Validity and Reliability of the Modified John Hopkins Fall Risk Assessment Tool for Elderly Patients in Home Health Care

by

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Abstract

This prospective cohort study was conducted to evaluate the validity and reliability of the modified Johns Hopkins Fall Risk Assessment Tool (mJH-FRAT) among elderly patients receiving home health care visits. Out of 107 patients, 33 (30.8%) had one or more falls and seven (6.5%) experienced falls with injury. Receiver Operating Characteristics of the tool in predicting falls showed an AUC (Area Under Curve) of 0.66 (p =0.011) with sensitivity and specificity of 72.5% and 52.2% at the cutoff score of 14. For predicting falls with injury, the AUC was 0.82 (p =0.016) with sensitivity and specificity of 100% and 65.9 % at score of 17. Inter-rater reliability of the tool at cutoff score of 17 was 85.7% agreement with Cohen's Kappa of 0.714 (p<0.001). The mJH-FRAT is a simple and easy-to-use multi-factor fall risk assessment tool with promising sensitivity, specificity and inter-rater reliability for prospectively identifying patients at risk of falls with injury among community-dwelling elderly populations.

Keywords: fall risk assessment tool, sensitivity, specificity, home health

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Introduction

Fall-related injuries among the elderly are major public health concern associated with not only pain and suffering for patients but also financial burden for the nation. Each year, about a third of elderly living in the community experience a fall (Chang & Ganz, 2007), 2.3 million are treated in emergency department for fall-related injuries and 662,000 are hospitalized with estimated direct medical cost of $30 billion in United States (Centers for Disease Control and Prevention [CDC], 2010a; CDC, 2010b).

Home health agencies (HHA) provide care to elderly, many of whom are at high risk for falls due to acute and chronic conditions associated with disability (Fortinsky, Baker, Gottschalk, King, Trella & Tinetti, 2008). Availability of an effective fall risk assessment tool designed to identify community dwelling elderly could help implement targeted preventive measures, which may reduce falls and fall-related injuries to maximize independent living, quality of life and potentially reduce healthcare costs.

Background

The National Institute for Health and Clinical Excellence (NICE, 2012) in the United Kingdom recommended a multi-factor fall risk assessment that encompasses a focused history and comprehensive physical, functional and environmental assessments. Several studies have identified factors that may increase the risk of falls and associated injuries. They include previous history of falls, urinary incontinence, impaired vision, gait or cognition, chronic pain, muscle weakness and use of multiple drugs associated with risk of falls, such as opiates, anti-convulsants, anti-hypertensives, diuretics, hypnotics, laxatives, sedatives and psychotropics (Agostini, Han, & Tinetti, 2004; Chang

et al., 2004; Kinn & Hood, 2001; Leveille et al., 2009; Mann, Locher, Justiss, Wu, & Tomita, 2005; Slomski, 2012; Tinetti & Kumar, 2010).

In the United States, the Centers for Medicare and Medicaid Services (CMS) has recently started requiring documentation of fall risk assessment as a measure of HHA quality. In the OASIS-C (Outcome and Assessment Information Set-C) being used by the CMS, item M1910 asks whether each patient under the care of the HHA has had a "multi-factor Fall Risk Assessment" performed; and if so, whether the assessment indicates a risk for falls or not (CMS, 2010; OASIS Central, 2010). The fall risk assessment must include a standardized instrument shown to be effective in identifying patients likely to fall when scientifically tested in a similar population as that being served by the HHA (CMS, 2011).

Although there are several fall risk assessment tools available for patients in acute care or long-term care facility settings (Berg, Wood-Dauphinee & Williams, 1995; Conley,Shultz & Selvin, 1999; Lundin-Olsson, Nyberg & Gustafson, 2000; Morse, Black, Oberle, & Donahue, 1989; Murphy, Olson, Protas & Overby, 2003; Rockwood, Awalt, Carver& Macknight, 2000) there is a dearth of assessment tools that have shown to be effective in discriminating elderly patients at risk for falls in the community setting. One measure of discriminant effectiveness of such a tool is the Area Under Curve (AUC) calculated by the Receiver Operating Characteristic (ROC) analysis: AUC of 0.50 indicates no discrimination; AUC less than 0.70 indicates inadequate discrimination; AUC between 0.70 to 0.80 is acceptable discrimination and AUC > 0.80 indicates excellent discrimination (Hosmer & Lemeshow, 2000). Sensitivity of a tool refers to the

fraction of the patients who had fall events correctly predicted by the tool, whereas the specificity is the fraction without fall events correctly predicted by the tool (Altman & Bland, 1994).

The Fall Risk for Older People in the Community (FROP-Com) tool showed sensitivity and specificity of 71% and 56%, respectively. The ROC analysis revealed the AUC of 0.68, indicating an inadequate discrimination of patients at risk for falls (Russell, Hill, Blackberry, Day, & Dharmage, 2008). In addition, the FROP-Com consists of four pages, covering 13 risk factors and 26 questions, with an average completion time of 12.5 minutes, which makes it difficult to use in practice.

A recent retrospective study examined the validity of the Missouri Alliance for Home Care Fall Risk Assessment (MAHC-10) in the home health population (Calys, Gagnon & Jernigan, 2012). A sensitivity of 96.9% and specificity of 13.3% was reported at the recommended cutoff score of 4. Although no AUC from ROC analysis was reported, the AUC was estimated to be 0.60 based on the published data, indicating inadequate discriminant ability and questionable usefulness of this tool.

The Johns Hopkins Fall Risk Assessment Tool (JH-FRAT) was originally developed for assessing multi-factor fall risks in acute-care hospital settings (Poe, Cvach, Dawson, Straus, & Hill, 2007). A recent validity testing of 356 hospitalized patients showed a sensitivity and specificity of 62.0% and 69.5% respectively at a cut-off score of 14 and AUC of 0.71 from the ROC analysis, indicating acceptable discriminative ability (Kim et al., 2011). Although this tool is easy to use and has promising discriminant properties, this tool has not been studied in community-dwelling elderly populations.

Methods

Aims

The purpose of this study was to evaluate the validity and reliability of the modified Johns Hopkins Fall Risk Assessment Tool (mJH-FRAT) among elderly patients receiving home health services. The specific objectives of the study were to characterize fall events and to estimate the sensitivity, specificity, and inter-rater reliability of the mJH-FRAT in predicting falls as well as falls with injury.

Design

A prospective cohort study design was used to collect data from patients receiving home health services from September to December of 2011 in southern California. In preparation for the data collection, an educational roll-out for home-health clinicians was carried out over a period of approximately one month to familiarize them with the study and data collection tool. The home-health clinicians including registered nurses, registered physical therapists, and speech therapists were qualified to assess the patients for risk factors.

Participants

The inclusion criteria for the sample were ambulatory patients 65 years of age and older admitted to home health services requiring for at least two visits. Bed-bound patients were excluded from the study as they are considered low risk for falls.

Instruments

The current study used the mJH-FRAT, a monthly fall calendar and a data extraction tool. Because the original JH-FART was designed for hospitalized patients,

the tool was modified with an author's permission to allow its use in the community-dwelling population. This tool was incorporated as part of the fall prevention program at a San Diego hospital-based home health agency for several years prior to the current study. The mJH-FRAT includes seven areas of evaluation: patient age, prior fall history, elimination, medications, use of patient care equipment, mobility, and cognition. Total scores ranging from zero to 35 were used to categorize patients into three risk groups: low risk (0 – 6), moderate risk (7-13) and high risk (14-35) (Poe et al, 2007).

The monthly fall calendar was used to collect fall incidence and bodily pain. In the current study, fall was defined as "an unexpected event in which the participant comes to rest on the ground, floor or lower level" (Russell et al., 2008, 635.) Instructions were given to patients to place either an "F or "N" on each calendar day for falls or no falls, respectively. During visits with home health clinicians, the completed calendar was reviewed with the patient, and if a fall was recorded on the calendar, the clinician assessed the patient for injury and documented the location of the fall, injury and any other fall-related information. Bodily pain experienced by the patient during the month was also collected on the calendar by asking a single-item question from Medical Outcome Study 36-Item Short Form Health Survey (SF-36) (Stewart, Hays, & Ware, 1988). The response options ranged from none (0) to very severe (5).

A data extraction tool in the form of an Excel spreadsheet was used to collect the following information from the patient's electronic health record: age, gender, ethnicity, living situation, history of falls in the past 6 months, primary medical diagnosis, use of various medications and duration of home health service.

Data collection procedures

This study was reviewed and approved by the Institutional Review Boards at the San Diego hospital-based home health agency and the university. At the initial home visit, patients were invited to participate in the study and if they agreed to participate, the informed consent was obtained.

Patients were signed up to the study from September to December 2011 and were followed until discharged from services. As part of the initial assessment, a qualified clinician completed the mJH-FRAT and entered it in the patient's electronic medical record. To assess inter-rater reliability, one of the study investigators conducted joint visits or made a home visit within 24 hours to independently complete the mJH-FRAT. After patients were discharged from services and the calendars collected, the investigators extracted the study data from the patient's electronic health record and transferred it into an Excel spreadsheet. The spreadsheet was later converted to the SPSS software program for analysis.

Data Analysis

SPSS software version 18.0 (SPSS Inc, Chicago, IL, USA) was used for data analysis. Descriptive statistics was utilized to examine the sample characteristics and fall events. Independent t-test and chi-square test were employed to compare the continuous and dichotomous sample characteristics between fall and non-fall groups. Cohen's Kappa statistics and percent agreements between two clinicians were calculated to assess the inter-rater reliability of the each category score of mJH-FRA. Cohen's Kappa statistics evaluates the 2-rater agreements beyond those expected by chance alone, ranging from 0

to 1.0 where 1.0 indicates perfect inter-rater agreement (Landis & Koch, 1977). The ROC analysis was performed to determine the optimal cutoff scores with acceptable sensitivity and specificity of the mJH-FRA. The Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were also calculated. For the purpose of this study, the significance level was set at $p < 0.05$.

Results

Sample characteristics

A total of 107 out of 125 consented patients completed the fall calendars (86% completion rate). Of the 18 patients excluded from analysis, five did not have the fall calendars collected, one refused to complete the calendar, and twelve did not meet the age requirements. Thirty-three patients had at least one fall event (30.8%) and seven patients had falls with injury (6.5%). The fall group was older (mean age 82.7 vs. 78.6; p=0.015), had longer average duration of home health service (30.5 vs. 21.7 days; p=0.016), and had more cardio-pulmonary medical diagnosis (36.4% vs. 17.6%; p=0.047) compared to the non-fall group. None of the other patient characteristics showed statistically significant difference between the two groups. Likewise, the age of the falls-with-injury group was numerically older, had longer average duration of home health service and had more cardio-pulmonary medical diagnosis compared to the non-fall group. In addition, all of them had a history of falls in the past 6 months (Table 1).

Table 1 Comparison of falls and non-fall groups (*N*=107)

	Falls (*n*=33)	Falls with Injury (*n*=7)	Non-Fall (*n*=74)
Age, mean ±SD (range), yr	82.7±7.9 (67-97)	83.1±10.2 (68-97)	78.6±7.4 (65-102)
Gender, Male	20 (60.6)	4 (57.1)	50 (67.6)
Ethnicity, white	26 (78.8)	7 (100.0)	64 (86.5)
Living alone	11 (33.3)	3 (42.9)	14 (18.9)
History of falls in past 6 months	21 (63.6)	7 (100.0)	32 (43.2)
Primary medical diagnosis			
Cardiac-pulmonary	12 (36.4)	5 (71.4)	13 (17.6)
Orthopedic	12 (36.4)	1 (14.3)	32 (43.2)
Neurological	4 (12.1)	0 (0.0)	8 (10.8)
Use of daily analgesics	24 (72.7)	6 (85.7)	54 (73.0)
Use of anti-hypertensives	29 (87.9)	7 (100.0)	58 (78.4)
Use of hypoglycemics	9 (27.3)	1 (14.3)	9 (12.2)
Use of anti-coagulants	17 (51.5)	4 (57.1)	47 (63.5)
Use of psychotropics	12 (36.4)	3 (42.9)	34 (45.9)
Feeling depressed > 1 day in past 2 weeks	7 (21.2)	2 (28.6)	6 (0.08)
≥moderate bodily pain in past month	16 (48.5)	3 (42.9)	29 (39.2)
Duration of home health service, days			
Mean±SD	30.5±18.5	39.1±17.6	21.7±12.7
(range)	(6-80)	(19-59)	(2-67)

Note. Values are expressed as n (%) unless otherwise indicated.
Percentage may not add up to 100% because of the missing data or rounding.

Fall event characteristics

Thirty-three patients (30.8%) experienced at least one fall, fourteen (13.1%) fell at least twice, and nine (8.4%) had three or more falls while enrolled in home health service. Seven patients (6.5%) had falls with injury, two of whom (1.9%) had two or more falls with injuries. Types of injuries included four closed head injuries, two contusions/abrasions and two lacerations. Five of the falls with injury occurred in the bathroom, one in the bedroom, and one in unknown location.

Modified Johns Hopkins Fall Risk Assessment Tool (mJH-FRAT)

The fall group has a higher mean mJH-FRAT score than the non-fall group (16.3 vs 13.6; p=0.013) with 63.6% in the high fall risk category (Table 2). Likewise, the falls-with-injury group had the highest mean mJH-FRAT score (20.0) with 100% in the high fall risk category.

The ROC analysis of mJH-FRAT in predicting falls resulted in AUC of 0.66 (95% Confidence Interval [CI], 0.55 to 0.78; p =0.011) (Figure 1A).

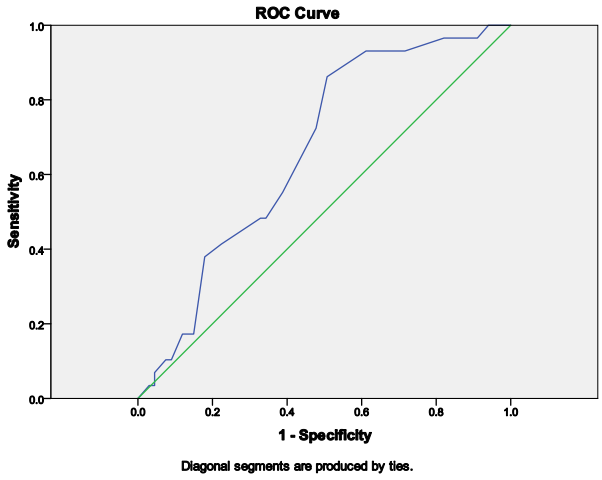

Figure 1A

Table 2 Modified Johns Hopkins Hospital Fall Risk Assessment Tool category results (*N*=107)

	Falls (*n*=33)	Falls with injury (n=7)	Non-fall (*n*=74)
Age category			
60-69	2 (6.1)	1 (14.3)	10 (13.5)
70-79	9 (27.3)	1 (14.3)	31 (41.9)
>80	18 (54.5)	5 (71.4)	26 (35.1)
Fall history	18 (54.5)	5 (71.4)	25 (33.8)
Elimination problems	18 (54.5)	5 (71.4)	37 (50.0)
High risk medications	28 (84.8)	5 (71.4)	62 (83.8)
Use of patient care equipment	2 (6.1)	1 (14.3)	15 (20.3)
Limited mobility	29 (87.9)	5 (71.4)	58 (78.4)
Altered cognition	9 (27.3)	1 (14.3)	16 (21.6)
Fall risk category			
Low risk	0 (0)	0 (0)	2 (2.7)
Moderate risk	8 (24.2)	0 (0)	33 (44.6)
High risk	21 (63.6)	7 (100.0)	32 (43.2)
mJHFRAT score			
Mean±SD	16.3±4.4	20.0±3.74	13.6±5.3
(range)	(7-26)	(17-26)	(4-26)

Note. Values are expressed as n (%) unless otherwise indicated.
Percentage may not add up to 100% because of the missing data or rounding.

The sensitivity and specificity at the recommended cutoff score of 14 were 72.5% and 52.2%, while PPV and NPV were 39.6% and 81.4%, respectively (Table 3).

Table 3 Modified Johns Hopkins Fall Risk Assessment Tool for fall (*n*= 96)

Cutoffs	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
6	100.0	0.03		
12	93.1	38.8	39.7	92.9
13	86.2	49.3	42.4	89.2
14	72.4	52.2	39.6	81.4

Note. PPV, Positive Predictive Value; NPV, Negative Predictive Value;

The second ROC analysis in predicting falls with injury showed the AUC of 0.82 (95% CI, 0.70 to 0.94; *p* =0.016) (Figure 1B).

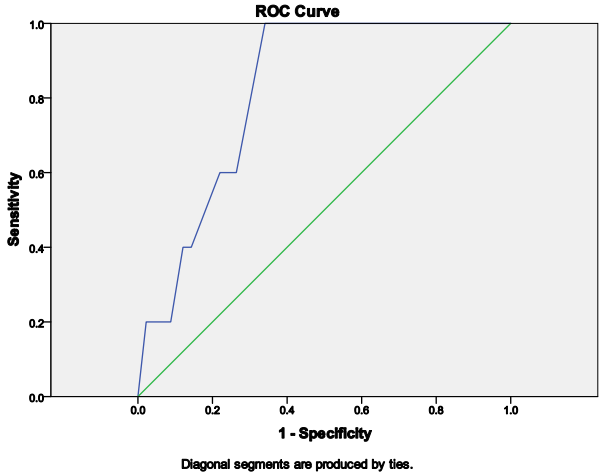

Figure 1B

The sensitivity and specificity at the cutoff score of 14 were 100% and 47.3%, while the PPV and NPV were 9.4% and 100%, respectively (Table 4).

Table 4 Modified Johns Hopkins Fall Risk Assessment Tool for falls with injury (*n*= 96)

Cutoffs	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
14	100.0	47.3	9.4	100.0
17	100.0	65.9	13.9	100.0

Note. PPV, Positive Predictive Value; NPV, Negative Predictive Value

However, the sensitivity and specificity at the cutoff score of 17 were 100% and 65.9%, respectively while the PPV and NPV were 13.9% and 100%, respectively.

The inter-rater reliability of mJH-FRAT expressed as the agreement percentage between two clinicians with cutoff score of 14 and 17 were 97.4% and 85.7 %, respectively; Cohen's Kappa values were 0.948 (p<0.001) and 0.714, respectively (Table 5).

Discussion

The findings from the current prospective cohort study indicate that the mJH-FRAT may be a useful tool in identifying patients at risk for falls with injury while receiving home health services. The AUC in predicting falls with injury was 0.82, which potentially indicates excellent discrimination ability in predicting falls with injury. At an

optimal cutoff score of 17, the sensitivity and specificity were 100% and 65.9%, respectively. The inter-rater reliability as assessed by inter-rater agreement percentage and Cohen's Kappa indicates good inter-rater agreement at cutoff score of 17. As far as the authors are aware, the current study is the first study to examine the receiver operating characteristics of a tool for predicting falls with injury among patients receiving home health care service.

Table 5 Inter-rater reliability of Modified Johns Hopkins Fall Risk Assessment Tool (*n*=39)

	Kappa	*p* value	% agree
Age	0.951	< 0.001	97.4%
Fall history	0.897	< 0.001	94.9%
Elimination problems	0.918	< 0.001	94.9%
High risk medications	0.414	< 0.001	79.5%
Use of patient care equipment	0.328	0.022	84.6%
Limited mobility	0.770	< 0.001	84.6%
Altered cognition	0.784	< 0.001	87.2%
mJH-FRAT score ≥14	**0.948**	**< 0.001**	**97.4%**
mJH-FRAT score ≥17	**0.714**	**< 0.001**	**85.7%**

Note. Cohen's Kappa; CI, Confidence Interval;

For the broader category of falls, the mJH-FRAT may be of limited value in discriminating patients at risk in this population with AUC of only 0.66. However, identifying the subset of patients at risk for falls with injury may help to focus the efforts of home health agencies to prevent avoidable hospitalizations as recommended by Home Health Quality Improvement (HHQI) National Campaign (West Virginia Medical Institute, 2012).

In the current study, the rate of falls in patients receiving home health care services was 30.8%, which is much higher than 1.5% or 19.9% reported for hospitalized patients (Dykes et al., 2010; Kim et al., 2011). This difference may be partly explained by the older population in the current study, as well as the longer length of care. Similarly, the 6.8% rate of falls with injury in the current study was much higher than the 0.25% reported by Dykes et al. (2010), but was slightly lower than the 7.3% rate reported by Kim et al. (2011).

There are several study limitations to the current study. First, the findings of the current study should be taken with caution because of the small sample size. Second, the longer duration of home health service for the groups with falls or falls with injury compared to the non-fall group may have had confounding effect on the fall events, although the longer service duration may simply indicate higher acuity levels. Finally, all participants in the current study were community-dwelling patients receiving home health services, which may limit generalizability to other populations. Further studies are needed to confirm the study findings.

Conclusion

The mJH-FRAT is a simple, easy-to-use multi-factor fall risk assessment tool with promising sensitivity, specificity and inter-rater reliability that may be useful for prospectively identifying patients at risk of falls with injury among elderly patients receiving home health care services. Following additional studies that confirm the usefulness of this tool for prospectively identifying individuals at risk of falls with injury, mJH-FRAT could allow focused interventions targeting high risk patients and perhaps reduce fall-related injuries among community-dwelling elderly.

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Appendix A

Modified Johns Hopkins Fall Risk Assessment Tool

Scripps Home Health Care

Fall Prevention and Management

TUG = ____

***FUNCTIONAL REACH =** ____

(*Functional Reach 0-5 = Fall Risk)

Fall Risk Factor Category

Scoring not completed for the following reason(s) (check any that apply).

Enter risk category (i.e. Low/High) based on box selected.

- ☐ Complete paralysis, or completely immobilized. Implement basic safety (low fall risk) interventions.
- ☐ Patient has a history of more than one fall within 6 months before admission. Implement high fall risk interventions throughout episode of care.
- ☐ Patient is deemed high fall-risk per protocol (e.g. seizure precautions). Implement high fall-risk interventions per protocol.

COMPLETE THE FOLLOWING AND CALCULATE FALL RISK SCORE. IF NO BOX IS CHECKED, SCORE FOR CATEGORY IS 0.	POINTS
AGE (SINGLE-SELECT, CHOOSE ONE)	
☐ 60 - 69 years **(1 point)**	0
☐ 70 - 79 years **(2 points)**	0
☐ 80 years and above **(3 points)**	0
FALL HISTORY (SINGLE-SELECT, CHOOSE ONE)	
☐ One fall within 6 months before admission **(5 points)**	0
ELIMINATION, BOWEL AND URINE (SINGLE-SELECT, CHOOSE ONE)	
☐ Incontinence **(2 points)**	0
☐ Urgency or frequency **(2 points)**	0
☐ Urgency/frequency and incontinence **(4 points)**	0
MEDICATIONS: INCLUDES PCA/OPIATES, ANTI-CONVULSANTS, ANTI-HYPERTENSIVES, DIURETICS, HYPNOTICS, LAXATIVES, SEDATIVES, AND PSYCHOTROPICS (SINGLE-SELECT, CHOOSE ONE)	
☐ On 1 high fall risk drug **(3 points)**	0
☐ On 2 or more high fall risk drugs **(5 points)**	0
☐ Sedated procedure within past 24 hours **(7 points)**	0
PATIENT CARE EQUIPMENT: ANY EQUIPMENT THAT TETHERS PATIENT, e.g., IV INFUSION, CHEST TUBE, INDWELLING CATHETERS, SCDS, ETC) (SINGLE-SELECT, CHOOSE ONE)	
☐ One present **(1 point)**	0
☐ Two present **(2 points)**	0
☐ 3 or more present **(3 points)**	0
MOBILITY (MULTI-SELECT, CHOOSE ALL THAT APPLY AND ADD POINTS TOGETHER)	
☐ Requires assistance or supervision for mobility, transfer, or ambulation **(2 points)**	0
☐ Unsteady gait **(2 points)**	
☐ Visual or auditory impairment affecting mobility **(2 points)**	
COGNITION (MULTI-SELECT, CHOOSE ALL THAT APPLY AND ADD POINTS TOGETHER)	
☐ Altered awareness of immediate physical environment **(1 point)**	0
☐ Impulsive **(2 points)**	
☐ Lack of understanding of one's physical and cognitive limitations **(4 points)**	
***Total Points**	**0**

***Low Risk = 0-5, Moderate risk = 6-13 Total Points, High risk > 13 Total Points**

version 1010

Appendix B

Monthly Fall Calendar

MRN_____

Instructions:

1. Write an "***F"*** on the days you have a fall and an "***N"*** on days there is no fall. Show the calendar to the home health clinician at each visit.

Monthly Fall-Calendar						
Sunday	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**

2. **In the past month, how much bodily pain have you had? Please circle your response.**

none very mild mild moderate severe very severe

Appendix C

Data Extraction Tool

Study Participant #:

Scripps MR #: SOC Date: DC Date:

Physical Characteristics/Demographics:

Age: Sex:

Living Status:

Medical History:

Hx of Falls/last 12 mo: none 1 >2

Primary Diagnosis:

Co-morbidities: (OP, cardiac, MD, Depression/Anxiety, blindness, etc)

Medication Use:

Total # of medications:

Types & # of meds: daily analgesics:

Anti-hypertensives: Hypoglycemics:

Anticoagulants: Psychotropics:

Physical Activity/Assessment:

TUG: FR: Tinetti: JH-FRAT:

Type of AD: Cane Walker Crutches

Pain level:

Orthostatic hypotension at SOC: Positive Negative

PHQ-2

Actual Falls:

Total # of Falls:

Fall #1 date: Where: Injury:

Fall #2 date: Where: Injury:

Appendix D

Approval to use Johns Hopkins Fall Risk Assessment Tool from original author

Dear Sandra,

We are pleased that you are interested in using the Johns Hopkins Fall Risk Assessment Tool. As we are in the process of completing extensive reliability and predictive validity testing, we are allowing individual hospitals and hospital systems to use the tool without fee with the stipulation that they display our copyright as below. Should you want to use the tool, you would need to do the following:

1. Your previous email to Stephanie Poe will serve as a request to use the tool.
2. Complete and submit the attached survey so we may gather any necessary information for our records and so that we can notify you of any updates.
3. We require that you display our copyright on the tool as follows:

Copyright (C) 2007 by The Johns Hopkins Health System Corporation.
All rights reserved
Also,
All information contained in this document is provided "as is" with no representations or warranties whatsoever. No part of this work may be modified, redistributed or reproduced in any form or by any means, electronic or mechanical, including photocopying, recording, or by any information storage and retrieval system without the prior written permission of Johns Hopkins.

In the event you would like to use the tool in an electronic format, we also require you to submit screen shots of how the tool will appear in this format.

Attached I have included copies of the tool along with any supporting documentation. Also, you will find the survey that needs to be completed.

Feel free to contact me if you have any questions.

Regards,

Christine Welch
Project Coordinator for Patricia Dawson
Assistant Director of Nursing, Clinical Quality & Magnet
The Johns Hopkins Hospital
600 North Wolfe St.
Billings Administration 220
Baltimore, MD 21287
(443) 287-0604 phone
(410) 614-1115 fax

Dear Ms Poe,

I am a graduate nursing student at Point Loma Nazarene University in San Diego working towards an MSN - CNS degree with a concentration in Gerontology. My thesis project is on the Usefulness of a Fall Risk Assessment tool for Home Health patients.

I currently work at Scripps Home Health where we have implemented the John Hopkins Fall Risk Assessment tool into our Fall Prevention program since 2006. Back then, Betty Lyons, our now retired nurse educator, obtained permission from your institution to adapt and use the tool in our setting. Alex Saluta corresponded with you in July 2010 and sent you our modified version of the tool which you approved.

The purpose of my study is to evaluate the usefulness of the John Hopkins Fall Risk Assessment for

predicting falls among patients 65 years and older receiving home health services in the community. The specific aims of the study are (a) to assess the incidence of falls; (b) to examine the fall risk factors; (c) to determine the optimal cutoff scores of the tool using ROC analysis; and (d) to estimate the inter-rater reliability, sensitivity and specificity of the John Hopkins Fall Risk Assessment tool.

To start my project I need to have direct permission from you to use the tool in the study. Please let me know of your decision at your earliest convenience.

I have obtained both of the articles you have published in 2005 and 2007. If you approve of the project, please let me know if any other studies or publications have been done that may be useful to me.

Respectfully,

Sandra Hnizdo RN, BSN
3900 Lomaland Drive
San Diego, CA 92106
work e-mail: hnizdo.sandra@scrippshealth.org

Appendix E

Script to invite participants

Hello, (patient name) we are collecting data on falls to evaluate our fall prevention program at Scripps Home Health. Our aim is to make sure that the treatment and instructions we provide in regard to falls are the best for you. We would like to invite you to participate in our research study by filling out the calendar provided. No personal or identifying information will be included in the study results. If you have a fall please inform your nurse or therapist as soon as possible. Rest assured, the visiting clinician will ask you at each visit if you have had a fall. They will also review the calendar with you during your home health visit. Your participation is voluntary. If at any time you do not want to participate, please inform your nurse or therapist. However, your eligibility for services will not be affected. If you have any questions or concerns about this study or the data being collected, please call Sandra Hnizdo, RN at 858-715-7324 or Raquel Archuleta, RN at 858-715-7300 x2710. You may also call the Scripps Institutional Review Board at (858) 652-5500.

Appendix F

Script to debrief participants at the end of the study

Hello (patient name) we would like to thank you for your participation in this study on falls. The study results will assist Scripps in providing the best possible care, treatment, and instructions to all our patients. If you have any questions or concerns about this study please call Sandra Hnizdo, RN at 858-715-7324 or Raquel Archuleta, RN at 858-715-7300 x2710. You may also call the Scripps Institutional Review Board at (858) 652-5500.

Appendix G

Informed Consent/Research Project Information Sheet

IRB NUMBER: IRB-11-5752
IRB APPROVAL DATE: 7/01/2011
IRB EXPIRATION DATE: 6/30/2012

CONSENT TO PARTICIPATE IN RESEARCH

Usefulness of the Modified Johns Hopkins Fall Risk Assessment Tool for Home Health Care

Principal Investigator: Sandra Hnizdo, RN

Sub-Investigators: Raquel Archuleta, RN; Son Chae Kim, RN, Ph.D.; Barbara Taylor, RN, Ph.D.

Study Coordinator (or Contact Person): **Sandra Hnizdo (858) 715-7324**

Research Site(s): Scripps Home Health Care

Before you start reading about this research, please read the California Experimental Subjects' Bill of
Rights, which is page 4 of this form.

Why is this research being done?

This research is being done to find out how useful the modified Johns Hopkins Fall Risk Assessment questionnaire is for predicting falls among people 65 years and older who are receiving home health services. You have been asked to participate because you are or will be receiving home health services.

How long is the study?

If you agree to join, you will be in the study for the duration of your home health care.

What will happen to me?

If you agree to participate in this study, you will be asked to complete a monthly fall calendar and return the completed calendar to your clinician.

Could I experience any side effects or discomforts?

Completing the questionnaires does not involve any risks. Your individual responses to the monthly fall calendar will be coded to keep your identity private. Any risks to your privacy are discussed under "What about Confidentiality?"

Will I benefit from this research?

No, but the researchers hope that information from this study may help improve fall risk assessment tools in the future.

Will I get paid?

No, you will not be paid.

Will it cost anything to be in the study?

No, completing the monthly fall calendars will not cost you anything.

IRB NUMBER: IRB-11-5752
IRB APPROVAL DATE: 7/01/2011
IRB EXPIRATION DATE: 6/30/2012
June 16, 2011 Page 2 of 6

What if I end the study early?

Your participation is voluntary. You can change your mind and quit at any time.

What other treatments could I take?

This study does not involve treatment. You can decide not to do it.

What are my rights?

- You can call the staff to ask any questions about this study. The telephone number is listed at the top of this form.
- You can decide not to be in this study or you can quit after starting. Whatever you do, your medical care at Scripps will not be affected.
- If you have any questions about your rights, call the Scripps Office for the Protection of Research Subjects at (858) 652-5500. You should also read the *Experimental Subject's Bill of Rights,* which is towards the end of this form.
- You do not have to be in this study. You still have all your legal rights whether you join the study or not.
- You will be told any new information that might make you change your mind about staying in the study.

What are my responsibilities if I join?

If you are in this study, you are expected to:

- Follow the instructions of the research staff
- Complete the monthly fall calendars

What about confidentiality?

The research staff will keep your personal information confidential whenever they can. They cannot promise that no one will see it.

Your individual responses to the monthly fall calendar will be coded to keep your identity private. The information from this study will be kept in a secure and locked area. Your individual responses will be added up with the responses of other participants and reported in a summary form. No personal information will be reported. For more information, see the **Authorization to use your Private Health Information** at the end of this consent form.

What if I have questions about the study?

If you have any questions about this study you may contact Sandra Hnizdo at 858-715-7324, Raquel Archuleta at 619-316-2536, Dr. Son Chae Kim at 619-849-7146, or Barbara Taylor at 619-849-2766.

IRB NUMBER: IRB-11-5752
IRB APPROVAL DATE: 7/01/2011
IRB EXPIRATION DATE: 6/30/2012
June 16, 2011 Page 3 of 6

I agree to participate.

I have read the explanation of the study and understand it. The study has also been explained to me by _____. I have had a chance to ask questions and have them answered to my satisfaction.

I agree to take part in this study. I have not been forced or made to feel obligated to take part.

I have read the attached ***Experimental Subject's Bill of Rights*** *and the* ***Authorization to use my Private Health Information****, which contain important information about research studies. I must sign this consent form, the* ***Experimental Subject's Bill of Rights*** *and the* ***Authorization to use your Private Health Information****. I will be given a signed copy of each to keep.*

_____
Printed Name of Subject

_____
Signature of Subject *Date*

_____ _____
Signature of person conducting the informed consent discussion Date

_____
Role of person named above in the research project

Appendix H

Experimental Subjects Bill of Rights

IRB NUMBER: IRB-11-5752
IRB APPROVAL DATE: 7/01/2011
IRB EXPIRATION DATE: 6/30/2012
June 16, 2011 Page 4 of 6

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS*

If I am asked to consent to be a subject in a research study involving a medical experiment, or if I am asked to consent for someone else, I have the right to: Learn the nature and purpose of the experiment (also called "study" or "clinical trial"). Receive an explanation of the procedures to be followed in the study, and any drug or device to be used. Receive a description of any discomforts and risks that I could experience from the study. Receive an explanation of any benefits I might expect from the study. Learn about the risks and benefits of any other available procedures, drugs or devices that might be helpful to me. Learn what medical treatment will be made available to me if I should be injured as a result of the study. Ask any questions about the study or the procedures involved. Quit the study at any time, and my decision will not be used as an excuse to withhold necessary medical treatment. Receive a copy of the signed and dated consent form. Decide to consent or not to consent to a study without feeling forced or obligated. If I have questions about a research study, I can call the contact person listed on the consent form. If I have concerns about the research staff, or need more information about my rights as a subject, I can contact the Scripps Office for the Protection of Research Subjects, which protects volunteers in research studies. I may telephone the Office at (858) 587-4444, 8:00 a.m. to 4:00 p.m. weekdays, or I may write to the Scripps Office for the Protection of Research Subjects c/o Scripps Clinic, Mail Stop GEN3, 10666 North Torrey Pines Road, La Jolla, CA, 92037.

By signing this document, I agree that I have read and received a copy of this Bill of Rights.

_____ _____

Signature of Subject or Legal Representative Date

**California Health & Safety Code, Section 24172*

Appendix I

Patient Authorization to use and/or Disclose Protected Health Information for Research

IRB NUMBER: IRB-11-5752
IRB APPROVAL DATE: 7/01/2011
IRB EXPIRATION DATE: 6/30/2012
June 16, 2011 Page 5-6 of 6

Authorization to use your Private Health Information
Name of Study: Usefulness of the Modified Johns Hopkins Fall Risk Assessment Tool for Home Health Care
Principal Investigator: Sandra Hnizdo, RN IRB Study Number: 11-5752

What is private health information? Private health information is any information that can be traced back to you. We need your authorization (permission) to use your private health information in this research study. The private health information that we will use and share for this study includes:

- Demographics such as your age, gender, ethnic background, and weather you live alone or with someone
- Medical history such as your medical conditions, previous history of falls, medications you currently take, type of assistive device you use for walking
- Information on some of the tests done as part of your routine care and information from the study calendars, and
- Information needed to contact you

Who else will see my information?

In addition to the Principal Investigator, this information may be shared with:

- Any member of the study team;
- Government agencies, such as the US Food and Drug Administration and agencies like it in other countries, or agencies of the Department of Health and Human Services, and
- Scripps committees that review research to help protect people who join research studies. Once we have shared your information we cannot be sure that it will stay private. If ***you*** share your information with people outside the research team, it will no longer be private. Your **name** will not be used in any report that is written.

How long will Scripps use and share my information?

- Your information will be used and shared until the research is completed, which we think will be in 2012.

What if I change my mind about sharing my research information?

If you decide not to share your information anymore:

- The sponsor and the research team can continue to use any of the private information that they already have.

Appendix J

IRB Approval – Scripps Health

As of January 27, 2009, all Scripps IRBs were combined into a single, system-wide IRB known as "Scripps IRB", which is registered with OHRP as IRB00004335

Office for the Protection of Research Subjects

Approval Notice

Investigator: Sandra Hnizdo, RN
Department: Scripps Home Health
Approved
Research Sites: Scripps Home Health
Project Title: Usefulness of the Modified Johns Hopkins Fall Risk Assessment Tool for Home Health Care
Protocol No: IRB-11-5752
Risk Category: Minimal
Type of Review: Expedited – NEW
Your research project indicated above was reviewed and approved by an IRB officer on the review date stamped below. Approval expires ***12 months*** from this date.
Approval carries with it the understanding that you will inform the Committee promptly should a serious adverse reaction occur, and that you will make no modification to the protocol or consent form (if applicable) without prior IRB approval.
The IRB may suspend or terminate the approval of research that is not conducted in accordance with the requirements set forth by the committee or that has been associated with unexpected serious harm to subjects.
Thank you for your cooperation.
(Modified Johns Hopkins Fall Risk Assessment tool and Informed Consent dated 6-16-11)
Signature applied by Barbara G Bigby on 07/01/2011 10:12:39 AM PDT
IRB Officer

Scripps IRB
11025 North Torrey Pines Road
Suite 200
La Jolla, CA 92037

Appendix K

IRB Approval - Point Loma Nazarene University

PLNU IRB
Expedited Review
907
Thursday, September 1st, 2011
PI: Sandra Hnizdo
Additional Investigators: Raquel Archuleta
Faculty Advisor: Barb Taylor, Ph.D. and Son Kim, Ph.D.
Title: Usefulness of the modified Johns Hopkins Fall Risk Assessment Tool for Home Health Care.

The research proposal was reviewed and verified as an expedited review under category 5 and has been approved in accordance with PLNU's IRB and federal requirements pertaining to human subjects protections within the Federal Law 45 CFR 46.101 b. Your project will be subject to approval for one year from the September 1st, 2011 date of approval. After completion of your study or by September 1st, 2012, you must submit a summary of your project or a request for continuation to the IRB. If any changes to your study are planned or you require additional time to complete your project, please notify the IRB chair.

For questions related to this correspondence, please contact the IRB Chair, Ross A. Oakes Mueller, Ph.D., at the contact information below. To access the IRB to request a review for a modification or renewal of your protocol, or to access relevant policies and guidelines related to the involvement of human subjects in research, please visit the PLNU IRB web site.

Best wishes on your study,

Ross A. Oakes Mueller, Ph.D.

Associate Professor

Department of Psychology

IRB Chair

Point Loma Nazarene University
3900 Lomaland Dr.
San Diego, CA 92106
619.849.2905
RossOakesMueller@pointloma.edu