenia evaluation*7, a locomotive syndrome assessment.*8 is also recommended.	Basic intervention is provided via evidence-based medical treatment and fall prevention*9 *10 as recommended by Guidelines for Prevention and Treatment of Osteoporosis, 2015 edition.*3	A long-term treatment plan should include drug therapy, fall incidents, secondary fracture state, everyday activity, and survival status. The degree of required care should also be used as a reference.	Educate patients about the relationship between the pathophysiology of osteoporosis and fractures, and the importance of drug therapy for osteoporosis. Provide guidance about fall prevention and nutrition improvement, emphasizing on the possibility that serious dysfunction may be caused by a chain of fractures. It is desirable to establish a hospital committee and use an inter-facility network after discharge. Cooperative education to learn multidisciplinary collaboration and enlightenment activities to local government agencies are also important.



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Clinical Standards for Fracture Liaison Services (FLS) in Japan

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Members of the Japan Osteoporosis Society (JOS), who are part of the FLS Clinical Standards Working Group, have submitted a Conflict of Interest (COI) disclosure to the JOS in accordance with the JOS COI application rules.

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Edited by: FLS Clinical Standards Working Group
Supervised by: General Incorporated Association Japan Osteoporosis Society
NPO Fragility Fracture Network Japan
Produced by: Pharma Information Network Inc.

Appendix H. Memo on the official launch of the UPM-PGH Orthogeriatric Multidisciplinary Fracture Management Model and Fracture Liaison Service.

22 October 2017

The University of the Philippines Manila-Philippine General Hospital Department of Orthopedics, in partnership with the Department of Anesthesiology, Department of Family and Community Medicine, Department of Medicine, and Department of Rehabilitation Medicine, officially launched the UPM-PGH Orthogeriatric Multidisciplinary Fracture Management Model and Fracture Liaison Service on October 20, 2017.

It is the thrust of the department to adapt and implement this globally accepted standard of care in managing acute hip fractures in elderly patients. With the implementation of the UPM-PGH Orthogeriatric Unit, a multidisciplinary approach was adapted with goals of reducing the time to surgery and hospital days, as well as decreasing inpatient morbidity and mortality. In line with these goals, we established the UPM-PGH Department of Orthopedics Hip Fracture Database, to properly document all cases we encounter, and further use this information to improve our management for our patients.

Appendix I. REDCAP Database System

SOFTWARE

REDCap (Research Electronic Data Capture) is a secure web application for building and managing online surveys and databases. It has many features, including:

Online or offline project design

Online using the Online Designer or offline using a “data dictionary” template in Microsoft Excel that can be uploaded later into REDCap.

Availability

Software is available at no cost for REDCap Consortium Partners.

Secure and web-based

Input data or build an online survey or database from anywhere in the world over a secure web connection with authentication and data logging.

Fast and flexible

Conception to production-level database or survey in less than one day.

Multi-site access

REDCap databases/surveys can be used by researchers from multiple sites and institutions.

Autonomous utilization

Research groups have complete autonomy and control to add new users.

Fully customizable

You are in total control of shaping your database or survey.

Audit trails

For tracking data manipulation and user activity.

Automated export procedures

For seamless data downloads to Excel, PDF, and common statistical packages (SPSS, SAS, Stata, R).

A built-in project calendar

A scheduling module

Ad hoc reporting tools

Many advanced features

Such as branching logic, file uploading, and calculated fields.

A quick and easy software installation process

So that you can get REDCap running and fully functional in a matter of minutes.

Regulatory compliance

REDCap can be installed in a variety of environments for compliance with such standards as HIPAA, 21 CFR Part 11, FISMA (low, moderate, high), and international standards. Because *you* have direct and total control over your system, REDCap is fully personalized to meet your security policies and user needs.

		Counterpart Funding	DOST-GIA Funding
I.	**PERSONAL SERVICES**		
	Direct Cost		
	Salaries		
	One (1) Science Research Analyst @ 26,779.20 X 24 mos.	P	P 642,700.80
	Seventeen (17) Project Staff Level 3 @ 7500/mo x 24 months		3,060,000.00
	Honoraria		
	One (1) Project Leader @ 8,800/mo x 24 months		211,200.00
	Four (4) Project staff @ 7,500/mo x 24 month		720,000.00
	Indirect Cost		
	Total for PS		**4,633,900.80**
II.	**MAINTENANCE AND OTHER OPERATING EXPENSES**		
	Direct Cost		
	1. Traveling Expenses		
	Foreign (attendance in conferences)	P	P 150,000.00
	Fragility Fracture network Global Congress October 2022 (Venue TBA, hotel & plane ticket)		
	2. Communication Expenses		
	Telephone Expenses		80,000.00
	Internet expenses	100,000.00	
	3. Repairs and Maintenance		
	Office Buildings, Office Equipment, Furniture and Fixtures, IT	200,000.00	
	Equipment and Software, Machineries and Equipment, etc.	200,000.00	
	Transportation and Delivery service		24,000.00

	4. Supplies and Materials Expenses				
	Office Supplies Expenses				240,000.00
	Print and Binding Expenses				240,000.00
	Representation Expenses (e.g. food for meetings, etc.)				120,000.00
	Professional Services				
	Statistician 6000/per consultation				48,000.00
	Taxes, Insurance Premiums and Other Fees				
	Research Institutional Fees/ Initial Research Review Fees per institution @ 30,000 x 14 institutions				420,000.00
	Continuing Review fee per year @10,000 x 14 institutions				140,000.00
	Indirect Cost				
	(Implementing Agency)				
	Ethics Review (initial review & continuing review)				40,000.00
	Supplies and materials				100,000.00
	Communication services				134,042.56
	Transportation and delivery expenses				69,750.00
		Total for MOOE	P **500,000.00**	P	**1,805,792.56**
III.	**Equipment Outlay**				
	Detailed List/ Breakdown of Equipment				
	Three (3) laptop and accessories included @ 30,000/unit				90,000.00
	Windows 10 Home 64 AMD Ryzen™ 5 processor AMD Radeon™ Vega 8 Graphics 12 GB memory; 256 GB SSD storage 17.3" diagonal HD+ display				
		Total for EO	P	P	**90,000.00**
			P **500,000.00**	P	**6,529,693.36**

LIST OF AFFILIATED SITES:

IMPLEMENTATION SITES NO.	REGION	PROVINCE	SITE LEAD INVESTIGATOR
Baguio General Hospital and Medical Center	CAR	Benguet	Dr. Leo Anthony Franco
Bicol Region General Hospital And Geriatric Medical Center	V	Bicol	Dr. Elvin Panliboton
Cagayan Valley Medical Center (CVMC)	II	Cagayan Valley	Dr. Anthony Abogado
East Avenue Medical Center	NCR	Quezon city	Dr. Geoffrey Battad
Jose B. Lingad Memorial Regional Hospital	III	Pampanga	Dr. Rene Edgardo Manalastas
Jose R. Reyes Memorial Medical Center	NCR	Manila	Dr. Melito Ramos
Northern Mindanao Medical Center	X	Cagayan de oro	Dr. Leonard Khu
Philippine General Hospital	NCR	Manila	Dr. Bernardino Alpuerto II
Philippine Orthopedic Center	NCR	Quezon city	Dr. Allan Brabante
Quirino Memorial Medical Center	NCR	Quezon city	Dr. David Vincent Antonio
Veterans Memorial Medical Center	NCR	Quezon city	Dr. Deejay Pacheco
Vicente Sotto Memorial Medical Center	VII	Cebu	Dr. Philippe Baclig
West Visayas State University Medical Center	VI	Iloilo	Dr. John Alfred Yap
Western Visayas Medical Center	VI	Iloilo	Dr. Lucille Detoyato

Multicenter Implementation of Orthogeriatrics and the Fracture Liaison Service for Elderly Hip Fractures: An Evidence-based Framework for a Sustainable Digital Health Registry

FRAGILITY HIP FRACTURE REGISTRY DATA LOGISTICS MANUAL

Principal Investigator:
Dr. Irewin A. Tabu

Co-Investigators:
Dr. Giorgio Delgado
Dr. Karla Teresa Araneta
Dr. Bernardino Alpuerto II

Project Advisory Board:

Dr. Edward H.M Wang (Head), Dr. Emmanuel Estrella, Dr. Mark Anthony Sandoval, Dr. Antonio Alan S. Mangubat, Dr. Dorothy Dy-Ching Bing Agsaoay, Dr. Leilani A. Nicodemus, Dr. Shelley Ann F. Dela Vega, Dr. Nathaniel S. Orillaza Jr, Dr. Kathrina Isabel Espino, Dr. Michael Joseph F. Agbayani, Dr. Jose Donato A. Magno, Dr. Maria Sonia S. Salamat, Dr. Minerva Vinluan, Dr. Anna Guia Limpoco, Dr. Marc Evans Abat, Dr. Peter Julian Francisco

Version 1.0 Updated by K. Araneta: 2021 June 17

The objective of this user manual is to provide an easy-to-follow, step-by-step, comprehensive guide to data entry through the REDCap system for the use of institutions involved in the hip fragility fracture registry project

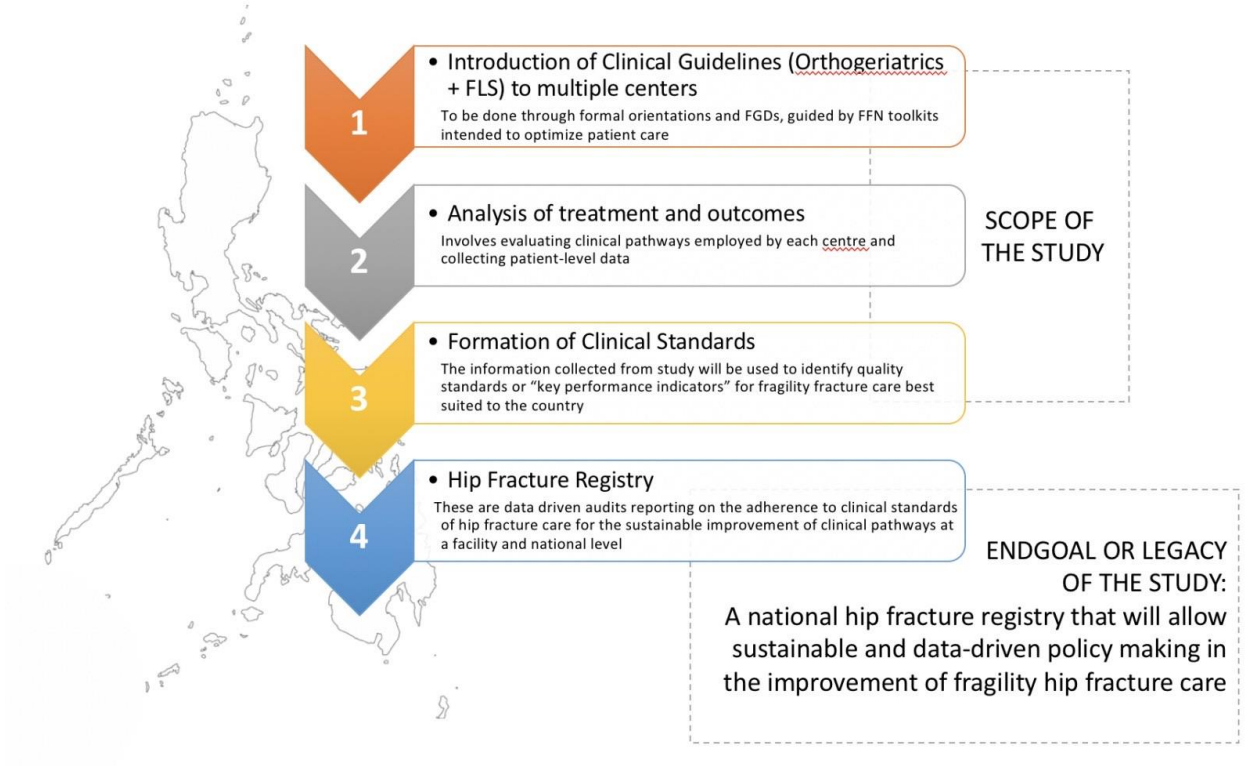
Please note that this manual belongs to the research team conducting the project:

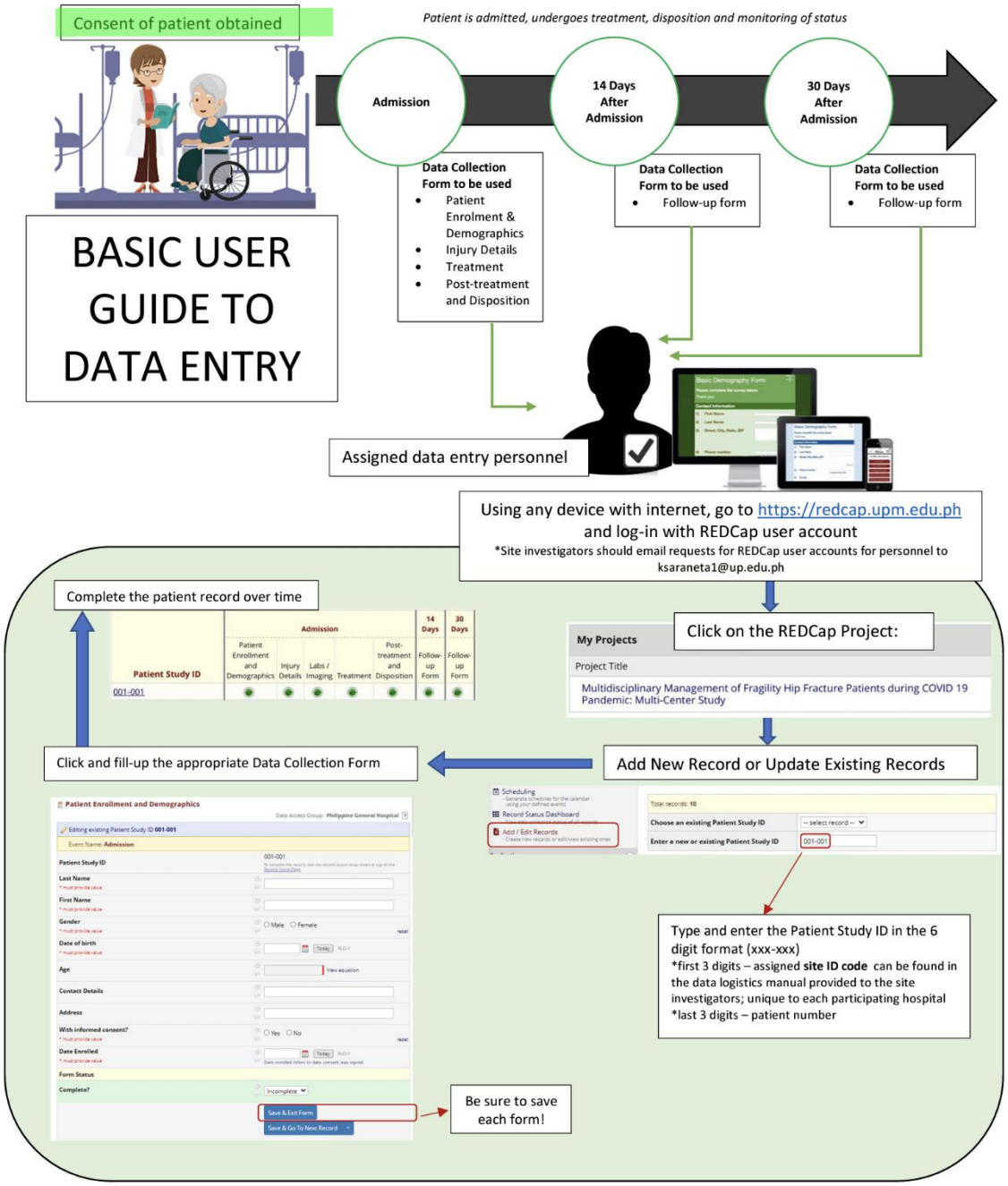
” Multicenter Implementation of Orthogeriatrics and the Fracture Liaison Service for Elderly Hip Fractures: An Evidence-based Framework for a Sustainable Digital Health Registry”

This manual is part of a checklist of documents provided in the Study Protocol Package:

Study Protocol Package	
Study Protocol (Revised)	☑
Data Logistics Manual	☑
Printable Informed Consent Forms	☑
Printable Data Collection Forms	☑
Copy of MOU	☑

*if any of these documents are missing from your protocol package, kindly inform the PI or the research field coordinator.




Consent of patient obtained
Patient is admitted, undergoes treatment, disposition and monitoring of status
Admission
14 Days After Admission
30 Days After Admission
Data Collection Form to be used
Patient Enrolment & Demographics
Injury Details
Treatment
Post-treatment and Disposition
Data Collection Form to be used
Follow-up form
Data Collection Form to be used
Follow-up form
BASIC USER GUIDE TO DATA ENTRY
Assigned data entry personnel
Using any device with internet, go to https://redcap.upm.edu.ph and log-in with REDCap user account
*Site investigators should email requests for REDCap user accounts for personnel to ksaraneta1@up.edu.ph
Complete the patient record over time
Click on the REDCap Project:
My Projects
Project Title
Multidisciplinary Management of Fragility Hip Fracture Patients during COVID 19 Pandemic: Multi-Center Study
Add New Record or Update Existing Records
Click and fill-up the appropriate Data Collection Form
Type and enter the Patient Study ID in the 6 digit format (xxx-xxx)
*first 3 digits – assigned site ID code can be found in the data logistics manual provided to the site investigators; unique to each participating hospital
*last 3 digits – patient number
Be sure to save each form!

▼

See Appendix for list of designated site ID codes

DATA MANAGEMENT TOOL: REDCap

What is REDCAP?

REDCAP (Research Electronic Data Capture) is a secure, web-based application for collecting and managing clinical and research data. It was developed by Vanderbilt University and includes more than 162,000 projects with 1,406 active institutional partners in 90 countries.

REDCAP structure and terminology

REDCap is a database application that provides online access to a project-by-project basis as determined by the project administrator. Each project may have many users. Users will only see projects listed in their My Projects page for which they have access. Please familiarise yourself with the following terms:

Data instrument – a form created by the project administrators for the purposes of capturing data such as a data entry form or survey. Physically, it is equivalent to a questionnaire form that a researcher may be handing out.

Data Instruments to be used in this study:

1. Patient Enrolment and Demographics
2. Injury Details
3. Labs / Imaging
4. Treatment
5. Post-Treatment/ Disposition
6. Follow-up

Study ID – a unique 6-digit code (xxx-xxx) that can identify each record in the database. The first 3 digits refer to the designated study site code while the last 3 digits refer to the patient number. See the Appendix for the list of designated site ID codes.

Event – a scheduled or unscheduled occurrence for which data is captured using a predefined data instrument (form). Because this is a longitudinal study, a patient record will consist of 3 events:

1. Admission – data collected during admission, this starts on the date of admission
2. 30 Days – data collected 14 days after date of admission
3. 120 Days – data collected 30 days after date of admission

Data Access Group – a unique security feature in REDCAP guaranteeing data privacy to each participating hospital such that no site has access to another's database. This operates on the assumption that all participating hospitals in this project maintain the privacy of their REDCAP user accounts. Only the research team will have overall access to de-identified records.

**De*-identified records – records automatically stripped of patient identifiers for data privacy (including Last Name, First Name, Contact Details, Address). De-identification occurs when the research investigators view or extract data from a site's database.

Patient Study ID	Admission					14 Days	30 Days	Completion Data
	Patient Enrollment and Demographics	Injury Details	Labs / Imaging	Treatment	Post-treatment and Disposition	Follow-up Form	Follow-up Form	Inclusion / Exclusion Form
001-001	●	●	●	●	●	●	●	●
001-002	●	○	○	○	○	○	○	○
001-003	●	●	●	●	●	●	○	○
001-004	○	○	○	○	○	○	○	○
001-005	●	○	○	○	○	○	○	○
001-006	●	○	○	●	○	○	○	○
001-007	○	○	○	○	○	○	○	○
001-008	●	○	○	○	○	○	○	○

The database structure appears as this.

User requests

Access to the REDCAP project will be granted to: lead investigators, co-site investigators and assigned data entry personnel through a REDCap user account.

Each lead investigator will be responsible for providing a list of names and email addresses of co-site investigators and assigned data entry personnel to a REDCap data coordinator (ksaraneta1@up.edu.ph) through this google form link: https://forms.gle/LEErPjS8sorJVh5G6

Access to REDCAP may be granted when the electronically signed end-user agreement is returned to the data coordinator. When a user is added to a REDCap project, an email containing login instructions will be automatically sent via REDCap to the newly assigned user.

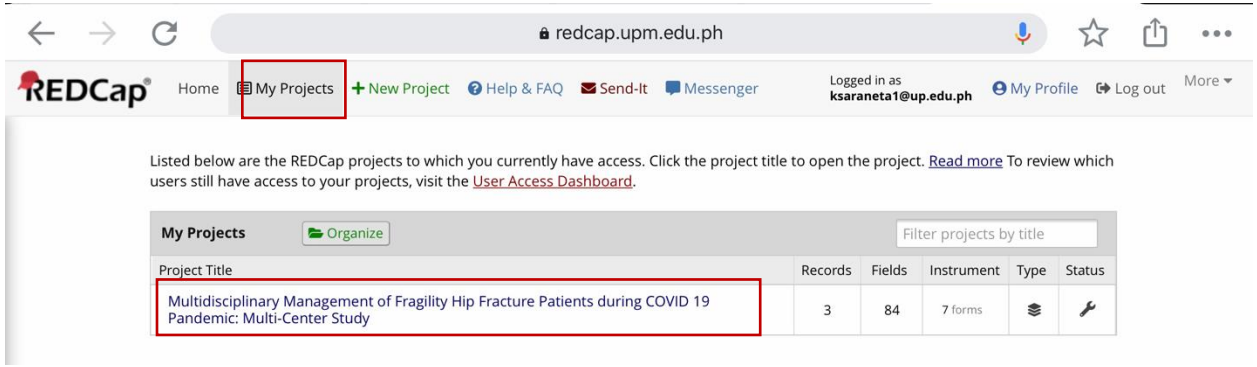
Logging in

Open a browser (Google Chrome recommended) and enter the following URL in the address line: https://redcap.upm.edu.ph

Enter the username and password provided to you when you were given access to REDCAP. After you first log in, you will be prompted to change your password. Do not share your username or password! You are responsible for any data entered under your username.
If you forget your password, select the “Forgot your password?” Hyperlink to the right of the “Log In” button to reset. You will be automatically logged out after 20 minutes of inactivity.
Please logout of REDCAP when you leave the computer.

Accessing the Study Project

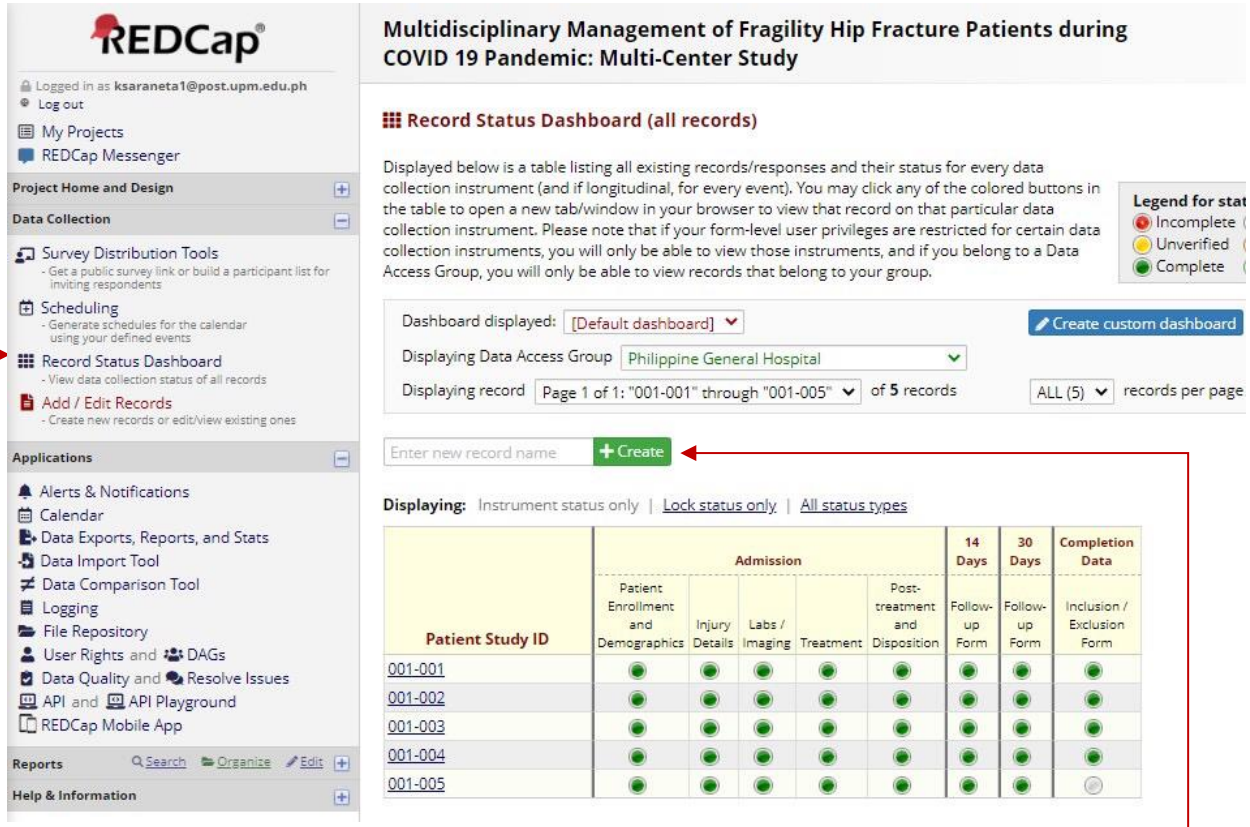
From the REDCap Home Screen select the My Projects tab to see a list of projects you are authorised to access. Click on the link to the REDCap Project for which you will be entering data.



Data Entry: STEP 1

Viewing Records

In the left hand pane, you will see a section called Data Collection. All records on a site's database may be accessed by clicking on the "Record Status Dashboard":



Adding New Records

There are 3 ways you can add a new patient record:

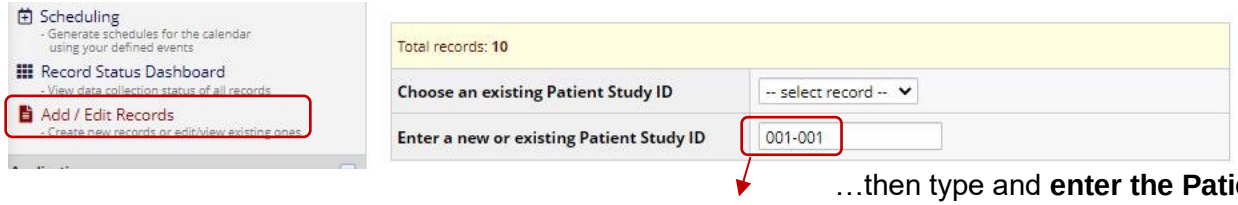
- *From the Record Status Dashboard, type the 6-digit **Patient Study ID** (xxx-xxx) then click the "Create" button:* 

001-001

  *first 3 digits – assigned site ID code

*last 3 digits – patient number

- *OR by clicking "Add/Edit Record" on the left hand pane*



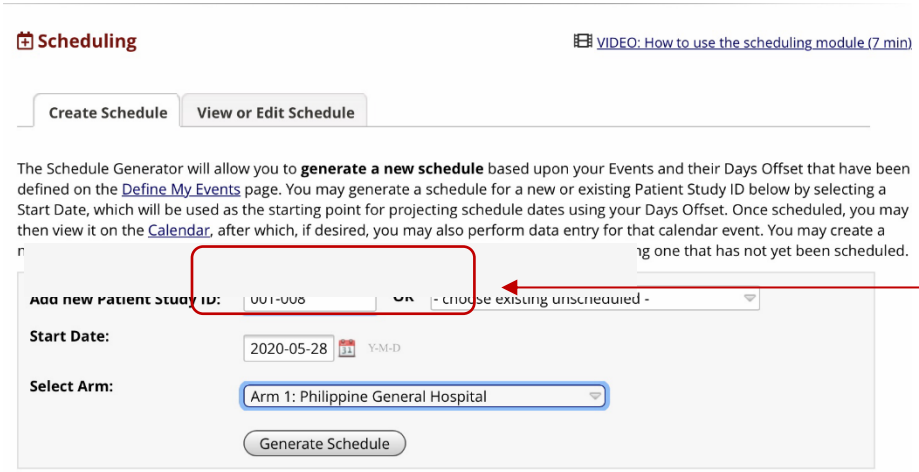
…then type and **enter the Patient Study ID**

If the ID you entered already exists, it will appear on a drop-down list.
This page also provides you with the option of selecting and editing an existing record.

All data entry activity can be tracked to user accounts. In no way does accidentally typing a different site code allow you access to that site's database. The record will merely be mislabelled and an inquiry will be sent by the research team to the site investigators to verify the patient record. Avoid this by checking the Site Code before entering the patient study ID.

- *OR by clicking the "Scheduling" button on left hand pane*

This third option of adding a record allows you to generate a Schedule for filling up patient records over time. Scheduling provides convenient reminders to when you should be following up these patients after their date of admission. Use this option when you already have an official Date of Admission for the patient.

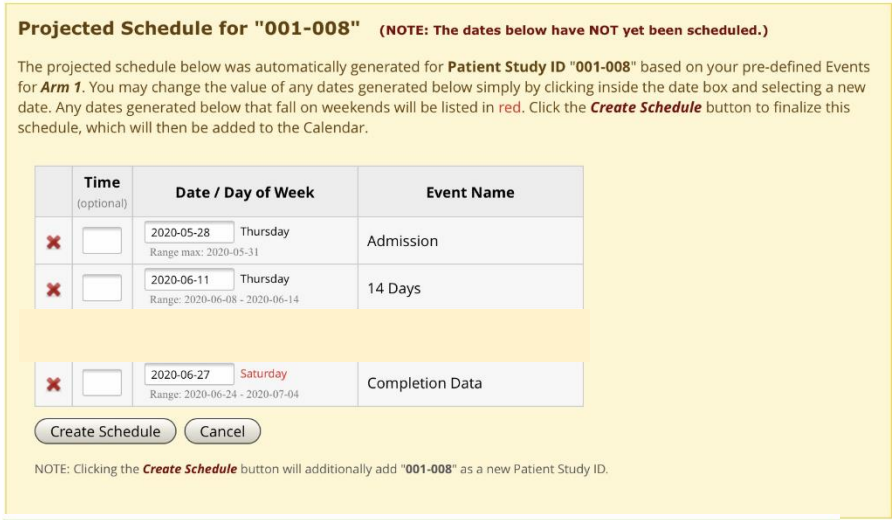


On the Scheduling page you may add a new patient record along with setting a "Start Date" for this patient's record. Ensure that the "Start Date" matches the official date of admission.

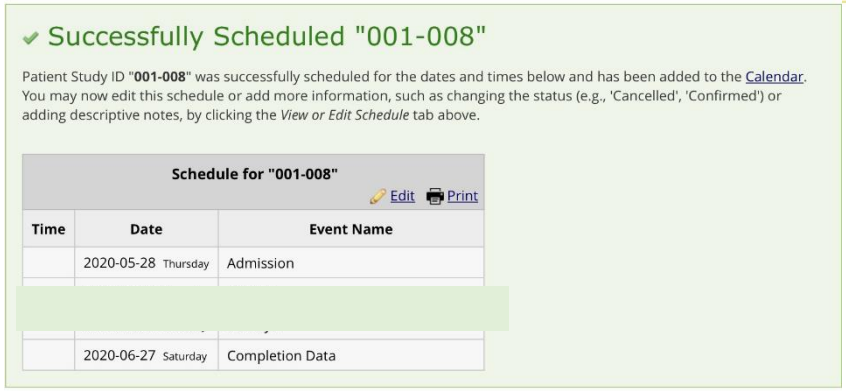
Then click "Generate Schedule".

This should prompt a projected schedule for the patient based on the date of admission, followed by 14 days and 30 days into the study. Intervals between dates are pre-set but **are flexible such that you may fill in forms earlier or later then**

the recommended date. It is important to fill out forms as soon as data is made available to ensure accuracy of the study and prevent recall bias.

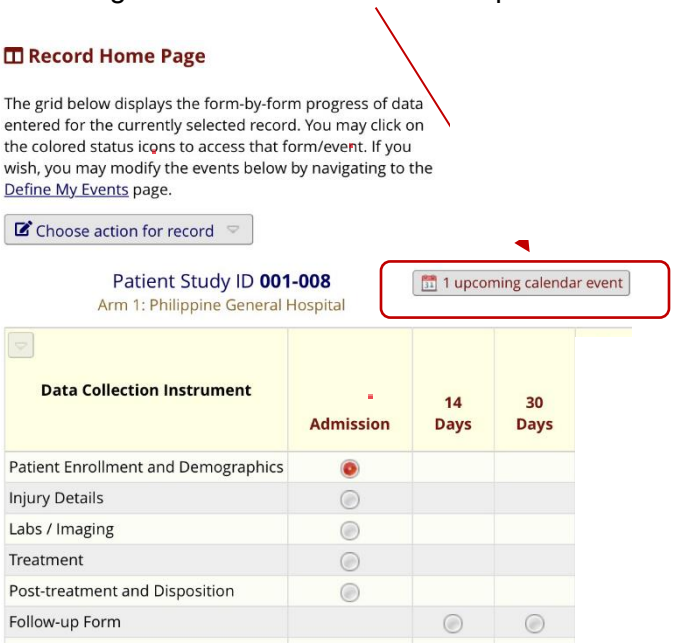


If satisfied with the schedule, click “Create Schedule”.

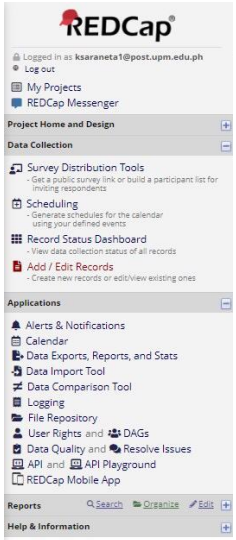


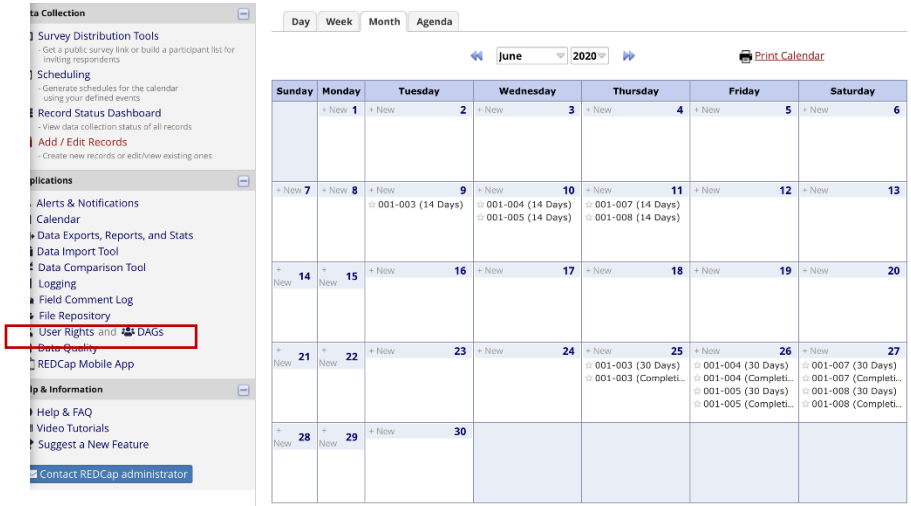
Along with a new patient record, schedule reminders will now appear when you access the patient records.

Scheduling reminders can be seen in a patient's record home page



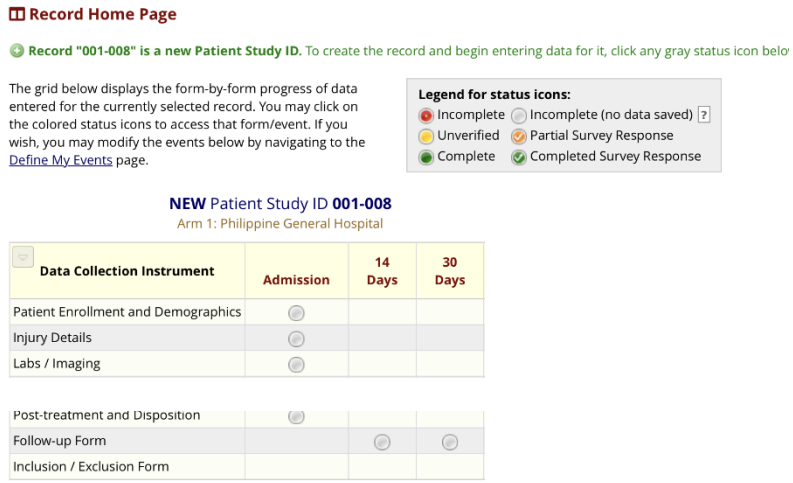
…or in the Calendar which is accessible in the left hand pane under Applications.





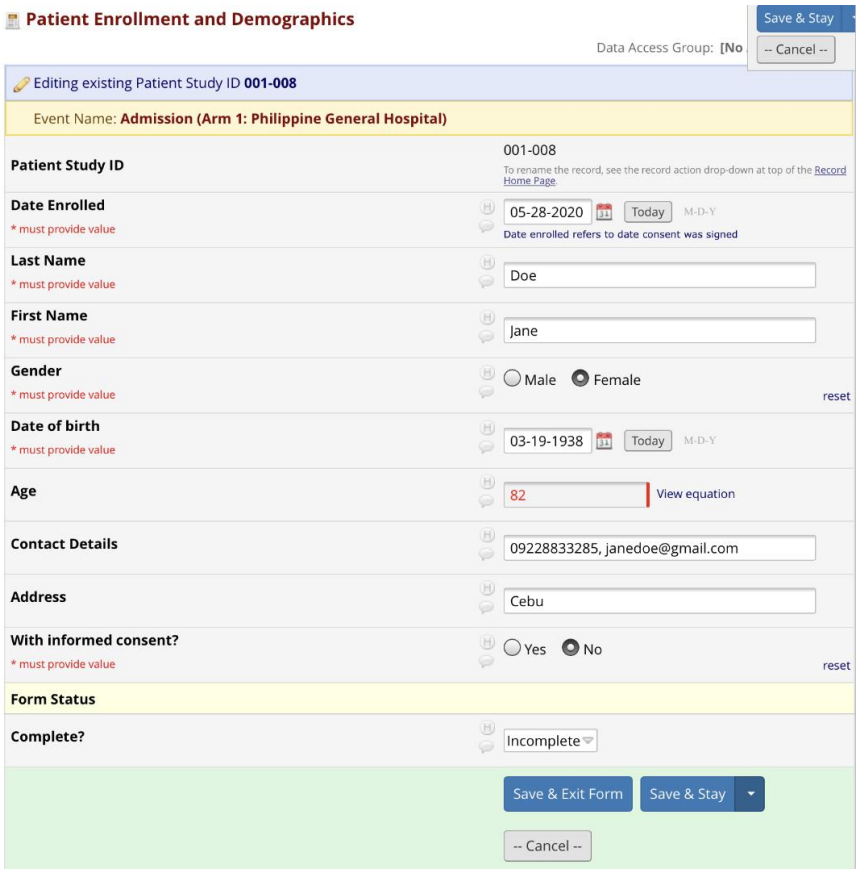
The calendar displays links to patient records scheduled for data entry on a specific date (as generated using the Scheduling feature). This way, data entry personnel know which patients are due for follow-up data entry (14 days and 30 days after admission).

Data Entry: STEP 2



Once you have created a new record, you will be brought to the patient's record home page. Colour-coded status icons on this records section displays the status of each instrument along the study.

To enter data, click on the circular status icon to access the particular instrument (form).



Start completing each question in the instrument.

When you have provided as much information on the instrument, you MUST click one of the save option buttons at the bottom of the screen.

"Save&Exit Form" – saves the data and returns user to the patient's records page

"Save&Go To Next Form" – saves and navigates to the next form on the list for the study ID

"Cancel" - leaves current screen and DOES NOT SAVE the new data or changes you entered. There is no warning message on screen when you leave without saving data

The Form Status section, located at the bottom, will allow you to identify if the form is incomplete, unverified or complete for the purpose of organising the display on the record grid.

*Field Notes: Some fields have a field note, shown in small blue type below the data field. These notes provide field-specific information to help the person entering data.

*Validation: if a field has validation associated with it you may see a warning or error message indicating that the value you entered does not match requirements set up for the field. REDCap will not prevent you from continuing but it will alert you to a value that is outside the pre-defined acceptable range.

Completing all records

As previously mentioned, when data entry has been completed for an instrument (form), use the drop down box in the form status section of the instrument and set the form to “Complete” status. Save using one of the save buttons.

Accessing your data

Site investigators and co-investigators are allowed to export any and all de-identified data from their site’s own database in this project. Data may be exported by creating a report using the “Create New Report” button. Data may be exported as a CSV file from a report, and also in the form of a PDF file from the data entry page when viewing a particular record. The report file(s) is stored on REDCAP and allows only the site investigators and co-investigators to download them.

Data Queries

The research coordinating team on reviewing data entry will sometimes find issues within a certain record. These issues will be made known to both the site investigator and data entry personnel through **queries** in REDCAP.

You can view and access queries made by investigators by clicking on the “Resolve Issues” on the left hand panel under “Applications”. This should take you to the Data Resolution Dashboard.

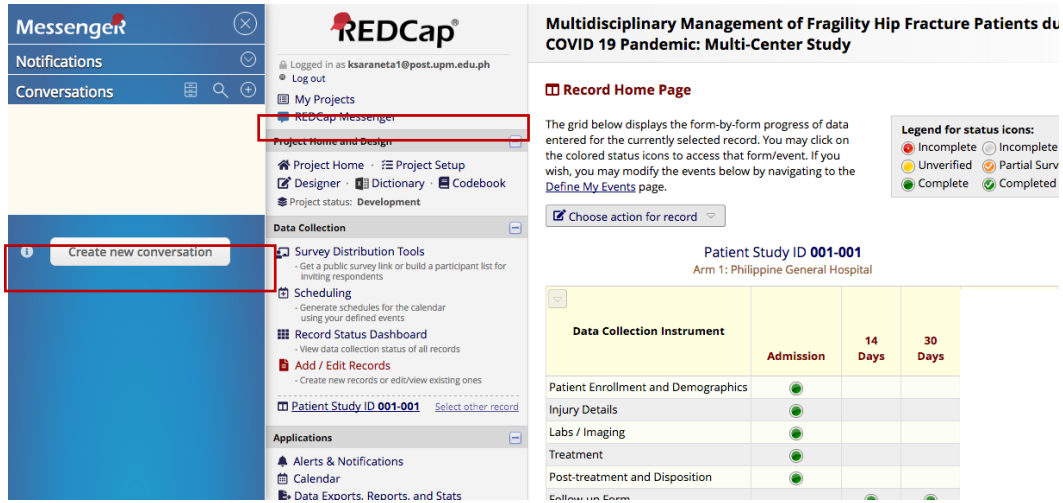
Click on the specific data query and follow instructions on how to resolve each one. Data entry personnel and site investigators can respond to queries but only the research coordinating team can close the query once resolved.

Printing Forms

To download and print a PDF of entered data or the blank form, scroll to the top of the desired form and click on the “Download PDF of instrument(s)” button. Select the “This data entry form with saved data” option, unless you want to print a blank copy of the form. There may be other ways to go about printing the data forms but this is the method that results in a prettier and more complete printout of the data.

REDCap Messenger

This is a communication platform built directly into REDCap, allowing users to communicate easily, efficiently, and securely. REDCap Messenger is a chat application that supports one-on-one direct messages and group conversations, as well as project-linking, document and image sharing. Feel free to use this should you require assistance.



Resources

More about REDCap: https://www.project-redcap.org/

REDCap also offers video training online, available at: http://projectredcap.org/resources/videos/

Appendix. Designated Study Site Codes

Study Site	First 3-digit code in Patient ID
Baguio General Hospital and Medical Center	001-xxx
Bicol Region General Hospital And Geriatric Medical Center	002-xxx
Cagayan Valley Medical Center (CVMC)	003-xxx
East Avenue Medical Center	004-xxx
Jose B. Lingad Memorial Regional Hospital	005-xxx
Jose R. Reyes Memorial Medical Center	006-xxx
Northern Mindanao Medical Center	007-xxx
Philippine General Hospital	008-xxx
Philippine Orthopedic Center	009-xxx
Quirino Memorial Medical Center	010-xxx
Veterans Memorial Medical Center	011-xxx
Vicente Sotto Memorial Medical Center	012-xxx
West Visayas State University Medical Center	013-xxx
Western Visayas Medical Center	014-xxx