Interpreting Studies of Fall Risk Tools

VALIDITY: The diagnostic validity is the extent to which a tool measures what it is designed to measure. With regard to fall risk tools, validity is the extent to which the tool correctly identifies patients at high risk for future falls. A number of statistical measures are commonly used to assess the diagnostic validity of predictive tools, including sensitivity and specificity. Because it is not possible, to create a tool that is 100% valid in the real world, diagnostic validity is measured by degrees. For most measures of tool validity, values close to 100% (or to 1, depending on the variable) reflect the optimal state of validity, but it is not realistic in the real world.

SENSITIVITY: A predictive fall risk assessment should be sensitive enough to identify high-risk persons/patients and specific enough to not over target persons who are not at an increased fall risk (specificity). The clinical goal is to use valid fall risk factors to help the clinician target evidence-based interventions for modifiable risk factors to minimize injurious falls and to promote healthy aging and independence. Zero falls is not a practical goal for many. However, eliminating injurious falls should be a goal, whenever possible, but there is often a trade-off between independence and risk taking. The person, if able, should help determine "what matters most to them" and this should be documented in the record.

- An effective tool should be:
- simple to use as part of a more comprehensive physical assessment and screening based on risk factors,
- easy to use by retrieving information already collected in the electronic health record continuously, and
- efficient to minimize burden on care provider time.

The fall risk assessment should also help direct interventions aimed at reducing the underlying cause of the identified modifiable risk factors. For example, confusion is not a diagnosis, and yet etiologies of confusion are among the most underdiagnosed factors in many acute

care facilities. Ideally, the presence of a risk factor like confusion should trigger an immediate evaluation of the patient; for patients with confusion, this evaluation should differentiate delirium from dementia, sepsis, or medication side effects.

> *"Reframing fall risk factors as a window into healthier aging and functionality, while reducing injurious falls, is the real opportunity of using a validated tool in today's care continuum"*
>
> **Ann Hendrich**
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Study Designs and Validity of Predictive Fall Risk Tools

When evaluating any research study, the study's design must be considered (e.g., prospective vs. retrospective, case-control vs. uncontrolled, observational vs. interventional, etc.), patient population (e.g., general acute care vs. specific populations), sample size (e.g., large vs. small, number of fall events), duration (long vs. short), and methods of data retrieval and analysis (e.g., chart review vs. prospective data collection). Larger and more diverse samples, particularly of the study event (i.e., falls), will increase the reliability and validity of the study findings and, possibly, foster broader applicability to real world populations.

The Institutional Review Board (IRB) approved study, that launched the course of the Hendrich Fall Risk Model (Hendrich I), enrolled more than 1100 non-fall patients and 254 fall events over 2 years. Each of the informed study participants had extensive physical exams completed by trained registered nurses, with standardized instruments, for mood, elimination, gait and balance, and medication categories etc. This study design produced a diverse patient population from a Level I Trauma Center, that included the continuum of care with skilled nursing, long-term care and rehabilitation populations. The study size and diversity of the population increased the generalizability and strength of the risk factor findings.

In prospective studies like the Hendrich Fall Risk Model® (HIIFRM) investigators determine before the study begins what variables will be assessed, which subjects will be enrolled, how standardized assessment tools will be administered, and the length and sample size of the study. This type of design (methodology) fosters consistency of tool application and data reliability. Other aspects of study design that can affect measures

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of diagnostic validity include the presence of fall prevention programs at the study sites. Effective fall reduction programs will often underestimate risk factors contribution since fall prevention efforts are often in place. This can reduce the actual specificity and sensitivity. However, it would not be ethical to withhold fall prevention efforts so studies can use more advanced statistical analysis to account for this impact.

Predictive studies must also enroll 3-4 times the number of non-fall study participants as falls to avoid 'false' assumptions about predictive risk factors. This is how age and history of falls are often included in fall risk models because non-fall patients are not compared and actual physical assessments are not used. The is why the Hendrich studies have not utilized a history of falls. A past fall will suggest additional falls, but it is not an independent risk factor. It is always associated with the "true" cause of the fall in the first place. The study demographics can also falsely affect the study results unless statistical tests are used by the researcher to controls for the population diversity (male/female, ethnicity, age, etc). Diversity strengthens the study and will also bring forward new evidence that may not have been tested in previous studies like socioeconomic factors, ethnicity etc.

Studies of the HIIFRM: High Validity Across Populations

The HIIFRM has been evaluated in multiple studies from the United States, Italy, Portugal, Singapore, China, Korea, and other countries (Table 1).[1-15] Study methodologies vary, but include case-control and prospective and retrospective designs. Validity metrics reported in these studies are relatively consistent: sensitivity in the range of 64.9% to 93.2% and specificity 51.3% to 89.3%, with positive predictive values (PPV) from 0.95% to 7.5% and negative predictive values (NPV) from 96% to 99.7%. These values reflect the percentage of fallers (PPV) and non-fallers (NPV) correctly identified by the tool.

It should be noted that lower sensitivities and specificities have been reported in some studies. For example, an Italian study reported a sensitivity of 45.8%, and two groups reported low specificities (43% and 35%), likely a result of the elderly patient populations enrolled in these studies.[3-5] Two emergency department (ED) studies reported sensitivities of only 23.8% to 37.5%. In one of these studies, the HIIFRM was not administered during the study, but rather, assessed only through review of risk factors in patient charts, which would not allow for an accurate functional test.[12] In the second study, only fall-related

visits to the ED were counted as falls, and falls that occurred in the home that did not lead to an ED visit were not counted.[15]

How to Use the Hendrich Tool

The Hendrich II Fall Risk Model® should be administered on admission, following changes in patient status, and after a fall event. However, many studies require assessment only on admission, with no re-evaluations during hospital stay, even following surgery or other changes in patient status. Person-centered care focuses on the "right care for the right person" and this is true of risk factors. Reassessment can detect changes in condition that may increase or decrease fall risk and avoid non value-added time for the provider. This validated tool allows for changes in risk factor presence so care plans can be adjusted as needed.

In 2020, the Hendrich research team published a large, electronic health record (EHR) validation study of the HIIFRM accuracy for prediction. The sample of 214,358 adult inpatients (625 falls) were admitted consecutively over a 3-year period to nine varied acute care hospitals. The study sites had patient populations that were diverse in race, gender, age, ethnicity, case-mix, and length of stay. The nine hospitals were of various sizes, in both urban and rural locations, and academic and nonacademic settings. The results confirmed the sensitivity and accuracy of the model to predict falls in practice and in the EHR (Download the full article here: http://hendrichfallriskmodel.com/wp-content/uploads/2021/01/Validation-of-the-HIIFRM-2020.pdf).

2020 Study Conclusion: Analysis of this very large, inpatient sample confirmed the strong psychometric characteristics of the HIIFRM.

- The study also identified many inpatients with multiple fall risk factors (n = 77,292), which are typically not actively managed during hospitalization, leaving patients at risk in the hospital and after discharge. This finding represents an opportunity to reduce injurious falls through the active management of modifiable risk factors to prevent injurious falls and promote healthy aging.

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Summary

The HIIFRM compares very favorably to other tools in terms of sensitivity, specificity, and positive and negative predictive value in multiple clinical studies and diverse patient populations. Moreover, the HIIFRM is the only tool to incorporate independent risk factors identified through systematic evaluation and regression analysis of more than 600 variables reported in peer-reviewed literature. These qualities make the HIIFRM a truly predictive tool and allow for the targeting of interventions to specific categories of injurious fall risk with a larger opportunity to build a care continuum approach that can reduce modifiable risk factors whenever possible to preserve health and function. Removing the underlying cause of risk can alter a person's risk state, if the provider views risk factors as part of a holistic approach to care and management.

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Table 1. Diagnostic validation studies of the Hendrich II Fall Risk Model (HIIFRM)

Study	N	Setting	Study design	Sensitivity, %	Specificity, %	PPV/NPV, %	AUC	Notes
General Acute Care Inpatients								
Hendrich et al, 1995[1]*	102 falls 236 control	General acute care	Case-control	77	72	NR	NR	Cross validation with a 1987 data set showed a sensitivity of 83% and specificity of 66%
Hendrich et al, 2003[2]	355 falls 780 controls	General acute care	Case-control	74.9	73.9	NR	NR	HIIFRM validation study
Kim et al, 2007[3]	5489 total	Acute care	Descriptive, prospective	70	61.5	2/99.5	0.73	Comparative study at single hospital in Singapore
Lovallo et al, 2010[4]	1148 total 59 falls	Acute care, patients > 50 years	Prospective, observational	45.8	71.0	6/96	NR	Comparative study at medical, surgical, and rehabilitation units at an Italian hospital
Chapman et al, 2011[5]	1540 total	Acute care	Descriptive, cross-sectional	64.9	69	7.5/98.1	NR	Comparative study of four fall-risk assessment tools in 17 units
Nassar et al, 2014[6]	1815 total	Acute care	Prospective	55.2	89.3	16.5/98.3	NR	Comparative study in Lebanese acute care hospital
Kim et al, 2013[7]	1026 total 32 falls	Acute care (neurological patients)	Prospective, descriptive	59.4	78.5	8.2/98.4	0.74	Comparative study of neurology, neurosurgery, and rehabilitation patients at a Korean hospital
Yip et al, 2016[8]	10381 total 64 falls	10 general adult wards, patients > 21 years	Prospective observational	75	51.31	.95/99.7	0.67	Comparative study at single hospital in Singapore
Jung and Park, 2018[9]	15,170 controls 310 falls	Acute care	Retrospective case-control	67.4-80.0	59.5-64.0	4/99	0.70-0.74	Evaluated on neurology, neurosurgery, hematology, and oncology units (255 beds) in tertiary care hospital in Korea

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Study	N	Setting	Study design	Sensitivity, %	Specificity, %	PPV/NPV, %	AUC	Notes
Cho et al, 2018[10]	14,307 total 238 falls	Acute care	Retrospective	NR	NR	NR	0.69	Modeling study conducted at tertiary care hospital in Korea
Cho et al, 2020[11]	447 falls 1,341 controls	Acute care	Retrospective, case-control	57.27	78	46.5/84.6	74.2	Comparative study at tertiary care hospital in Korea
Hendrich et al, 2020[12]	625 falls 213,733 non-falls	Acute care and critical access	Retrospective	78.72	64.07	0.64/99.9	0.765	Nine hospitals with patient populations representative of US diversity of race, gender, age, ethnicity, case-mix, length of stay, licensed bed size, academic and nonacademic settings, and urban and rural locations. All levels and acuity of inpatient care, including behavioral health, skilled nursing, observation, and ED
Geriatric Inpatients (> 60 years of age)								
Ivziku et al, 2011[13]	179 total 14 falls	Geriatric acute care, patients > 65 years	Descriptive, prospective	86	43	11/97	0.72	Italian validation study
Caldevilla et al, 2013[14]	586 total 104 falls	Acute care, patients > 65 years	Prospective	93.2	35	17.2/97.3	0.65	Portuguese validation study
Zhang et al, 2015[15]	989 total 32 falls	Acute care, patients > 60 years with chronic diseases	Prospective cross-sectional	72.0	69.0	7/98	0.82	Chinese validation study

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Other Clinical Settings

Terrell et al, 2009[16]	57 falls	Emergency Department	Retrospective chart review	37.5	NR	NR	NR	HIIFRM was not administered during study; risk factors estimated via chart review
Van Dyke et al, 2014[17]	50 total 2 falls	12-bed rural psychiatric unit	Prospective	100	67.8	1.9/100	NR	Pilot study comparing two tools in adult psychiatric unit
Campanini et al, 2018[18]	147 total 11 falls	Inpatient Rehabilitation	Prospective	100	49	NR	0.78	Italian rehabilitation department with patients from orthopedic, pulmonary, and neurology services; HIIFRM administered only on admission to unit
Baran and Gunes, 2018[19]	159 total 51 falls	Nursing home, patients >65 years	Prospective, observational	80.4	43.5	40.2/82.5	0.62	Comparative study conducted a nursing home in Turkey
Patterson et al, 2018[20]	4366 total 363 falls with ED visit	Emergency Department, patients > 65 years	Retrospective chart review	23.8	90.0	NR	0.64	Outcome was fall-related visit to ED within 6 months of index ED visit, population limited to discharged patients > 65 years of age with PCP in network

*Previous version of HIIFRM, which did not include Get-Up-and-Go test.
AUC: area under the receiver operating characteristic curve; PPV/NPV: positive predictive value/negative predictive value; NR: not reported; ED: emergency department; PCP: primary care physician

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