

Patient Acuity Related to Clinical Research: Concept Clarification and Literature Review

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Caitlin W. Brennan¹, Michael Krumlauf¹ ,
Kathryn Feigenbaum¹, Kyungsook Gartrell^{1,2},
and Georgie Cusack³ 

Abstract

In research settings, clinical and research requirements contribute to nursing workload, staffing decisions, and resource allocation. The aim of this article is to define patient acuity in the context of clinical research, or research intensity, and report available instruments to measure it. The design was based on Centre for Reviews and Dissemination recommendations, including defining search terms, developing inclusion and exclusion criteria, followed by abstract review by three members of the team, thorough reading of each article by two team members, and data extraction procedures, including a quality appraisal of each article. Few instruments were available to measure research intensity. Findings provide foundational work for conceptual clarity and tool development, both of which are necessary before workforce allocation based on research intensity can occur.

Keywords

patient acuity, research intensity, nursing workload, clinical research, literature review

¹National Institutes of Health Clinical Center, Nursing Department, Bethesda, MD, USA

²National Library of Medicine, Bethesda, MD, USA

³National Heart, Lung, and Blood Institute, Bethesda, MD, USA

Corresponding Author:

Michael Krumlauf, National Institutes of Health Clinical Center, Nursing Department, 9000 Rockville Pike, Bldg 10, Room 2B09A2, Bethesda, MD 20892-1504, USA.

Email: michael.krumlauf@nih.gov

Extensive research has been conducted over the last several decades in the area of patient acuity measurement, with particular emphasis on the severity of illness of patients and their related nursing intensity (Brennan, Daly, & Jones, 2013). In settings where clinical research is performed, nursing care needs of patients are derived not only from clinical needs (clinical intensity), but also from research requirements (research intensity), which contribute to nursing workload and have implications for staffing decisions, resource allocation, and patient outcomes. Accurately measuring research participants' clinical and research intensity is an important feature of ensuring patient safety and that high-quality clinical and research care are provided. This review of the literature aims to report on the availability of instruments to measure patient acuity and/or research intensity related to nursing care needs of patients enrolled in clinical trials.

Nurse Staffing and Patient Acuity

Historically, nurse staffing decisions have been determined by census, hours per patient day, and/or nurse to patient ratios, which provide key information for executives to determine the number of employees to hire, yet, in general, are insufficient for nurse assignment decisions because they do not take into consideration variation in specific patients' nursing care needs on a day-to-day, shift-to-shift basis. In an environment in which patients are enrolled in research protocols or clinical trials, there is a need to base hiring decisions as well as nurse assignment decisions not only on the clinical needs of patients, but also on their care needs driven by the research protocol.

Nurse staffing researchers have recommended that staffing decisions be made in part based on patient demand for care (Needleman et al., 2011). Patient acuity is one way of measuring patient demand (Brennan & Daly, 2009). Use of acuity data for nurse assignment decisions theoretically allows charge nurses to allocate the supply of nurses in an efficient manner each shift. The process of matching the supply of nurses with patient demand for care theoretically balances nursing workload and maximizes patient safety and quality of care.

Many types of tools to measure acuity have been proposed over the past several decades, their use varies widely, and reliability and validity assessments are infrequently conducted or reported (Brennan et al., 2012). A subset of acuity tools have been successfully validated for use in clinical settings. For example, the Acute Physiology, Age, Chronic Health Evaluation (APACHE) is a widely used severity of illness tool utilizing physiologic parameters that has been validated for predicting mortality, but not for measuring nursing care needs or determining nursing workload in intensive care

units (Knaus et al., 1991). Similarly, the Therapeutic Intervention Scoring System has also been validated for measuring severity of illness in ICUs, but not for measuring nursing workload (Yee Kwok, Chun Chau, Pau Le Low, & Thompson, 2005). Finally, a few patient acuity tools exist that are linked to electronic health record data (Business Wire, 2003; Business Wire, 2004; Harris Healthcare, 2017). However, due to the proprietary nature of these tools, data on development and validation are unpublished.

There is some agreement among these articles that nursing workload involves more than the patient's care needs. Suggested additional content are number of interruptions such as admissions and discharges, nursing skill mix, and physical layout or geography of the unit (Ball & McElligot, 2003; Carayon & Gurses, 2005; Upenieks, Kotlerman, Akhavan, Esser, & Ngo, 2007). Fasoli and Haddock (2010) suggested that any approach to predicting staffing should seek to minimize additional nursing workload, be based on expert nursing judgment, be a true reflection of nursing workload, and include indicators that measure patient complexity, required nursing care, available resources, and relevant organizational attributes.

In our setting, both research and clinical care are provided to patients. Integrity of the science demands attention to detail and that research activities be completed as written in the protocol. A proprietary patient classification instrument is in use in which weighted critical indicators objectively categorize acuity levels of patients. This system measures patient acuity and it remains unclear the extent to which it measures the nursing care needs that are driven by research protocols. For instance, the need for two nurses to complete blood sampling and patient monitoring as part of a protocol, to maintain safety and ensure valid collection of samples as specified, is not captured in the proprietary system. The system also does not capture multiple psychological rating scales performed on a single patient as written in protocols. Not having a method of measuring the nursing care needs of patients participating in clinical research impacts the ability of managers to make accurate staffing and budget projections and resource allocation decisions. It also affects the nurses caring for the patients in that aspects of their workload are not measured, which affects workflow and efficiency, which in turn have the potential to affect quality of care, patient safety, and integrity of research outcomes. These challenges will become increasingly widespread as more research is conducted in academic medical centers.

Purpose

The aim of the review was to identify patient acuity instruments that measure research intensity available in the literature.

Method

The design of the review was based on recommendations from the Centre for Reviews and Dissemination (2009). The process included defining the search terms, developing inclusion and exclusion criteria, followed by abstract review by three members of the team, thorough reading of each article by two team members, and finally, data extraction procedures to generate a table of evidence, including a quality appraisal of each article.

An initial literature search was conducted in October, 2014, in PubMed, CINAHL, and PsycNET with search terms patient acuity, research intensity, and workload. Limiters were years 2008 to 2015 and English language. To ensure no articles were missed related to measurement of acuity and research intensity of research participants, in April, 2016, the literature search was updated without date limiters in PubMed and CINAHL using the following search terms: clinical trials, clinical research nurse (CRN), workload, nurse patient ratio, patient acuity, research intensity, manpower, workflow, and task performance with a filter of “nursing journal.”

The search yielded 210 records in PubMed, 45 records in PsycNET, and 153 records in CINAHL (Figure 1). The titles of the records were reviewed and those that did not relate to nursing or were duplicates were eliminated. This produced a list of 96 articles. Three team members then independently reviewed the abstracts from these articles to determine by consensus if the full article should be reviewed. Articles were included if the abstract or title mentioned tool development or reliability and validity, or background information or outcomes related to acuity measurement. Exclusion criteria were acuity or intensity topics not related to nursing care needs of patients or research participants, such as workload related to professions other than nursing, workload pertaining to specific nonnursing research roles (e.g., study coordinator) or tasks (e.g., budget development). This process resulted in 51 articles selected for full review. At least two members of the team read and conducted a quality appraisal of each article, using criteria adapted from the Centre for Reviews and Dissemination’s recommendations and Brennan et al. (2012). Specifically, level of evidence was evaluated as part of the quality appraisal, as follows: Level 1: systematic review; Level 2: randomized controlled trial; Level 3: nonrandomized studies; Level 4: case control/cohort studies; Level 5: systematic qualitative review; Level 6: single qualitative study; Level 7: expert opinion, integrative reviews. Quality appraisal also included strengths and limitations (quality of evidence), including whether a conceptual framework was used, a summary of the tool measurement methods, the acuity attribute being measured (severity of illness or intensity; Brennan & Daly, 2009), and quality of psychometric testing. Data were

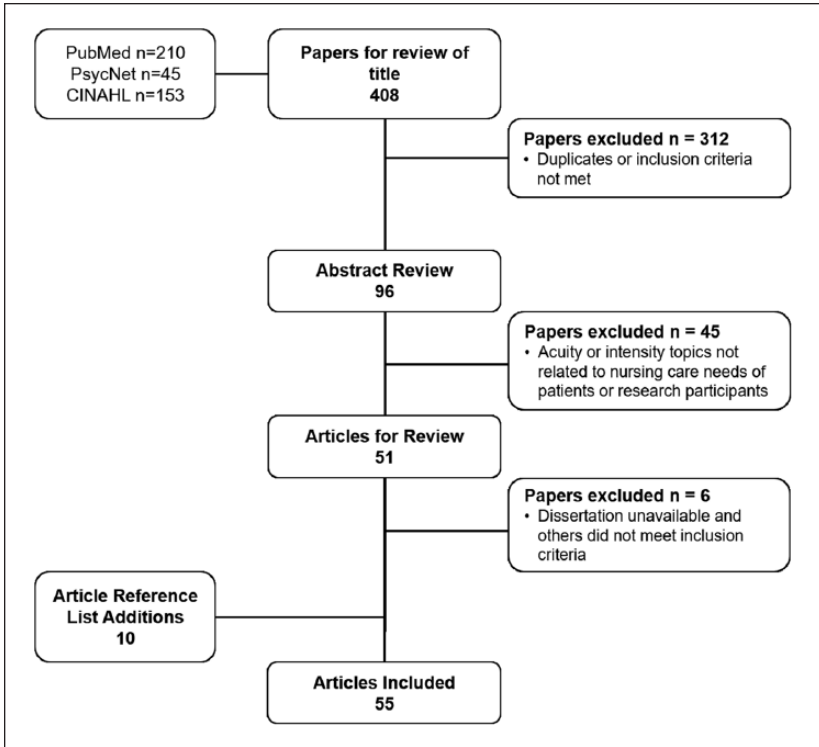


Figure 1. Literature search flow chart.

extracted from each article and summarized into a table of evidence (TOE; Table 1 and Online Resource 1). The first author reviewed all articles and collaborated with the other authors to ensure consistent data extraction and synthesis.

Results

After reading each article, one was excluded because it was a dissertation that was not obtainable and five were excluded because they did not meet inclusion criteria. Topics of the five excluded articles were research intensity pertaining to schools of nursing, automation of the clinical trial eligibility process, nursing workload specific to a particular clinical task (tight glycemic control) or research topic (effects of the Health Insurance Portability and Accountability Act on trial budget), and a research staff salary survey. Ten

Table 1. Table of Evidence: Research Intensity.

Citation	Level/Type of Evidence ^a and Tool Name (If Applicable)	Strengths and Limitations (Quality of the Evidence)	Summary and/or Tool Measurement Methods	Acuity Attribute: ^b Subcategory ^c	Reliability and Validity Testing ^d
Berridge, Coffey, Lyddiard, & Briggs, 2010	Instrument development WMI	<ul style="list-style-type: none"> Strengths: Prospective study to validate four modules related to clinical trial activities Limitations: Some concepts not clearly defined, conceptual framework not described, methods not clearly delineated 	<ul style="list-style-type: none"> Focus was on tasks for research staff working on trials, non-profession-specific, including planning, implementation, data management, and closure 	<ul style="list-style-type: none"> Intensity: Workload, frequency and time required to complete tasks related to research 	A
Briggs, 2008	Instrument development complexity scoring tool	<ul style="list-style-type: none"> Strengths: Described need for a measure to capture workload and complexity; provided recommendations for future research on tool development, including conducting semistructured interviews of participants, incorporating expert advice and flexibility within the tool to adapt for changes in trial requirements, developing training, linking with existing information technology, setting-up audit processes Limitations: Concepts and methods not clearly defined, conceptual framework not described 	<ul style="list-style-type: none"> Presented draft criteria for each section (set up, recruitment, follow-up) and proposed defining them on a 5-point complexity scale 	<ul style="list-style-type: none"> Unclear 	C
Cassidy & Macfarlane, 1991	Level 7 Expert opinion commentary	<ul style="list-style-type: none"> Strengths: Comprehensive description of role of nurse in clinical trials Weaknesses: Not research study or instrument development study, did not assess role of the nurse across multiple research settings 	<ul style="list-style-type: none"> Overview of role of nurse in clinical trial processes such as eligibility, providing information and assurance to patients and encouraging patients to verbalize concern; administering treatments; toxicity assessments and monitoring; coordination; teaching, documenting, reporting; motivating protocol patients to return for therapy and tests at specified times 	<ul style="list-style-type: none"> Intensity: Nursing care needs 	N/A

(continued)

Table 1. (continued)

Citation	Level/Type of Evidence ^a and Tool Name (If Applicable)	Strengths and Limitations (Quality of the Evidence)	Summary and/or Tool Measurement Methods	Acuity Attribute ^b : Subcategory ^c	Reliability and Validity Testing ^d
Cusack, Jones-Wells, & Chisholm, 2004a, 2004b; Jones, Cusack, & Chisholm, 2004 ^e	Q1 Ambulatory Nursing Intensity System	<p>Strengths: Descriptors developed for research participant clinical care and categories for serial tests; pharmacokinetics, coordination of care; concepts clearly defined; used conceptual framework</p> <p>Limitations: Generalization to other institutions may be limited; manual data entry, not linked to budgetary software, methods not specific; did not include reliability measurements</p>	<ul style="list-style-type: none"> • Prototype system with nursing activities organized into five categories of complexity based on time required to complete care 	Severity: Physical, psychosocial Intensity: Nursing care needs, complexity, workload	C
Ellis et al., 2012	Level 3 Descriptive study	<p>Strengths: Several centers included, assessed time required for research duties</p> <p>Limitations: Varying amounts of time spent on activities at each center; varying levels of support at each center for recruiting patients, no standardization of clinical and nonclinical activities; no validity or reliability assessments conducted, no conceptual framework described</p>	<ul style="list-style-type: none"> • Impact of recruiting patients to randomized controlled trials at several large centers • Quantified clinical and nonclinical time for recruitment activities (19 min clinical time, 110 min of administrative or nonclinical activities) 	Intensity: Workload, frequency and time required to complete tasks related to recruitment activities	A

(continued)

Table 1. (continued)

Citation	Level/Type of Evidence ^a and Tool Name (If Applicable)	Strengths and Limitations (Quality of the Evidence)	Summary and/or Tool Measurement Methods	Acuity Attribute ^b : Subcategory ^c	Reliability and Validity Testing ^d
Good, Lubeljko, Humphries, & Medders, 2013	Instrument development WCCOP Acuity-Based Workload Assessment Tool	<ul style="list-style-type: none"> Strengths: Introduced key components useful for monitoring workload for staffing decisions Limitations: No validity or reliability assessments conducted, data collected manually on paper rather than electronically, acuity levels and protocol determinants not clearly defined, no conceptual framework described, patient, nurse, and protocol levels of analysis are all taken into consideration but not clearly defined or measured 	<ul style="list-style-type: none"> Workload at the clinical trial level, grouped as treatment- or cancer control-focused Classified patients as "on" study (active or follow-up) or "off" study Workload range: Observational, oral agents, chemo/radiation, complex multiple drugs regimens Six workload-related determinants: complexity of treatment, trial-specific laboratory and testing requirements, treatment toxicity potential, complexity and number of data forms required, number of trial random assignments or steps, degree of coordination required 	Intensity: Complexity of clinical trials	A
Gwede, Johnson, & Trotti, 2000a; 2000b ^e	Level 3 Cross-sectional survey with mailed questionnaire Modified version of the Cancer Clinical Investigations Review Committee (CCIRC) algorithm developed in 1992	<ul style="list-style-type: none"> Strengths: Quantitative assessment of workload based on survey of CRCs nationally. Authors clearly articulated conceptual and measurement challenges and gaps in research focused on workload intensity measurement Limitations: Modified CCIRC algorithm used does not relate to traditional work measures (such as hours worked per week), complexity and acuity of trials are not factored into the algorithm, lack of verification of data 	<ul style="list-style-type: none"> Survey to CRCs (40% response rate) with content on employment characteristics, duties and responsibilities, perceived support, salary, estimated workload (subject accrual and follow-up), certification, and Internet access/skills Most respondents exceeded target 40 credits per year that CCIRC determined is equal to one full-time equivalent (1.0 FTE) 	Intensity: Workload of CRCs	A

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Table 1. (continued)

Citation	Level/Type of Evidence ^a and Tool Name (If Applicable)	Strengths and Limitations (Quality of the Evidence)	Summary and/or Tool Measurement Methods	Acuity Attribute ^b : Subcategory ^c	Reliability and Validity Testing ^d
Hancock, Wiland, Brown, Kermer-Siemons, & Brown, 1995	Instrument Development Complexity Rating Tool	<p>Strengths: Goal was establishing protocol-scoring system based on complexity</p> <p>Limitations: Methods for IRR and content validity were unclear. IRR was measured as correlation between subjective assessment of complexity and actual complexity scores, rather than across raters. IRR was moderate among raters of similar skill level and from the same institution, low for raters from different institutions. No conceptual framework</p>	<ul style="list-style-type: none"> Measured complexity of managing clinical trial protocols Consisted of 25 activities rated on a 3-point scale. Total scores were sum of all ratings 	Intensity: Workload and complexity (on protocol level of analysis)	E One form of IRR completed Content validity mentioned but no results reported
James et al., 2011a, 2011b ^e	Instrument Development Web-based RETA	<p>Strength: Goal was to define workload of research coordinators and quantify data management and regulatory activities to project budget for future studies, estimate ways to earn back costs of current trials, and adjust staffing.</p> <p>Limitations: Did not focus on needs of research participant. Measured workload of all staff and thus specific workload of nurse is unclear; no conceptual framework described, challenges allocating time across multiple concurrent studies</p>	<ul style="list-style-type: none"> Web-based system with 12-item task list separated into categories (data management, regulatory and nontrial). Staff required to account for 95% of their work time 	Intensity: Time required to complete Tasks performed for research implementation	A

(continued)

Table 1. (continued)

Citation	Level/Type of Evidence ^a and Tool Name (If Applicable)	Strengths and Limitations (Quality of the Evidence)	Summary and/or Tool Measurement Methods	Acuity Attribute ^b : Subcategory ^c	Reliability and Validity Testing ^d
Coffey, M., Berridge, J., Lyddiard, J., & Briggs, J., 2011	Level 4 prospective study WMI	<p>Strengths: Methods included listing tasks and time required to complete them for 36 protocols</p> <p>Limitations: Participants included only research staff, concepts not clearly defined or described, conceptual framework not described, focused solely on time without delineating complexity</p>	<ul style="list-style-type: none"> Workload modules created for four clinical trial phases (planning, implementation, data management, closure), as well as financial agreements, training, administrative/IT preparations, communication, screening, informed consent, treatment and follow-up care, audit visits, financial management, protocol amendments, procedures for closure 	Intensity: Workload, frequency and time required to complete tasks related to research	C
McCarthy, 1997	Level 3 descriptive study	<p>Strengths: Addressed complexity of conducting clinical trials and time needed to complete specific tasks at multiple sites</p> <p>Limitations: Convenience sample, no conceptual framework described</p>	<ul style="list-style-type: none"> Retrospectively evaluated data from four AIDS clinical trial units Determined number of protocols, number of patients on protocols, number of research nurses assigned to protocols, and assigned protocol intensity as "intensive" or "non-intensive" based on phase of study 	Intensity: Workload (nurse to patient ratio)	A

(continued)

Table 1. (continued)

Citation	Level/Type of Evidence ^a and Tool Name (If Applicable)	Strengths and Limitations (Quality of the Evidence)	Summary and/or Tool Measurement Methods	Acuity Attribute ^b ; Subcategory ^c	Reliability and Validity Testing ^d
Moore & Hastings, 2006	Instrument development Ambulatory nursing intensity system	<p>Strengths: Day hospital setting; descriptors developed for both clinical care and research, as well as direct and indirect care needs High reliability and content validity</p> <p>Limitations: Generalization to other institutions may be limited, manual entry and double data entry, not linked to budgetary software, unclear how often data were used for staffing decisions</p> <p>No conceptual framework described</p>	<p>A Adapted from (Cusack et al., 2004a, 2004b; Jones et al., 2004) for the day hospital setting: Prototype system with nursing activities organized into six categories of complexity based on time required to complete care</p>	<p>Severity: Physical, psychosocial Intensity: Nursing care needs, complexity, workload</p>	<p>D Only one type of validity assessed (content validity)</p>
Oddone, Weinberger, Hurder, Henderson, & Sime1, 1995	Level 3 Random work sampling to capture research activities for one protocol at multiple sites	<p>Strengths: Rigorous study design using random work sampling methods at nine sites and a pilot. Purposefully chose timing to align with midpoint of trial so that nurses were familiar with protocol.</p> <p>Clear rationale for use of binomial proportion model and nurses as the level of analysis for cluster sampling technique</p> <p>Limitations: Self-reported activities may have led to underestimation for the "personal time" category, only sampled for 15 days, potential for inaccurate sample size estimates due to using nurses, rather than time points, as the unit of analysis</p>	<p>Described research nurses' work activities in mean time estimates, attributed intervention costs and cost effectiveness, described contributions of nurses to interventions in trials</p> <p>Random frequency beeper signalled nurse to record type of activity</p> <p>Research-related activities consumed largest proportion of work day (43% vs. 29% for patient care)</p>	<p>Intensity: Nursing care needs (measured as time and portion of work day spent in various clinical and research-related activities)</p>	<p>C</p>
Penberthy, Dahman, Petkov, & DeShazo, 2012	Level 4 Prospective study Clinical Trials Eligibility Database	<p>Strengths: First study to estimate cost of recruiting patients for clinical trials prospectively</p> <p>Limitations: Only focused on time, without other estimates of complexity. Total cost of process was underestimated</p>	<p>Incorporated real-time tracking tool to capture time spent by research staff on patient eligibility determination for clinical trials and associated costs</p>	<p>Intensity: Time spent and the probability of successful enrollment</p>	<p>C</p>

(continued)

Table 1. (continued)

Citation	Level/Type of Evidence ^a and Tool Name (if Applicable)	Strengths and Limitations (Quality of the Evidence)	Summary and/or Tool Measurement Methods	Acuity Attribute ^b Subcategory ^c	Reliability and Validity Testing ^d
Roche et al., 2002	Level 3	<ul style="list-style-type: none"> Strengths: Addressed complexity of conducting clinical trials and time to complete specific tasks at multiple sites Limitations: No conceptual framework described 	<ul style="list-style-type: none"> Research tasks compiled into four categories (protocol management, eligibility and entry, treatment, and follow-up and final stage) Data collectors recorded time for tasks daily for 30 consecutive days 	Intensity: Time required to perform protocol management tasks	A
Smuck et al., 2011	Level 7 OPAL Pyramid Scale	<ul style="list-style-type: none"> Strengths: Protocol-level scale to capture workload of all trial phases at 17 Ontario cancer centers Limitations: Optional weighted elements and total OPAL scoring are complex, no conceptual framework described 	<ul style="list-style-type: none"> Used to determine protocol, case, and department workload Feasibility of protocol decisions based on trial manager's knowledge, experience of staff 	Intensity: Protocol workload, time required to perform tasks	A

Note. WMI = workload measurement instrument; QI = quality improvement; WCCOP = Wichita Community Clinical Oncology Program; CRCs = clinical research coordinators; IRR = interrater reliability; RETA = research effort tracking application; OPAL = Ontario Protocol Assessment Level; FTE = full-time equivalent; AIDS = acquired immunodeficiency syndrome.

^aLevels of evidence: Level 1 = systematic review; Level 2 = randomized controlled trial; Level 3 = nonrandomized studies; Level 4 = case control/cohort studies; Level 5 = systematic qualitative review; Level 6 = single qualitative study; Level 7 = expert opinion or integrative review.

^bAcuity attribute assignments based on severity of illness or nursing intensity or both, described in Brennan and Daly (2009).

^cSubcategory assignments based on severity of illness or nursing intensity or both, described in Brennan and Daly (2009).

^dKey for reliability and validity testing: (A) no reliability and validity data reported, (B) reliability and validity established for measuring severity of illness but not for nursing workload, (C) reliability and validity mentioned but no data presented, (D) psychometric data reported with acceptable levels of reliability and validity data, (E) authors deemed tool not reliable and/or results were inconsistent or weak, (F) reliability and validity data proprietary are not reported, and (G) authors reported that tools underwent initial validation but lacked updated assessments. Many of these tools are no longer in use.

^eStudies, which had multiple, successive publications based on the same study were represented as a single entry or article.

articles were added based on reference lists of other included articles. The final count of articles was 55. The TOE is organized into three sections: (a) acuity tools pertaining to research intensity, (b) acuity tools pertaining to clinical intensity, and (c) articles describing the relationships among acuity, staffing, the nurse assignment process, and/or outcomes of care. Results according to each TOE section are described below.

Acuity Tools Pertaining to Research Intensity

The review of the literature revealed 16 studies related to patient acuity in terms of research intensity. Three studies were published as a series of articles published within the same year on the same topic and are counted once for the purposes of the review, with all articles included in the reference list (Cusack, Jones-Wells, & Chisholm, 2004a, 2004b; Gwede, Johnson, & Trotti, 2000a, 2000b; James et al., 2011a, 2011b; Jones, Cusack, & Chisholm, 2004). For level of evidence, six used instrument development methods (Berridge, Coffey, Lyddiard, & Briggs, 2010; Briggs, 2008; Good, Lubejko, Humphries, & Medders, 2013; Hancock, Wiland, Brown, Kerner-Slemmons, & Brown, 1995; James et al., 2011a, 2011b; Moore & Hastings, 2006). Two were prospective studies (Coffey, Berridge, Lyddiard, & Briggs, 2011; Penberthy, Dahman, Petkov, & DeShazo, 2012). Five were nonrandomized studies (Ellis et al., 2012; Gwede et al., 2000a, 2000b; McCarthy, 1997; Oddone, Weinberger, Hurder, Henderson, & Simel, 1995; Roche et al., 2002). Finally, one was a quality improvement study (Cusack et al., 2004a, 2000b; Jones et al., 2004) and two were expert opinion or commentary (Cassidy & Macfarlane, 1991; Smuck et al., 2011).

In relation to psychometric assessments, eight had no reliability and validity data reported (Berridge et al., 2010; Ellis et al., 2012; Good et al., 2013; Gwede et al., 2000a, 2000b; James et al., 2011a, 2011b; McCarthy, 1997; Roche et al., 2002; Smuck et al., 2011). Five studies mentioned reliability and validity but no data were presented (Briggs, 2008; Coffey et al., 2011; Cusack et al., 2004a, 2000b; Jones et al., 2004; Oddone et al., 1995; Penberthy et al., 2012). Two articles reported psychometric data with adequate reliability and validity (Hancock et al., 1995; Moore & Hastings, 2006). Hancock and colleagues (1995) reported moderate and significant correlations between complexity rating scale scores and nurses' subjective ratings of clinical trial protocols' complexity levels as a measure of interrater reliability (IRR). The authors mentioned content validity; however, specific methods and results were not described. Moore and Hastings (2006) developed an ambulatory intensity system with both clinical and research needs represented and reported a high content validity index (0.87) and substantial IRR (0.8). All

articles focused on at least one aspect of the intensity attribute of acuity and two articles (Cusack, Jones-Wells, & Chisholm, 2004a, 2004b; Jones et al., 2004; Moore & Hastings, 2006) focused on both severity of illness and intensity. The articles focused on a variety of roles, from nurses only to all members of research team.

Although the majority (13) of the 16 articles related to research intensity at least mentioned the “intensity” attribute of acuity and two of them mentioned both the “severity of illness” and “intensity” attribute, very few articles focused on a comprehensive, validated measurement tool for research intensity in terms of nursing care needs of patients enrolled in clinical research. Two articles focused on developing the Ambulatory Nursing Intensity System, a tool for measuring acuity in an ambulatory setting for both clinical and research needs, and mentioned or provided psychometric assessment data (Cusack et al., 2004; Moore & Hastings, 2006). The tool encompassed both clinical and research intensity for an outpatient setting and data were collected manually. One article proposed a tool to measure the impact of a study on workload at different phases, including planning, implementation, data management, and closure (Berridge et al., 2010). Many articles (Berridge et al., 2010; Briggs, 2008; Coffey et al., 2011; Ellis et al., 2012; Good et al., 2013; Gwede et al., 2000a, 2000b; Hancock et al., 1995; James et al., 2011, 2011b; McCarthy, 1997; Oddone et al., 1995; Penberthy et al., 2012; Smuck et al., 2011) introduced the importance of capturing workload and complexity of clinical trials and proposed methods of measurement, but did not discuss conceptual frameworks or report data on psychometric testing.

Acuity Tools Pertaining to Clinical Intensity

Eighteen studies pertained to patient acuity in terms of clinical intensity (Section 1 of Online Resource 1). Six articles had no reliability and validity data reported (DeLisle, 2009; de Raad et al., 2010; Gedmintas, Bost, Keijzers, Green, & Lind, 2010; S. M. Green, 2012; Swan & Griffin, 2005; Trope, Vaz, Zinger, & Sagy, 2015). One article commented on face validity without presenting data and mentioned psychometric testing as an area for future research (Willis, Henderson, Toffoli, & Walter, 2012). Six articles mentioned reliability and validity but no data were presented (Chiulli, Thompson, & Reguin-Hartman, 2014; Fasoli & Haddock, 2010; E. Green et al., 2012; Hoi, Ismail, Ong, & Kang, 2010; Medvec, 1994; Myny et al., 2012). Two articles reported psychometric data (Brennan et al., 2012; Incesti, Bender, & Delunas, 2015). Brennan et al. (2012) validated a patient acuity tool in a hematology/oncology/bone marrow transplant unit and reported high and statistically significant

IRR (0.95), high scale-level content validity (0.82), high item-level content validity (0.78, with kappa statistic \geq 0.74 for 70% of the tool items), and moderate, statistically significant concurrent validity (0.58). For predictive validity, for every one unit increase in acuity score, patients were twice as likely to require a rapid response team consult, which was statistically significant (Brennan et al., 2012). Incesti and colleagues (2015) reported moderate IRR (0.633) for a patient acuity tool developed for an inpatient rehabilitation unit and validity was not assessed. One article deemed the tool not accurate and recommended additional research (Barnett, Bird, Francis, & Pinikahana, 2008). Two articles presented on topics related to patient acuity but are not applicable in terms of psychometric assessments because the subject matter was a concept analysis of patient acuity (Brennan & Daly, 2009) or methodological challenges associated with developing acuity tools (Brennan & Daly, 2015). Seven articles mentioned or used a conceptual framework (Brennan et al., 2012; Hoi et al., 2010; Medvec, 1994; Myny et al., 2012; Trope, Vaz, Zinger, & Sagy, 2015; West et al., 2014; Willis et al., 2012).

Articles Describing the Relationships Among Acuity, Staffing, Nurse Assignment Process, and/or Outcomes of Care

This review of the literature revealed 17 articles that described the relationships among acuity, staffing, nurse assignment process, and/or outcomes of care (Section 2 of Online Resource 1). Three articles were not applicable to conducting psychometric assessments (Choi & Staggs, 2014; Engelking, 1992; Spilsbury et al., 2008). Eight articles had no reliability and validity data reported (Acar, 2010; Baker et al., 2010; Fram & Morgan, 2012; Gabbay & Bukchin, 2009; Gaits, 2005; Gall, Molin, & di Giulio, 2000; Herdman et al., 2009; West et al., 2014). One abstract reported IRR between Optilink acuity system scores and nurse competence designations using the Synergy Model and found that competence did not predict IRR on acuity scores (Gilmore, Matney, Godaire, Phelan, & Morse, 2014). Rogowski and colleagues (2015) reported high IRR (kappa statistic of 0.79) with the classification of infants into acuity levels prior to their first data collection. One article reported the initial validation of the Practice Environment Scale of the Nursing Work Index (PES-NWI; Lake, 2002). Boev (2012) found that satisfaction with nurse manager on the PES-NWI was statistically significantly correlated with patient satisfaction. Breckenridge-Sproat, Johantgen, and Patrician (2012) found that higher acuity was associated with medication errors and patient falls, however, did not provide psychometric data for the acuity system. Another article deemed the tool not accurate and recommended additional

research (Pitkaaho, Ryyanen, Partanen, & Vehvilainen-Julkunen, 2011). Four articles grounded their work in a conceptual framework (Acar, 2010; Breckenridge-Sproat et al., 2012; Lake, 2002; Pitkaaho et al., 2011).

Discussion

Of the sixteen articles found pertaining to research intensity, only two provided information about psychometric assessments. Similarly, of the 18 articles pertaining to clinical intensity, only two provided psychometric assessments. Reported reliability of these instruments was moderate to high. Reported validity was high, yet mainly focused on content validity. More robust measures of validity, such as concurrent, discriminant, and/or predictive validity, were lacking from the majority of the articles. In terms of level of evidence, a number of articles used weaker research designs, such as expert opinion or commentary. With the exception of Moore and Hastings (2006) and Cusack and colleagues (2004a, 2004b) studies, research intensity articles mainly focused on the role of research nurses or coordinators, rather than the clinical nurses caring for research participants. Similarly, most articles focused on protocol-level workload, rather than the patient level of analysis, which is likely to be more useful and relevant for staffing decisions. Thus, very little information is available in the literature with regard to rigorous measurement of acuity of patients cared for by CRNs who are providing both clinical and research care in inpatient and outpatient settings. In addition to a paucity of psychometric assessments, few authors included a conceptual model that delineates, clarifies, and defines the concepts being measured during instrument development. These findings are similar to Brennan and colleagues' (2012) findings from a report of a psychometric assessment of an oncology acuity tool. The authors conducted an extensive review of the literature of acuity tools from 1960s to 2008 and found that very few authors used conceptual frameworks when developing acuity tools and very few had conducted psychometric assessments (Brennan et al., 2012).

Conceptual clarity and sufficient reliability and validity are two key features of instrument development and their absence explains the lack of availability of instruments to adequately measure acuity pertaining to research participants. As a first step to filling this gap, proposed definitions of clinical intensity and research intensity, based on the findings from the table of evidence presented here and using the conceptual foundation of Brennan and Daly (2009) and Hastings (2012), are presented in Table 2. The two main conceptual attributes of patient acuity are patient-level severity of illness and nurse-level intensity (Brennan & Daly, 2009). Nurse-level intensity incorporates three subcategories, including nursing care needs (concentration/

Table 2. Conceptual Clarity and Definitions.

Concept	Definition	References
Nursing care needs	Concentration/amount of nursing care required Time needed to provide nursing care	Brennan and Daly (2009)
Complexity	Level of difficulty of care needs	
Workload	Dependence/reliance of patient on nursing staff Demand for nursing services/skills	
Clinical intensity	Nursing care needs, complexity, and workload driven by presenting/underlying condition and comorbidities of research participant, including physical, psychiatric, psychosocial, spiritual/existential, educational, and coordination of care needs	
Research intensity	Research participant’s nursing care needs, complexity of care requirements and associated workload, driven by the research protocol	
Research-based clinical intensity	Nursing care needs, complexity, and workload that arise from the interaction of research participant with the research process. Temporally related, i.e., encompasses what happens clinically to a patient after he or she starts a research protocol	Initial definitions for clinical intensity, research intensity, and research-based clinical intensity are from Hastings (2012) and expanded upon based on Brennan and Daly, (2009) and the review of the literature presented here

amount of nursing care required, time needed to provide nursing care), complexity (level of difficulty of care needs), and workload (dependence/reliance of patient on nursing staff; demand for nursing services/skills). Hastings (2012) proposed the terms “clinical intensity” and “research intensity” to delineate care requirements in a clinical research setting. The definition of acuity is applied to Hastings’s (2012) conceptualization of clinical and research intensity.

These definitions of the concepts serve as a foundation for the generation of a conceptual model of research participant acuity (Figure 2). Clinical intensity can influence research intensity; however, research intensity seldom influences the initial presenting clinical intensity of the research participant,

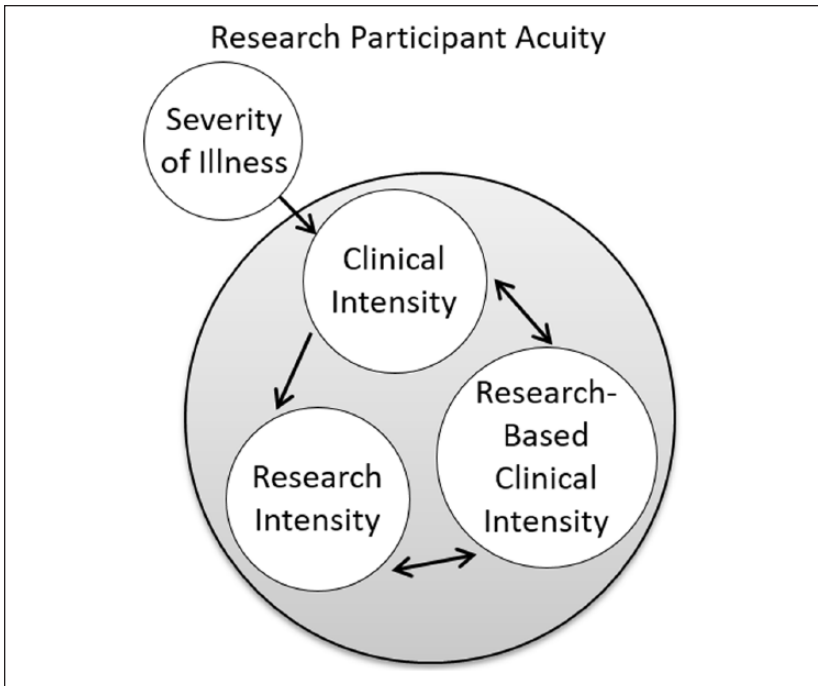


Figure 2. Proposed conceptual model.

unless these changes are expected and written into the protocol (such as when a behavioral health research participant is weaned off all medications as part of the protocol and exhibits signs and symptoms of their underlying disease). Thus, a one-way arrow links clinical and research intensity in Figure 2. Two-way arrows link research-based clinical intensity to both clinical intensity and research intensity because they all influence each other. The “research-based clinical intensity” circle in Figure 2 represents what occurs after the protocol is initiated and highlights that a patient’s nursing care needs could be driven by both their underlying severity of illness and the research.

A theoretical framework highlighting the relationships among research participant acuity and other structures, processes, and outcomes of care is presented in Figure 3. Holzemer’s model for health care research (Holzemer & Reilly, 1995), Brennan and Daly’s (2009) concept analysis of patient acuity, and the integrated framework for a systems approach to nurse staffing research (Brennan et al., 2013) were used to ground the concept of research participant acuity within this framework. This framework could be used to

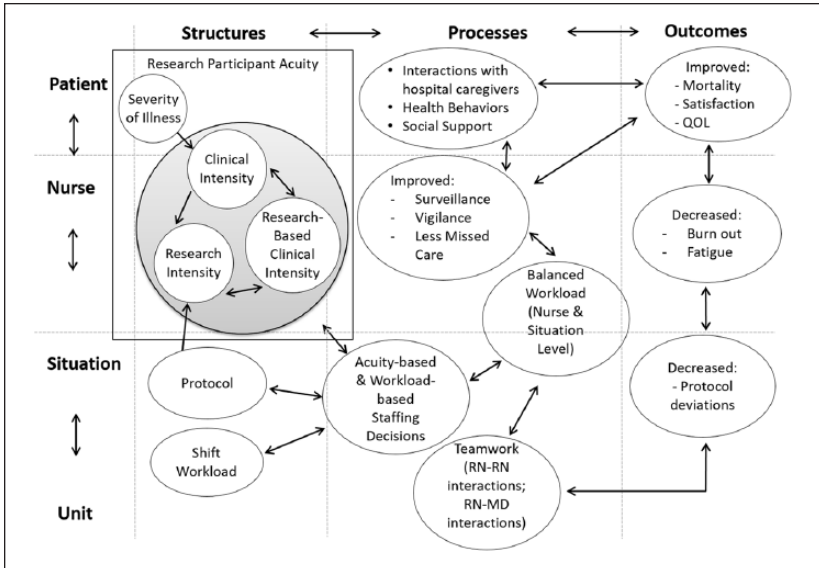


Figure 3. Sample theoretical framework.

conduct empirical research on the various factors that affect patient, nurse, situation, and unit outcomes. It conceptualizes research participant acuity as nurse-level intensity, which is influenced by the protocol and the patient’s underlying severity of illness. It postulates that acuity-based nurse assignments have the potential to balance nursing workload, thereby improving nurse surveillance and vigilance and providing more opportunities for interactions with patients/families. These nurse-level processes influence patient outcomes, which are also affected by patient factors (e.g., social support) and unit/system factors (e.g., teamwork). Before formally testing the relationships among these variables, reliable and valid measures of acuity are needed.

Strengths of this article include a rigorous, two-person review of each article and use of a specific, predetermined format for consistent appraisal of the articles. In addition, the project team included individuals with diversity among clinical and operations experts, researchers, and acuity experts, which ensured that a variety of perspectives were represented. Limitations of the review are that the literature search included a step-wise process in which a search was conducted in 2014 with limiters for years 2008 to 2015, with the intention of excluding older tools that may be outdated for the current clinical research environment. The second step included an updated search in 2016

with the intention of ensuring nothing new had been published on tools specific to nursing care needs of patients. This review was specific to nursing, with limited applicability to other professions. In addition, the proposed conceptual model is just one model and may not be the only or best way to describe the relationships among concepts. The authors of this article work in a clinical research hospital and the lens through which the results were interpreted may not be generalizable to settings in which research is not the primary focus. However, academic medical centers nationally continue to expand clinical research portfolios and thus, results may be useful to settings that provide both clinical and research care.

In clinical research, nursing workload is influenced by the participants' clinical condition, or clinical intensity, and research needs, driven by the protocol. Clinical research nursing was recently recognized by the American Nurses Association as a specialty area of nursing practice (Zaparoni, 2016). The clinical research nursing domain of practice is part of a taxonomy that was developed to classify concepts and roles within the specialty of clinical research nursing. It incorporates five validated dimensions, including clinical practice, study management, care coordination and continuity, contributing to the science, and human subjects protection (Castro et al., 2011). Activities most frequently completed by CRN and research nurse coordinators within each dimension have been described (Bevans et al., 2011). The authors concluded that CRNs spend most of their time in the clinical practice dimension and that the focus of CRNs' work includes both direct clinical care and research care across a variety of specialties (e.g., medical/surgical, oncology, neurology, etc.), whereas research nurse coordinators' time is spent mainly in the study management dimension (Bevans et al., 2011). This review of the literature builds on this prior work by clarifying the definitions of clinical intensity and research intensity within the context of the CRN domain of practice.

Accurately capturing research intensity with a reliable and valid tool will potentially allow for more efficient staffing decisions and balanced workforce allocation. Clinically, measurements of research intensity will potentially provide charge nurses, nurse managers, and nurse executives nationally and internationally with more objective data to make decisions about allocation of nursing resources, not only in terms of how many staff to hire, but also how to make unit-level staffing decisions and nurse-level patient assignment decisions on a shift-to-shift basis.

In summary, currently, there are few tools available to measure the acuity of research participants. The results of this review provide the beginning foundation for grounding the concepts within a conceptual framework for subsequent development and validation of a tool to measure research

intensity. Having a validated tool will assist unit and hospital leaders in our setting with staffing decisions and formulating nurse staffing policies and, in the future, other academic medical centers that care for research participants. A validated tool will also provide the opportunity to study the effect of acuity-based nurse assignment and staffing models on patient and nurse outcomes. Before this type of research can be conducted, reliable and valid measurements of research intensity are needed. Our findings have the potential to make a contribution to advancing scientific knowledge for clinical decision making related to nurse staffing and patient outcomes. Defining concepts related to research intensity is a first step toward developing a tool to accurately measure acuity of research participants. Future work will involve developing and validating the tool and assessing its use for measuring acuity on the patient, nurse, protocol, and unit levels of analysis. For the nurse level of analysis, research that investigates the role of not only research nurse coordinators, but also CRNs, is needed. For protocol level of analysis, future research on measuring acuity and workload at various trial phases, including pre-, during, and postprotocol time periods, budgeting, and allocation of resources, will be important. Having a method of measuring acuity that is conceptually clear and psychometrically valid has the potential to contribute to assignment decisions and workload allocation for specific protocols and/or patient care areas, and assess the impact on patient outcomes.

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ORCID iDs

Michael Krumlau  <https://orcid.org/0000-0002-2955-2998>
George Cusack  <https://orcid.org/0000-0003-4038-5649>

Supplementary Material

Supplementary material is available for this article online.

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