

## EVALUATION OF THE QUALITY OF REHABILITATION TREATMENT IN NEURODEVELOPMENTAL DISORDER

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### SUMMARY

Complex disability is very difficult to manage. It usually subtends very serious clinical pictures, because it affects several body systems, or because it is associated with intellectual disability and behavioral disorders. Often affected patients are unable to communicate their basic needs. All these factors combine to make the management of these patients very complex, and those who care for them realize how important it is to find a way to detect their state and to identify their potential capabilities.

Developing appropriate rehabilitation programs for these patients requires additional effort and an assessment capacity that is as objective as possible. Few scales cited in the literature are capable of evaluating these aspects in patients with complex disabilities, among them the Barthel Index (Mahoney & Barthel 1965) and the Vineland Adaptive Behavior scale II (Sparrow et al. 2005). The majority of these scales often tend to depict the data regarding the disease to a degree of severity that precludes adequate individual rehabilitation program development. There is a dire need for a more appropriate instrument, an observational grid that is capable of identifying the potential of this patient population and evaluate the effectiveness of rehabilitation interventions provided.

The aim of the study is to evaluate the efficacy of rehabilitation interventions in a group of patients with IQ <32 (determined by the Vineland II scale) using an evaluation tool created ad hoc called D-Rubrics, designed with the intent to identify "micro-differences" between baseline (T0) and post-rehabilitation (T1). The goal is part of a more long term-term objective which involves developing an effective assessment tool for patients with complex disabilities. Such an assessment tool should be practical, easy to administer and useful in both clinical and research settings.

**Key words:** rehabilitation – interventions – scale - neurodevelopmental disorders - disability

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### INTRODUCTION

Complex disability is characterized by the co-presence of clinical symptoms and multisystemic signs, often severe, and usually associated with the patient's inability to communicate verbally.

Although the benefits of a range of disability-focused therapies have been well studied, little remains known about how they work, let alone how to monitor these benefits in a precise and reliable way (Poquérusse et al. 2018). This justifies the need for specific assessment systems capable of addressing such complex and difficult issues. In daily practice, rehabilitation facilities manage complex clinical situations and are required to establish the most appropriate and specific rehabilitation-educational interventions for individual users. This process requires the action of a multidisciplinary team, and quantitative instruments that are as objective and reliable as possible. Both of these are fundamental aspects essential when assessing the patient's condition, as well as in evaluating any changes and responses to the interventions proposed. Evaluation scales exist in the literature, most of which are designed to be concise and simple to complete, aspects which often result as inadequate for the special needs of patients with complex

disability. The results often tend to demonstrate an extremely severe condition, without any possibility of either differentiating individual abilities, or, most of all, of highlighting the potential, even if modest, that patients with complex disability may possess.

For example, the "Barthel Index", BI (Mahoney & Barthel 1965), is a widely used scale in many practice areas, that provides a quantitative measure of patient performance in the context of activities of daily life (ADL: Activities of Daily Living). The same argument applies to other evaluation scales such as the "Functional Independence Measure" (FIM) scale (Granger et al. 1986), which aims to provide a quantitative index of a person's degree of disability, and the "Supervision Rating Scale" (SRS) (Boake 1996) which provides an indication of the subject's need to be monitored and supervised.

Other scales exist which are more comprehensive and explanatory, but they are very complex and require a significant amount of time as well as the presence of highly qualified personnel to complete. These scales do not allow for frequent and flexible verification, both important prerequisites in clinical-rehabilitative practice. This is the case of the "Vineland II" scale (Vineland Adaptive Behavior) (Sparrow et al. 2005), designed to

assesses adaptive behaviors in those activities that an individual usually performs to meet the expectations of personal autonomy and social responsibility as compared to a cohort of the same age and cultural context. Specifically, it aims to measure adaptive behavior in the following domains: communication, everyday life skills, socialization and motor skills.

The lack of sensitivity of measurement tools in severe disability is well documented in the literature: in 1989 Shah and colleagues proposed a scale capable of implementing the sensitivity of the Barthel Index by expanding the number of categories used to record improvement in each subscale, while simultaneously revising the scoring method, thus developing the "Modified Barthel Index", or MBI (Shah et al. 1989). Despite these improvements, over the years even the latter scale was deemed not very sensitive in assessing patients with severe and complex disabilities.

This introduction allows us to highlight the need for an evaluation tool capable of measuring the functional status / level of independence of a patient at any given time. The systematic nature of this process would allow for appropriate planning of rehabilitation-educational interventions, and the effectiveness of these interventions could be assessed by re-verification utilizing same instrument.

In 2012 our rehabilitation facility, the Serafico Institute, was included in a research study promoted by A.R.I.S. (Religious Association of Socio-Health Institutes), AGE.NA.S. (National Agency for Regional Health Services) and eight Italian IRCCS and sponsored by the Ministry of Health, entitled: "*Study of the developmental prospects of rehabilitation services aimed at satisfying the demand for health and functional independence of disabled subjects with emphasis on sustainability of central and regional policies in the health care sector and the integration between social welfare and health*".

The research study in question led to the formation of a permanent, multi-regional observatory, later extended nationally, whose responsibilities include monitoring rehabilitation needs, responses and expenditures in the evaluation forms available to the centers involved, while empowering these centers to guarantee and verify essential levels of assistance provided in each region.

The Serafico Institute's contribution to the study was in providing comprehensive assessment on a group of 10 boys between the ages of 14 and 18 with varying degrees of intellectual disabilities. The assessment was conducted using the Vineland functional scales for adaptive behavior (Sparrow et al. 1984) and the Praxia Examination (Scuccimarra et al. 2004) in two different time periods: before treatment, and at 6 months post-onset of treatment. Any changes detected during the treatment period were documented and all treatments conducted were assessed both in a quantitative and qualitative manner. In addition, competencies in ADL performance were identified via compilation of an *ad*

*hoc* checklist developed by the promoters of the project and referred to as the "Basic ADL Exam" which included four macro areas of evaluation: dressing, feeding, personal hygiene and transfers/mobility. Each area contained a number of specific items to assess. For each of these items the skill level of the individual patient could be assessed via a 0 to 4-point scoring system, (from "0" corresponding to 0% of task completion, to "4" corresponding to between 75% to 100% of task completion). We immediately realized that in order to guarantee maximum accuracy in the scores provided it became important to introduce a greater level of detail in the individual ADL items proposed for each of the four macro areas indicated so that the actual abilities of each subject in each item assessed could be more appropriately identified.

Our search for a more precise and valid assessment instrument oriented us towards utilizing a unique methodology involving the application of assessment grids referred to as rubrics (Cawley 2013). Upon further research, we adopted various checklists purchased from [www.YourTherapySource.com](http://www.YourTherapySource.com), an online resource for special education, pediatric occupational and physical therapy publications used in the clinical setting.

Specifically, the following checklists were purchased:

- for the clothing macro area: the Dressing Skills Rubrics (2011);
- for the feeding macro area: the Meal Time Rubrics (2011);
- for the personal hygiene macro area: the Personal Hygiene Rubrics (2011);
- for the movements macro area: Mobility Rubrics (2011).

The instruments were well received by the staff involved in the project who appreciated its ease of application in both educational and rehabilitation areas. The multidisciplinary work group formed during the study suggested that an evaluation tool of this nature would be invaluable for the entire patient population with complex disability residing in the institute. Following an initial assessment of the instrument's applicability to different types of complex disability, the study group formulated several proposals for adapting the instrument to assess patients with very severe illness as well as for those patients with visual deficits. An initial draft of a specialized task analysis resulted (analysis of abilities / activities) that was introduced in all living groups, followed by a period of staff training regarding assessment and documentation procedures, where meticulous observation for precise detection of ability was emphasized. These aspects served as core elements in developing the actual ADL assessment project now referred to as D-Rubrics.

The primary aim of this study is to analyze preliminary data obtained from compilation of the current version the D-Rubrics with the goal of establishing concurrent validity of the instrument.

We expect a strong correlation between this new assessment tool and the MBI, which is validated and assesses the same construct. We did not take the BI into consideration given its very low sensitivity in severe disability.

The secondary aim of this study is to evaluate any differences between the values obtained from the above-mentioned instruments (D-Rubrics versus MBI) administered at baseline (T0) and following rehabilitation intervention, already a fundamental cornerstone of the Serafico's practice model, but patient-specific using specific items targeted for reevaluation at T1. We expect that only the D-Rubrics tool will highlight differences in the scores observed between T0 and T1, while no differences in scores will emerge by the other measure.

## SUBJECTS AND METHODS

### Subjects

A power analysis was used to estimate the adequate sample size for the repeated measures analysis of variance. A total sample size of 189 subjects allowed us to highlight, at a threshold of  $\alpha = 0.05$  and with a power (1-beta) of 0.8, an average of the effect (Effect size  $f$ ) equal to 0.25 standard deviations, as described by Cohen (1988).

In consideration of the small size of the sample used, the study is classified as a pilot and, if the expected results will be confirmed, will eventually be extended to a greater number of patients.

For this study, the inclusion criteria were as follows: age 18 and over, QI less than 70 (valuated by Vineland II) and SRS (Supervision rating scale)  $\geq 4$ .

The group studied ( $n$ ) consisted of 33 patients, 28 male, 5 female, with ages ranging from 18 to 40 years (Mn 27.12; Sd 7.40), classified secondary to DSM-V diagnostic criteria: Autism spectrum disorders (ASD) ( $n=8$ ), Intermittent Explosive Disorder (IED) ( $n=10$ ), dual ASD and IED diagnosis ( $n=6$ ) and other behavioral disorders ( $n=10$ ). QI was evaluated via assessment using Vineland II and demonstrated the following distribution: a score of 20 for  $n=32$  patients (classified as having profound intellectual disability), and a score of 31 for  $n=1$  patient (classified as severe intellectual disability) (Mn 20.32; Sd 1.89). Every patient in the group presented a pathological syndrome affecting neurodevelopment,  $n=5$  patients with a definite genetic diagnosis (Down Syndrome, Angelman Syndrome, Dravet Syndrome, Fragile X syndrome and WAGR syndrome),  $n=2$  patients with cerebral palsy, and the remaining  $n=26$  patients without a definite diagnosis.

All patients in the study were classified as independent for ambulation.

### D-Rubrics

This evaluation grid is structured to permit the user to assign a numerical score to the ability to perform the components of a specific ADL task.

The grid is divided into 4 main groups, referred to as "macro areas", each related to different aspects of the basic activities of daily living: feeding, personal care, dressing, mobility.

These macro areas are further divided into sub-groups, or "items", which define very specific activities (for example: "bringing food to the mouth with the hands"). Each item belonging to a macro area is broken down further into a series of "components" describing the individual actions that the patient is required to perform to complete the sequence required by the item. For example, for item 1 in the macro area of Feeding ("Bringing food to the mouth with the hands"), the patient's ability to "grab the food in question" is assessed first, followed by the ability to "maintain the food between the fingers without dropping it", etc...).

Each component is assigned a score ranging from 0 to 4, and defined as follows:

- 0 - corresponds to "totally dependent";
- 1 - corresponds to "important physical assistance and/or verbal cues required to complete the task (gestures or icons/symbols)";
- 2 - corresponds to "slight physical assistance and / or verbal cues required to complete the task (gestures or icons/symbols)";
- 3 - corresponds to "capable of performing the action but the quality of the performance, the attention level and participation are inconsistent";
- 4 - corresponds to "independent and appropriate task performance".

The scores assigned to each "component" of an item are then added up, and the total obtained allows the evaluator to quantify individual performance relative to the "item" in question. The individual total scores of each item are added up and the totals generate a numerical value for the macro area in question. The higher the numerical value, the greater the patient's level of independence in that macro area.

### Modified Barthel Index (Shah et al. 1989)

The Barthel Index explores items related to mobility, transfers, ambulation, personal hygiene, feeding, and bowel and bladder control. Scores of 0, 5, 10 or 15, are assigned based on the degree of independence demonstrated by the subject performing the single action.

The resulting score measures the level of assistance that the patient requires in order to perform the activities of daily living in question.

The minimum value possible ("0") indicates complete dependence, while the maximum value possible ("100") represents complete independence.

Due the diversity of the population being studied a more sensitive scale was deemed necessary to ensure accuracy in evaluating competence in this specialty area of rehabilitation. The Modified Barthel Index was identified as more sensitive when compared to the original

Barthel Index. The MBI provides a detailed scoring system, with shorter numerical intervals between competence levels (scoring distributions: 0, 2, 5, 8, 10; or 0, 1, 3, 4, 5; or 0, 3, 8, 12, 15).

The scoring of the MBI is no more difficult to score than the original Barthel Index, nor does it increase completion time for trained assessors. In addition, its use improves internal consistency and provides improved discrimination of functional ability.

### **Vineland II** (Sparrow et al. 2005)

This scale evaluates level of adaptive behavior, which is necessary when forming a diagnosis of intellectual disability disorder and, in agreement with DSM-5 criteria (Diagnostic and Statistical Manual of Mental Disorder, fifth edition). It is also required for establishing the severity of the disorder.

Consequently, according to the diagnostic criteria for intellectual disability, patient performance which is at least 2 standard deviations lower than the reference group will be sufficient for making a positive diagnosis.

This instrument consists of 4 scales, or "domains," with each domain divided into 11 subdomains:

- Communication (Receptive, Expressive and Written).
- Daily Living Skills (Personal, Domestic and Community).
- Socialization (Interpersonal Relationships, Play and Leisure Time, Coping skills)
- Motor skills (gross motor and fine motor).

Compilation of these scales was carried out by designated personnel based on the type of scale. The compilation of the D-Rubrics, the Barthel Index and the Modified Barthel Index were carried out by a selected group of assistants/carers and were supervised by the assessment team composed of the following members: pedagogist/educational specialist, psychologist, various rehabilitation specialists, occupational therapist, physiatrist and neurologist (from this point referred to as the rehabilitation team).

The Vineland-II was completed by a psychologist trained in test administration and scoring of the assessment.

### **Procedure**

This observational study was approved by the local ethics committee of the Umbria Region (Italy). Informed consent was obtained from parents and/or guardians of the patients involved in the study following full disclosure of the study's purpose and possible implications. Data was collected once informed consent was obtained.

Prior to actual data collection 10 assistants/carers on staff were identified and received specific training in item analysis and scoring procedures. Each staff member was assigned a patient in the study and was responsible for completing both the D-Rubrics and the

Modified Barthel Index for the assigned patient at two different times: at baseline (T0) and at three months post-intervention (T1).

In accordance with the Serafico Institute's practice model, upon completion of the initial evaluation phase (T0) the rehabilitation team established a specialized rehabilitation treatment plan for each patient, focusing on those skills identified as having potential to improve. Each treatment intervention lasted for three months; at the end of the intervention phase the carers/assistants completed the entire evaluation protocol for a second time.

### **Statistical Analysis**

Descriptive statistics including mean and standard deviation were performed for all scales analyzed. To analyze the Internal Consistency of each macro area comprising the D-Rubrics (feeding, dressing, personal care and mobility), Chronbach's alpha values were calculated with a value of  $\geq 0.70$  being considered acceptable (George & Mallery 2003). In terms of concurrent validity Spearman's rank correlation coefficients were calculated for these preliminary results in order to examine the strength of the relationship between D-Rubrics macro areas and total score with those subscales that take into consideration the same activities and total score of the Modified Barthel Index. For example, the D-Rubrics Feeding macro area was compared to the MBI Feeding subscale, and the D-Rubrics Mobility macro area was compared to the MBI Transfers, Mobility and Stair Climbing subscales. A coefficient  $\geq 0.70$  was considered adequate. Finally, in order to investigate the sensitivity of the D-Rubrics in demonstrating the differences in performance between pre- and post-rehabilitative interventions, Repeat Measure Analysis were run for all measures. For all statistical evaluations  $p < 0.05$  was considered indicative of significant differences. The Statistical Package for Social Science (IBM SPSS Version 21) was used for conducting all data analysis.

### **RESULTS**

Mean levels of each D-Rubrics macro area and total score as well as of each subscale and total scores of MBI are reported in Table 1.

As shown in table 1 Cronbach's alpha of each D-Rubrics macro area was calculated to analyze internal consistency. It was excellent for all macro areas ranging from 0.986 to 0.918.

In Table 2 data regarding Spearman's rank correlation between the D-Rubrics macro areas and total score and MBI subscales and total score are reported. Data showed correlation from moderate to strong between the single D-Rubrics macro areas and the MBI subscales that assess the corresponding ability. Only the Mobility subscale showed a slightly lower than 0.70 correlation. A close correlation also emerged between the Total scores of D-Rubrics and the MBI total score.

**Table 1.** Descriptive statistics means and standard deviations for D-Rubrics macroareas and MBI subscales and total scores. Cronbach's alpha of D-Rubrics macroareas

	Totale Sample		Cronbach's $\alpha$
	Mn $\pm$ Sd	Min - Max	
<b>D-RUBRICS</b>			
Feeding	49.63 $\pm$ 28.62	1.60-100	0.939
Personal Care	35.44 $\pm$ 26.24	0-93.42	0.961
Dressing	45.43 $\pm$ 31.91	1.67-100	0.986
Mobility	73.30 $\pm$ 24.45	7.42-100	0.918
Total	48.68 $\pm$ 27.19	2.29-98.61	
<b>MBI</b>			
Feeding	6.09 $\pm$ 2.55	0-10	
Personal Hygiene	1.71 $\pm$ 1.60	0-4	
Bathing Self	1.71 $\pm$ 1.60	0-4	
Toilet	5.12 $\pm$ 2.54	0-8	
Bowel Control	6.29 $\pm$ 3.96	0-10	
Bladder Control	6.44 $\pm$ 4.00	0-10	
Dressing	5.76 $\pm$ 2.71	0-10	
Ambulation	11.09 $\pm$ 2.58	0-15	
Chair/Bed Transfers	13.00 $\pm$ 2.65	3-15	
Stair Climbing	6.32 $\pm$ 2.92	0-10	
Total	63.21 $\pm$ 21.83	6-94	

MBI: Modified Barthel Index

**Table 2.** Spearman's rank correlation to explore the Concurrent Validity of the D-Rubrics

MBI	D-RUBRICS	Feeding	Personal Care	Dressing	Mobility	Total
Feeding		0.758**				
Personal Hygiene			0.807**			
Bathing Self			0.753**			
Toilet			0.843**			
Bowel Control			0.851**			
Bladder Control			0.814**			
Dressing				0.761**		
Ambulation					0.669**	
Chair/Bed Transfers					0.740**	
Stair Climbing					0.676**	
Total						0.879**

\*\* p<0.001; MBI: Modified Barthel Index

Table 3 demonstrates the Mean and SD at T0 and T1 of each single scale of D-Rubrics and MBI, the respective delta scores ( $\Delta$ ) and the results of Repeat Measure Analysis.

The Repeat Measure Analysis highlighted significant differences between T0 and T1 in specific macro areas of the D-Rubrics following rehabilitation intervention. The measures demonstrated slight differences in two areas, in feeding ability (F=11.14; p=0.002), in personal care ability (F=12.75; p=0.001) as well as in the Total score (F=8.79; p=0.006). The differences between pre- and post-interventions of the Mobility macro area was also near statistical significance (p=0.06). It was not possible to perform the Repeat Measure Analysis for any of the MBI subscales having reported the same scores in both cases ( $\Delta=0$ ).

## DISCUSSION

In the complex disability field, the literature provides limited data regarding appropriate evaluation methods. This study arises from an awareness of the lack of instruments capable of detecting and measuring patients' clinical-functional status and any changes which result, however minimal, over time, with the goal of monitoring the effectiveness of rehabilitation interventions.

One of the main goals of this study was to analyse preliminary data regarding the validity, reliability and sensitivity of a new assessment tool designed to evaluate and detect changes in functional status / level of independence following rehabilitation intervention of patients with complex disability. A strong limitation of this study is the small sample size, yet this is justified

**Table 3.** Repeat Measure for D-Rubrics macroareas and MBI subscales and total scores

	T0 Mn ± Sd	T1 Mn ± Sd	Δ	F	p
<b>D-RUBRICS</b>					
Feeding	49.63±28.62	50.68±28.22	1.05	11.14	0.002
Personal Care	35.44±26.24	36.08±25.86	0.64	12.75	0.001
Dressing	45.43 ±31.91	45.73 ±31.69	0.30	1.85	0.183
Mobility	73.30±24.45	73.62±24.43	0.32	3.87	0.060
Total	48.68±27.19	49.17±26.96	0.50	8.79	0.006
<b>MBI</b>					
Feeding	6.09±2.55	6.09±2.55	0	-	-
Personal Hygiene	1.71±1.60	1.71±1.60	0	-	-
Bathing Self	1.71±1.60	1.71±1.60	0	-	-
Toilet	5.12±2.54	5.12±2.54	0	-	-
Bowel Control	6.29±3.96	6.29±3.96	0	-	-
Bladder Control	6.44±4.00	6.44±4.00	0	-	-
Dressing	5.76±2.71	5.76±2.71	0	-	-
Ambulation	11.09±2.58	11.09±2.58	0	-	-
Chair/Bed Transfers	13.00±2.65	13.00±2.65	0	-	-
Stair Climbing	6.32±2.92	6.32±2.92	0	-	-
Total	63.21±21.83	63.21±21.83	0	-	-

MBI: Modified Barthel Index

by the fact that developing systematic and reproducible programs with patients with complex and severe disabilities is complicated. Another limitation is represented by the brief period for follow-up, which was designed to obtain a preliminary idea of the instrument's ability to capture minimum variations even in a short amount of time. Despite these limitations, the results have demonstrated some very interesting data revealing excellent internal consistency, proof that the D-Rubrics is capable of measuring the abilities in question and does it in a coherent and reliable manner.

Even the data regarding the Spearman's rank correlation between the D-Rubrics and the MBI demonstrated a moderate to strong correlation, indicating that the construct measure of the D-Rubrics is comparable to the construct measure of the MBI, a measure which is already validated and widely utilized in the field of disability assessment.

The data were collected at the baseline (T0) and following a 3-month period of educational/ rehabilitation intervention (T1). The interventions included in the routine treatment plan focused on those aspects / items identified via D-Rubrics as having the greatest potential for improvement. This allowed for an exploration of the instrument's sensitivity to change and also proved the insensitivity of the MBI to measure minute differences in functional status of those patients who demonstrate very little improvement their abilities ( $\Delta$  score=0). The D-Rubrics reaches significant sensitivity particularly in the macro areas of feeding, personal care, and in the total scores. Statistical significance is not obtained in the mobility

macro area, most likely because patients show exceptionally high scores at T0. In this case it is possible to hypothesize that the patients in question have already reached their maximum level of performance at baseline, considering previous rehabilitation interventions carried out in the institute.

For the dressing macro area, the data are far from reaching statistical significance. This may depend on the complexity of the skill components involved in the ability to dress oneself. The degree of dexterity and fluidity required by the motor prerequisites necessary to dress oneself is high, and 3 months of rehabilitation intervention is most likely insufficient to achieve any appreciable result.

Despite the limitations of the study the data obtained were extremely encouraging. Future studies are being planned to prove the consistency of these results over time and with a larger patient population.

## CONCLUSIONS

This study identifies the urgent need for an evaluation scale capable of establishing the clinical condition of patients prior to educational/rehabilitative intervention with a high degree of sensitivity, as well as identifying even minimal improvements post-intervention. The D-Rubrics scale seems to represent a very solid evaluation tool for use in complex disability, with an acceptable degree of sensitivity and excellent internal consistency.

A larger cohort of patients with a longer follow-up period is required to confirm the data presented.

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**Conflict of interest:** None to declare.

### Contribution of individual authors:

Moreno Marchiafava, Chiara Bedetti & Silvia Ilicini: study conception and preparation.

Silvia Ilicini & Sandra Cicuttin: identification and acquisition of the original assessment instrument, adaptation of the original assessment instrument, drafting and manuscript translation.

Patrizia d'Alessandro, Antonella Baglioni, Marina Menna, Gianni Alberto Lanfaloni & Maria Grazia Rossi: study preparation.

Livia Buratta: statistical contribution, data interpretation.

Massimo Piccirilli, Marilena Gubbiotti & Sandro Elisei: manuscript revision.

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