

# Clinical assessment instruments validated for nursing practice in the Italian context: a systematic review of the literature

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## Abstract

**Aims.** With the aim to identify the instruments validated for Italian nursing practice, a systematic review of the literature was undertaken.

**Results.** A total of 101 instruments emerged. The majority (89; 88.1%) were developed in other countries; the remaining (14; 13.9%) were developed and validated in the Italian context. The instruments were developed to measure patient's problems (63/101; 62.4%), outcomes (27/101; 26.7%), risks (4/101; 4%) and others issues (7/101; 6.9%). The majority of participants involved in the validation processes were younger adults (49; 48.5%), older adults (40; 39.5%), children (4; 4%), adolescents (3; 3%), and children/adolescents (1; 1%). The instruments were structured primarily in the form of questionnaires (61; 60.4%), as a grid for direct observation (27; 26.7%) or in other forms (12; 11.9%). Among the 101 instruments emerged, there were 1 to 7 validation measures documented with on average 3.2 (95% CI 2.86-3.54) for each instrument.

**Conclusions.** Developing validation studies giving priority to those instruments widely adopted in the clinical nursing practice is recommended.

## Key words

- tool
- questionnaire
- scale
- patient
- validation
- nursing
- Italy

## INTRODUCTION

In recent years, health-care providers have increased the adoption of instruments aimed to assess the clinical conditions of patients. These instruments (e.g., questionnaires, indexes, checklists, and scales) consist of a combined collection of items detecting theoretical variables that are not typically directly assessable [1]. Their adoption in daily practice ensures an objective, standardised and communicable evaluation of the actual or risk problems of the patients [2]. In addition, they ensure valid data [3], patient safety and cost containment [1].

At the national level, ministerial decrees, laws and guidelines have recommended some instruments. As an example, the recent Italian ministerial decree on neuromuscular diseases [4] recommended the adoption of specific assessment tools. One year later, according to national law, "Measures to ensure access to palliative care and pain therapy" [5] in which recommendations for the adoption of specific tools in the evaluation of patients' pain was approved. Also at the international level, scien-

tific guidelines such as those produced by the European Pressure Ulcer Advisory Panel for pressure ulcers [6] and by the Registered Nurses Association of Ontario for pain assessment and management [7] have both recommended the adoption of valid and standardised instruments. Given the limited research available in the field regarding whether and how the adoption of these tools affect patient outcomes, remains an unresolved issue [8, 9]. However, the systematic adoption in the assessment of the patients needs, seem to facilitate the health-care professionals' decision-making process [10].

Over the past thirty years, in line with the above-mentioned international and national debate, Italian nurses have increased their scientific and professional interest regarding how to measure actual or potential patients problems. As has occurred in other health-care disciplines, nurses in Italy have transferred several validated tools developed in other countries (e.g., [11-13]) as well as, undertaken studies aimed to develop new tools [14] following the validation processes recommended in the literature.

At the moment, in the Italian context, there is no census on the tools available for the clinical evaluation of patients and the degree to which they were subjected to a validation process. The purpose of this study is, therefore, to identify the instruments (*i.e.*, tools, scales, questionnaires, and checklists) validated in the Italian context.

### **Methodological issues concerning instrument validation**

Guillemin [15] has defined the steps that should be undertaken when an instrument developed in another context is validated in a new cultural and language environment. According to Guillemin [15] the preliminary transcultural adaptation, should be followed by the subsequent validation of the instrument evaluating its validity and reliability, the same steps undertaken for a new instrument. The preliminary transcultural adaptation allows the intrinsic characteristics of the tool to remain stable and may be developed under different approaches [15] as, for example, assuring an independent translation from the original format to the target language (*e.g.*, Italian) by a group of native speakers (forward-translation) or by a bilingual multi-disciplinary committee [15].

The second step determines whether the instrument is able to measure the intended construct evaluating its psychometric properties [1-16]:

- 1) validity is assured by evaluating different aspects of the instrument (*e.g.*, face, content, construct, and criterion-related validity). In face validity, the degree of appearance that the instrument in assessing what it is supposed to assess is evaluated. In content validity, the judgment of expert(s) regarding whether or not the included items represent the domain of the construct is assured. Criterion validity compares the instrument under validation with another instrument recognized as a gold standard in the field [17-19]. Construct validity, reveals the underlying theory through explorative factorial analysis and confirmative factor analysis [16];
- 2) reliability refers to the ability of the instrument to produce the same or similar results when it is being used by different individuals or at different time intervals by the same individual.

The evaluation might include:

- internal consistency measures, such as the extent to which one item is a good indicator of performance of any other item of the same instrument (*e.g.*, Cronbach's  $\alpha$ );
- test-retest reliability (or stability), regarding the extent to which an instrument produces stable results over time (*e.g.*, observations of a patient on two different occasions);
- inter-rater reliability, measuring the agreement of evaluation obtained by two raters in the same moment and in a blinded fashion (*e.g.*, K Cohen);
- intra-rater reliability, as the agreement between measures made by the same rater in two different occasions [16-20].

The adoption of instruments that have not received any cultural or language validation, or that have not received any appropriate validation process, or even worse, freely adapted by adding, modifying or remov-

ing items, returns inaccurate measures. In addition, if these not-validated instruments are adopted into clinical practice they may threaten: a) the decision-making process; b) the comparability of the measures collected across facilities both at the national and at the international level (*e.g.*, number of falls in patients at risk) and; c) the evaluation of the effectiveness of nursing interventions.

### **METHODS**

A systematic review of the literature was undertaken adopting the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) [21].

#### **Search strategy**

The Searching Validated Instruments for Italian nursing practice (SVITA) research group was established. After having shared the aims of the project, MedLine, CINAHL and Embase databases were selected. The following search strategy was applied: ("Questionnaires" (MeSH) OR scale OR tool OR instruments) AND validation AND nursing AND Italian.

Grey literature was also searched preliminarily via Google Scholar (since 1992 when the Google scholar catalogue has been established) using the following keywords: "validation" "nurse" "nursing" "Italy" "Italian" "tool" "instruments" and "questionnaire" both in Italian and in English language. A hand-search was also performed including no-indexed nursing journals. Therefore, *L'Infermiere*, *Nursing Oggi*, *Scenario*, *Rivista di Scienze Infermieristiche* and *Nursing American Review* journal indexes were scrutinised. Aiming to identify any additional articles to be included, the list of references of the articles retrieved, were also analysed. The research was carried out from 22 September 2011 to 31 March 2012. Selected keywords were searched in the full-text of the articles. Any limitation (year of publication and population age) was applied.

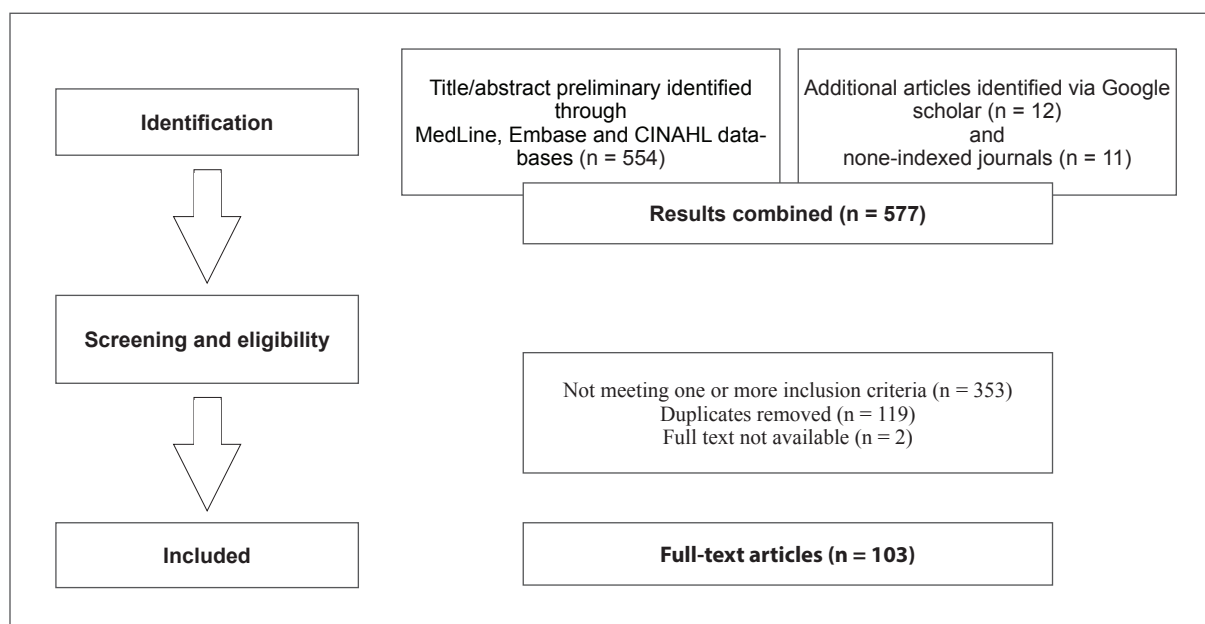
Articles documenting any Italian validation process at any stage (*e.g.*, face validation, factorial analysis), undertaken for instruments aimed to evaluate patients' problems, published in Italian or in English, were included.

Aiming to avoid any selection bias, a pilot phase was performed selecting a sample of 49 full-text articles that were evaluated for their eligibility criteria in a blinded fashion by two researchers. The agreement achieved was high ( $K = 0.97$ ) and disagreements were discussed with a third researcher. Therefore, the full-text articles retrieved were analysed for their eligibility. The articles included and excluded, and the reasons for their exclusion are reported in the *Figure 1*.

#### **Data analysis**

Each included article was analyzed by the SVITA research team who extracted the following data.

- 1) Tool origin and relevance:
  - origin: where the validation of the original instrument was undertaken (in Italy or in another country) and the language in which the tool was originally validated (Italian or another language);
  - original name of the instrument: the name was identi-



**Figure 1**  
Articles included and reasons for exclusion.

fied in its full extension, in Italian and in English, and also in its acronyms when reported in the article(s);

– national or international relevance of the instruments: was identified analysing where the article was published, in an Italian or in an International journal.

2) Domain, population, setting and other methodological issues:

– domain: each instrument was categorized in its prevalent domain (e.g., evaluating risks, problems – physical or psychological – outcomes or other).

– population and setting: the population on which the instrument was validated was classified by age based on the MedLine criteria (children = 0 to 12 years; adolescents = 13 to 18 years old; younger adults  $\geq$  19 years; older adults  $\geq$  65 years). Regarding the setting, hospital, home and residential care were considered.

– the nature of the instrument: questionnaire (e.g., self-report, administrable via interview), or observational grid and its complexity as the number of items included, were evaluated.

3) Validation processes measures undertaken:

– validation measures documented in the article(s) (validity and reliability): 1) face, 2) content, 3) internal consistency; 4) stability measures, 5) inter-rater reliability, 6) intra-rater reliability when appropriate (excluding self-reports), 7) criterion validity and 8) construct validity [6]. Among these eight different measures, the average number of measures assessed for each instrument was calculated. In addition, the year/s when the data collection for tool validation was performed, if reported in the article, was documented.

In accordance to the international debate, results were categorised into three section: instruments retrieved, issues related with their domain and the validation processes which were subjected as documented in the articles.

Data were evaluated with descriptive statistics (i.e.,

frequencies, percentages, averages) and inferential estimations (Confidence Interval, 95% CI) using SPSS system package, Version 19. Some characteristics of instruments developed and validated in the Italian context with those developed and validated in other countries, were compared using Chi-Square Test, T Test and ANOVA Test, according to the nature of the variables and to their distribution. The statistical significance was set at  $p < 0.05$ .

Given that some instruments were reported in more articles, the analysis was fixed at the instrument level.

## RESULTS

### Origin and relevance

A total of 101 validated instruments were published in the 103 articles reviewed (Table 1). Among them, 31 (30.7%) were published in national journals and 72 (71.3%) in international journals. The majority of the instruments were developed in other countries (89; 88.1%); while 14 (13.9%) were validated in an Italian context. Among those developed in other countries, in the process of Italian validation, 67 (75.3%) have left the original tool name while the remaining 22 (24.7%) have renamed the tool adapting it to the Italian context (Table 2).

### Domain, population, setting and other methodological issues

As reported in Table 3, the instruments reviewed were developed to measure patient's problems (63/101; 62.4%), outcomes (27/101; 26.7%), risks (4/101; 4%) and others issues (7/101; 6.9%). When the assessment was on a patient problem, the majority were focused on physical problems (35/63; 55.6%) and the remaining (28/63; 44.4%) on psychological problems. Among those focused on physical problems, pain (15/35; 43%), functional dependence (12/35; 34.4%) and nutritional

**Table 1**

Origin and relevance of the instruments documented in the articles retrieved (n = 103)

	n (%)
<b>Origin</b>	
Italian	14 (13.9)
International	89 (88.1)
<b>Publication</b>	
Italian journals	31 (30.7)
International journals	72 (71.3)

status (3/35; 8.6%) were the main problems measured. In the case of psychological problems, those related to dementia (8/28; 28.6%), depression (6/28; 21.4%) and anxiety (3/28; 10.7%) mainly occurred. Some instruments were focused on outcomes such patient satisfaction (14/27; 51.9%) and quality of life (13/27; 48.1%). The only risk taken into consideration by the retrieved instruments was falls (4/101; 4%). The majority of the tools that emerged from the review (99; 98.0%) were target to patients problems while the remaining (2; 2.0%) were dedicated to family/care-givers members problems.

The majority of participants involved in the validation processes were younger adults (49; 48.5%) followed by older adults (40; 39.6%), children/adolescents (8; 8.0%). However, four instruments (3.9) did not report the population in which they were validated.

The instruments have been validated on average in a population of 434 subjects (ranging from 10 to 8280). Stratified by age of the population, the largest group involved was that of adolescents (3 instruments) consisting of an average of 2037 people (from 812 to 3261); less numerous was the population size in which instruments were tested with older adults (40 studies) in which on average, 654 people were involved (from 20 to 8280). Finally, the population less involved in validating measures was that composed by younger adults (49 studies), with an average of 200 subjects (from 21 to 657).

The tools have been validated in a specific setting (e.g., hospitals, home care or residential care) in 88 cases (79/101; 78.2%); in the remaining studies, the setting(s) where the validation process was undertaken (22/101; 21.7%) was not reported. Where indicated, the setting was the hospital (53; 60.2%), the home-care (18; 20.4%) and the intermediate/residential care (8; 9.1%).

The instruments were structured in the form of questionnaire (61; 60.4%), as a grid for direct observation (27; 26.7%) or in other forms (12; 11.9%); for example, in a graphic structure collecting patient clinical data. In one case, the article did not report the structure of the instrument (1; 1%). On average, the instruments were composed by 21.5 items/questions (95% CI 17.1-25.7, range 3-140) without any statistical differences among instruments devoted to different patient groups (e.g., adolescents, young adults, older adults) ( $F = 0.267$ ;  $p = 0.849$ ). The items were measured primarily with a Likert-scale (37;

36.6%) and with a Numerical Rating Scale (21; 20.8%).

The instrument compilation was intended for use mainly by health-care workers (55; 54.5%) or by patients (42; 41.6%) and only on one occasion by the caregiver (1; 0.9%). Moreover, only three tools were structured for an integrative compilation by nurses and patients (3%).

### Validation processes undertaken

For only 51 instruments (49.6%) the year when data were collected had been documented. For those where the data was reported, the instruments were validated from 1994-2011.

As reported in Table 4, the trans-cultural validation of the instruments has been documented for 55 out of 87 developed in other countries (63.2%). The process was based on forward-translation (47/55; 85.5%) and backward-translation (41/55; 74.5%); a complete linguistic validation including backward- and forward-translation was reported for 39/55 (70.9%) instruments.

Face validity was evaluated for 49/101 (48.5%) instruments, while content validity was documented for 45/101 (44.6%) instruments. Face validity was most frequently documented in the tools developed in the Italian context (10/14; 71.4%) compared to those developed in other countries (38/87; 43.8%) ( $p = 0.03$ ). Similarly, the content validity was more often documented in those instruments developed in the Italian context (10/14; 71.5%) compared to those developed abroad (35/87; 40.2%) ( $p = 0.01$ ).

The internal consistency was evaluated in 71/101 instruments (70.3%). The instrument stability (test – retest) measures were assessed in 47/101 instruments (46.5%) while the inter-rate reliability, which were considered appropriate as a measure in 59 instruments, were measured in 28 (47.4%).

Criterion validity has been documented in 49 instruments (48.5%) adopting a concurrent criterion validity (35/49; 71.4%), and less often a predictive criterion validity (13/49; 26.5%). In addition, factor analysis was documented in only 35 instruments (34.6%) and no statistical differences have emerged between instruments developed and validated in Italy and abroad ( $p = 0.978$ ).

Without considering the evaluation of the trans-cultural validity, appropriate only for those instruments validated in other language and contexts, among the 101 instruments reviewed, from 1 to 7 validation measures were reported; with the average number of validation measures being 3.2 (95% CI 2.86-3.54) with no difference between those developed in the context of Italy and abroad.

## DISCUSSION

### Origin and relevance

A total of 101 instruments devoted to the clinical assessment of the patients conditions in which one or more validation process have been documented, emerged from the literature. Most of the validation processes reported in the retrieved articles have been developed at the international level: nursing education in the academic setting, a privileged place of research

**Table 2**

Instruments emerged from the systematic review of the literature: original denomination and acronym

Original name of the instrument*	Acronym*
Abbey Pain Scale	APS
Abbreviated Mental Test	AMT
Acuteness Burst Constancy Scale	ABC
Advanced Instrumental Activities of Daily Living Scale	AIADL
Alzheimer's Disease Assessment Scale	ADAS
American Pain Society-Patient Outcome Questionnaire	APS-POQ
Average 8h Pain Intensity	8HA
Bedford Alzheimer Nursing Severity Scale	BANS-s
Berg Balance Scale	BBS
Brief Pain Inventory	BPI
Cambridge Cognitive Examination	CAMCOG
Care Dependency Scale	CDS
Center for Epidemiologic Studies – Depression Scale	CES-D
Chronic Pain Grade	CPG
Clinical Historical-Objective Scale of Carpal Tunnel Syndrome	Hi-Ob scale
Cohen-Mansfield Agitation Inventory	CMAI-LONG FORM
Comprehensive Assessment of Satisfaction with Care	CASC
Computerized Skin Score	CSS
Comunicazione Medico-Paziente nella Sclerosi Multipla revisionata	COSM-R
Critical-Care Pain Observation Tool	C-POT
Cumulative Illness Rating Scale	CIRS
Delirium Rating Scale-Memorial Delirium Assessment Scale	DRS-MDAS
Dependence Medical Index	DMI
Disability Assessment for Dementia Scale	DAD
Discomfort Scale-Dementia of Alzheimer Type	DS-DAT
Disordered Eating Questionnaire	DEQ
Doloplus	
Drug Hypersensitivity Quality of Life Questionnaire	DrHy-Q
Edinburgh Post Natal Depression Scale	EPDS
Edmonton Symptom Assessment Scale	ESAS
European Organisation for Research and Treatment of Cancer Patient Satisfaction 32 items	EORTC IN-PATSAT 32
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Head and Neck 35	EORTC QLQ H&N 35
European Project on Patient Evaluation of General Practice Care	EUROPEP
Falls Efficacy Scale International	FES I-FES I BREVE
Fear of Falling Measure	FFM
Five-Item Geriatric Depression Scale	FIVE-ITEM GDS
Food Frequency Questionnaire	FFQ
Functional Independence Measure	FIM
Geriatric Anxiety Inventory	GAI
Geriatric Depression Scale	GDS
Geriatric Index of Comorbidity	GIC
Hendrich Fall Risk Model II	HFRM II
Identification of Seniors at Risk	ISAR
Impact of Event Scale	IES
Italian Telephone Version of the Mini-mental State Examination	Itel-MMSE
Italian Version of the Mini-Mental Adjustment to Cancer Scale	MINI-MAC
Italian Version of the Telephone Interview for Cognitive Status	I-TICS
Juvenile Arthritis Functionality Scale	JAFS
Kidney Disease Quality of Life Short Form	KDQOL-SF
McGill Quality of Life Questionnaire	MQOL

(continues)

Table 2 (continued)

Modified Mini Nutritional Assessment Short Form	MNA-SF
Modified Overt Aggression Scale	MOAS
Modified Transplant Symptom occurrence and Symptom Distress Scale	MTSOSD-59
Modified-Multidimensional Prognostic Index	m-MPI
Neck Pain and Disability Scale	NPDS
Neuropathic Pain Scale	NPS
Neuropathic Pain Symptom Inventory	NPSI
Newcastle Satisfaction with Nursing Scale	NSNS
Non-Communicative Patient's Pain Assessment Instrument	NOPPAIN
Nurse's Observation Scale for In-Patient Evaluation	NOSIE
Oral Health Impact Profile	OHIP-14
Oxford Shoulder Score	OSS
Paediatric Quality of Life	PEDSQL
Paediatric Rheumatology Quality of Life Scale	PRQL
Pain Assessment in Advanced Dementia	PAINAD
Pain Treatment Satisfaction Scale	PTSS
Palliative Prognostic Score	PAP SCORE
Patient Satisfaction Scale	PSS
Patient-Physician Relationship Index	PPRI
Pavia Instrumented Tinetti Test	PITT
Poststroke Depression Rating Scale	PSDRS
Postural Changes Scale	PCS
Quality of Life in Depression Scale	QLDS
Questionario di Moynihan sulle Conoscenze Alimentari	
Questionario per la Valutazione della Soddisfazione per l'ADI	
Questionario sulla Soddisfazione del Paziente Ospedalizzato	V-48
Questionario sulla Soddisfazione Ospedaliera	
Ronchi Brief Evaluation Battery	RBEB
Rorschach Alexithymia Scale	RAS
Royal Free Interview for Religious and Spiritual Beliefs	
Satisfaction with Nursing	SNQ-10
Scala di Conley	
Scala di Soddisfazione del Paziente nei Confronti della Qualità delle Cure in degenza riabilitativa	
Scala di Soddisfazione del Paziente nei Confronti della Qualità delle Cure	
Scheda di Accertamento della Dipendenza	ADI 8
Scleroderma Logopedic Scale	SLS
Score per la Valutazione del Rischio di Reazioni Avverse ai Farmaci	ADR RISK SCORE
Screen for Child Anxiety Related Emotional Disorders	SCARED
Self Report Instruments	MOODS-SR
Severe Impairment Battery	SIB
Snaith-Hamilton Pleasure Scale	SHAPS
Spence Child Anxiety Scale	SCAS
Stroke Impact Scale 3.0	SIS 3.0
Structured Assessment of Depression In Brain-Damaged Individuals	SADBD
Test di Daniels-Test di Deglutizione Dell'acqua	
Toronto Alexithymia Scale	TAS
Triple Q Questionnaire	
Ureteral Stent Symptoms Questionnaire	USSQ
Valutazione Grafica del Paziente Anziano Ospedalizzato	VALGRAF
Wisconsin Brief Pain Questionnaire	BQVD
World Health Organization – Well-Being Questionnaire / World Health Organization-Diabetes Treatment Satisfaction Questionnaire	WHO-WBQ/WHO-DTSQ

\*The original name of the instrument was reported. Therefore, the Italian names or acronyms were not translated.

**Table 3**

Characteristics of the instruments retrieved (n = 101): domain, population, setting and other methodological issues

	n (%)
<b>Domain</b>	
Patients problems	63 (62.4)
Patients outcomes	27 (26.7)
Patients risks	4 (4.0)
Other issues (e.g. therapy, prognosis)	7 (6.9)
<b>Population involved in the validation study</b>	
Children/adolescents	8 (8.0)
Younger adults (> 19)	49 (48.5)
Older adults (> 65)	40 (39.6)
Not indicated	4 (3.9)
<b>Setting chosen for the validation study*</b>	
Hospital	53 (60.2)
Home care	18 (20.4)
Residential care	8 (9.1)
Not indicated	22 (21.7)
<b>Tool form</b>	
Questionnaire	61 (60.4)
Observation grid	27 (26.7)
Other (e.g., graphic structure)	12 (11.9)
Not indicated	1 (1.0)
<b>Number of items (95% CI)</b>	21.5 (17.1-25.7)
<b>Instrument compilation</b>	
Health-care workers	55 (54.5)
Patient	42 (41.6)
Nurse/patients	3 (3.0)
Care-givers	(0.9)

\*Some instruments were validated in more than one setting.

and instrument development, has been recently established in Italy. More impulse to pursue instrument development might be well received by PhD students and doctorates in nursing science in the near future [22].

Although the adoption of specific keywords such as "nursing", instruments not typically used in nursing practice have emerged (e.g., Geriatric Depression Scale, Geriatric Index of Co-morbidity). This may suggest that instruments are adopted interchangeably by health-care workers according to the needs of the patients overcoming the borders of the professional profiles.

Instruments developed in Italy are mainly published among Italian journals and in Italian language given that the national circuit makes these tools more accessible

**Table 4**

Instruments validation processes documented in the article retrieved

Validation processes	n (%)
<b>Trans-cultural validation*</b>	
Documented	55/87 (63.2)
Not documented	32/87 (36.8)
Forward translation	47/55 (85.5)
Backward translation	41/55 (74.5)
Forward + backward translation	39/55 (70.9)
<b>Validity**</b>	
Face	49/101 (48.5)
Content	45/101 (44.6)
Criterion validity	49/101 (48.5)
Construct validity (factor analysis)	35/101 (34.6)
<b>Reliability</b>	
Internal consistency	71/101 (70.3)
Test-retest (stability)	47/101 (46.5)
Inter-rate reliability***	28/59 (47.4)

\*Appropriate only for those instruments developed in other countries (n = 87); \*\*appropriate for all instruments (n = 101); \*\*\*appropriate only for 59 instruments.

in the clinical practice. However, international visibility may be threatened. The tools developed abroad, and therefore validated in the Italian context, are instead published mainly in international journals. In addition, the majority of those instruments originated in other countries and then were validated in Italian language; maintaining their original name assuring easy adoption in cross-national studies, and equally easy comparison of the data collected across different settings.

To our knowledge, no previous studies have been published with a similar aim: therefore, any comparison with the instruments available in other countries, especially in that none-Anglophone countries, where the trans-cultural validation should be undertaken for instrument developed in English language, is possible.

#### **Domain, population, setting and other methodological issues**

Patients' problems, in particular, pain, functional dependence and depression, were the primary domains considered by the tools. These issues are in line with the recommendation made by the available national guidelines (e.g., pain control [23]), with epidemiological data/trends (e.g., disability, co-morbidities) and with the clinical assessment tools needed in nursing daily practice [24]. However, while more attention has emerged towards actual problems (e.g. pain, malnutrition), few instruments were focused on risk factors (e.g., falls, confusion, pressure sores) despite the emerging risk management policies [25]. The lack of instruments evaluating the risk of the patient also threatened any possibility to develop accurate indicators measuring the occurrence of a problem (e.g., malnutrition, pressure sores) among the at risk patients. In addition, no instruments were focused on pressure ulcers, and few instru-

ments were focused on the risk of falls both of which are considered outcomes sensitive to nursing care [24].

The population involved in the validation processes were, primarily younger adults and older adult patients. The validation processes have involved a large number (from 10 to 8280) of patients or their care-givers mainly in the hospital setting; this is to be expected, given that the hospital is still the privileged place of clinical training and research. The selection of the population and the setting involved in the validation process is crucial because it affects the external validity of the instrument [25]. Therefore, more diversification is suggested in the included population in further studies; especially those involving the care-givers, who are important informants in measuring the problems affecting patients not cognitively competent. More attention should also be given to the development of tools dedicated to community, home and residential care settings where a consistent number of patients are cared for in long-term processes of care.

The instruments were structured primarily in the form of questionnaires, which require cognitively competent patients. Considering the lack of instruments available for care-givers, patients not cognitively competent or those with some deficits in speaking, reading or listening are at risk of not having their need measured [26]. Few instruments (around 26.7%) were grids based on patients' observation while any objective measure of performance (asking an individual to perform a specific task by detecting pre-defined standards) was retrieved. Nurses should also develop and validate instruments for cognitively impaired patients and instrument objectively measuring patients' problems.

The instruments retrieved were composed by a variable number of items, according to the complexity of the phenomena measured. On average, the instruments were composed by 21 items, ranging from 3 to 140, with inevitable problems of timing of completion and compliance by health-care workers, patients and care-givers.

### **Validation processes undertaken**

The first validation process formally published in Italy dates back to 1983 (GDS – Geriatric Depression Scale and CES-D – Centre of Epidemiologic Studies Depression). Only some years early (1980) at the international level, the first publication of a validation study was published [27].

According to the data, the validation processes of some instruments dates from the early eighties: some variations have occurred in the health-care settings, problems, and also in the health-care professional competences that may affect the generalisability of findings [25] in the current clinical nursing practice. Therefore, it is necessary to re-consider some instruments already validated, with the aim to update their psychometric values in the current clinical practice.

The tools developed in the Italian context appear to be more accurate in documenting the face and content validity. Differently, when tools have been originally developed in other countries and therefore transferred to the Italian practice, cultural and linguistic validation processes seem to be documented to a lesser extent.

Possibly, many validation processes, although conducted, are not reported in the articles. However, before undertaking any decision regarding the adoption of an instrument in the clinical practice, it is also recommended that the evaluator verify the cultural and linguistic appropriateness of the tool.

Less than half of the instruments have been fully validated in their construct validity and criterion; similarly, less than half were evaluated with reliability. The criterion validation is limited by the fact that few instruments evaluating the same constructs are available as a gold standard [18-20]. Regarding the limited number of instruments in which construct validity was retrieved, Watson & Thompson [28] have reported similar results. Analysing studies published in the *Journal of Advanced Nursing* from 1981 to 2004, the factor analysis was reported for only a limited number of cases (14/100 articles included in the review). In our systematic review, the percentage is slightly higher (34.6%) and thus suggests that more completeness in the validation process is achieved in recent years both at the international and at the national level.

On average, each instrument has been evaluated on three different validity/reliability properties (95% CI 2.86 - 3.54). According to the number of validation processes suggested by the literature [1; 16-20] comprising eight evaluations (content validity, face, internal consistency, inter-rater, and intra-rater reliability, stability of the measures and factor /confirmative analysis), it is suggested that additionally validation measures should be undertaken in further validation processes. Among those reviewed, the Geriatric Anxiety Inventory evaluating anxiety in older adults, has been widely validated: documentation regarding face validity, content validity, internal consistency, inter-and intra-rater reliability, stability and criterion validity is reported in the retrieved article [29].

### **Study limitation**

Only articles reporting validation studies were included; however, not all instruments that undertook a validation process have been published. In addition, this systematic review has included articles published up to March 2012 thus, it is possible some in process-publications have been excluded due to the time-lag of publication [30]. Aiming to update the census of the instruments available, a periodical systematic review of the literature is, therefore, suggested.

Furthermore, some validations processes are also contained in clinical articles when author(s) justify the use and the appropriateness of the instrument(s) adopted in their research. Therefore, articles documenting validation processes described synthetically but not mentioned in the abstract, keywords (MeSH) or title might be excluded. Aiming to facilitate researchers and clinicians in retrieving instruments psychometric properties, the word "validation" is suggested to be included among the key words of articles when the instruments properties are assessed.

The literature review was aimed to develop a census of the instruments available. According to this aim, the quality of the validation process conducted was not critically assessed.

## CONCLUSIONS

Deciding which instrument is appropriate is crucial both for clinicians and researchers [16]. Instruments adopted in clinical practice and research may affect the quality and validity of the information obtained, as well as the effectiveness of the decision-making process, patient safety and health-care services costs [1].

A total of 101 instruments, which provide a wide range of possible clinical assessments on patients, were retrieved. However, according to the emerging need of nursing discipline (e.g., estimating the risk of pressure ulcer healing, malnutrition), and to the well established knowledge on nursing sensitive outcomes, a limited number of validated instruments has emerged. Therefore, promoting the development of validation studies giving the priority to those instruments widely adopted in the clinical practice (e.g., falls, malnutrition, and pressure ulcers) is recommended. In addition, given that the majority of the instruments reviewed have

been validated in the hospital, undertaking re-validation process aiming to compare their psychometric properties in different settings and populations is also recommended. In addition, with the aim to help nurses in adopting validated instruments as well as to identify the best instrument available, it would be useful to develop a database reporting all available validated instruments in Italian language as well as data on the critical evaluation of the quality of the validation process adopted and on the validation properties documented.

## Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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