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Abstract

BACKGROUND: The use of standardized assessment protocols is strongly recommended to identify patient's needs, outcomes, and predictors of response to specific interventions in Stroke rehabilitation. In 2008, the Italian Society of Physical and Rehabilitation Medicine (SIMFER) published the minimal protocol for the person with stroke (PMIC), in reference to the International classification of Functioning, Disability and Health.

AIM: In 2019, the SIMFER appointed a working group (WG) to provide a revised, updated version in line with the most recent literature and suitable for all rehabilitation settings: the PMIC2020.

DESIGN: descriptive study based on the consensus of a panel of experts

SETTING: all the rehabilitation settings

POPULATION: stroke survivor people with disability

METHODS: the coordinator of the SIMFER national Stroke Section appointed the WG, including the 8 Stroke Section board members, and 4 more experts (3 physiatrists; 1 neurologist). An extensive revision of the international literature on stroke assessment recommendations was performed; each proposed change from PMIC was written and motivated, discussed and voted.

RESULTS: The PMIC2020 is a single form, to be administered at any time of the rehabilitation pathway, including a minimum set of variables, consisting of a demographic/anamnestic section, and a clinical/functional assessment section. Newly introduced tools included measures of malnutrition (BMI<18,5); pain in verbal and non-verbal patients (Numeric Rating Scale-pain, Pain Assessment in Advanced Dementia Scale); neurological impairment (National Institute of Health-stroke scale); activity (Modified Barthel Index, Short Physical Performance Battery); and participation (Frenchay Activity Index).

CONCLUSION: The PMIC2020 provides an updated tool for the multidimensional rehabilitation assessment of the stroke patient, at any stage of the rehabilitation pathway; it aims to provide a shared minimum set of variables defining patient's needs and outcomes across different rehabilitation facilities and settings.

CLINICAL REHABILITATION IMPACT: The PMIC2020 identifies patient's needs, outcomes, and predictors of response to specific interventions in Stroke rehabilitation and provide ground for a highly needed Stroke Registry.

Key words:

Introduction

Although the treatment of acute cerebrovascular diseases has greatly advanced in the past two decades, stroke remains a catastrophic event and a major public health issue, as the second leading cause of death and the third leading cause of disability, worldwide[1]. In Europe, the Stroke Alliance for Europe (SAFE) has recently published a report predicting a 34% increase in the total number of strokes in the European Union between 2015 and 2035, with a move from 613,148 cases in 2015 to 819,771 in 2035, since the reduction in the incidence, essentially due to improved control of risk factors, does not balance the steady increase of stroke prevalence, due to both the greater longevity of the population and the lower mortality in the acute phase[2]. The Italian data are in line with the European: a decrease in the age-adjusted incidence of ischemic stroke, from 128 to 114/100,000 cases per year from 1990 to 2013, but not of hemorrhagic stroke, as from 53 to 54/100,000 cases per year were observed. The increase in prevalence was mainly due to the lower mortality in stroke acute phase; overall stroke mortality (standardized by age) decreased by 20% in ischemic stroke and by 25% in hemorrhagic stroke[2]. In the recent Coronavirus-19 pandemic, the European Stroke Organization warns against the even higher risk of death and post stroke disability due to much fewer persons with stroke symptoms actually seeking care, and to the suboptimal levels of acute and post-acute care they have received[3].

More than two thirds of stroke survivors experience post stroke disability and the recovery of participation is even more challenging, as more than 30% persons report persistent restrictions by 4 years after stroke onset[4]. Rehabilitation is effective in reducing post-stroke disability burden[4], but 80% stroke patients still report walking problems 3 months from the event, and only 50% recover independent walking at the end of rehabilitation[5].

The Individual Rehabilitation Plan (IRP) of the person with stroke must tackle not only sensorimotor impairment, but also all the possible associated problems, such as language, swallowing, sphincter and respiratory impairments, as well as pain, depression, cognitive and/or communication disability[6]. Furthermore, the rehabilitation process needs to promote the recovery of participation by addressing possible psychosocial problems emerging during the reintegration phase to the community; thus, teaming up with both patient and family/caregivers, to offer the best possible treatment options along the rehabilitation pathway, is a complex clinical and organizational challenge[5,7].

A comprehensive multidimensional assessment of the person with stroke is the first step in developing a patient-centered rehabilitation plan. The use of standardized assessment protocols is strongly recommended[6,8] to evaluate the effectiveness of rehabilitation treatments on large populations, and to allow the early identification of patient's characteristics predicting outcome and the response to specific interventions. Indeed, the SAFE has recently recommended that "the European Commission and the Joint Research Center should support and to promote at European level the development of a set of tools for assessing prevention and treatment needs, as well as the quality of assistance along the entire path of stroke "[2]. However, in many countries, including Italy, no national standard for rehabilitation assessment have been provided, and no quality benchmarking of different rehabilitation facilities and approaches is therefore possible[9].

In 2004, the Italian Society of Physical and Rehabilitation Medicine (SIMFER) and the IRCCS S. Lucia Foundation appointed a working group (WG) to draw up the first version of the minimal assessment protocol to follow the person with stroke from the acute to the chronic phase. In 2008, the "Minimum protocol for stroke - PMIC" was published and implemented in many rehabilitation units throughout Italy. Although it had been developed within the SIMFER, the PMIC implementation was promoted by individual

physiatrists, and only subsequently sponsored by SIMFER. This probably reduced the involvement of Italian physiatrists. Actually, the initiative was not promoted by the capillary structures of the SIMFER such as the regional secretariats, and its official adoption was sparse. Therefore, the aim of implementing the protocol as a common reference for all Italian physiatrists and as basis for a national Stroke Registry was not achieved. Moreover, with time, some critical points of the PMIC emerged. First, the PMIC consisted of three different forms, the first to evaluate the acute phase, dedicated to those physiatrists who carried out their activity in acute care wards as support to teams such as stroke units; the second to evaluate the post-acute hospital phase, dedicated to those who worked in inpatient intensive or extensive rehabilitation units; the third for those who worked in the community (outpatient rehabilitation, nursing homes). Thus, it was difficult to describe the patient' rehabilitation pathway as a continuum, and much information needed to be retrieved every time the setting changed. In fact, it was generally found that only the inpatient rehabilitation form was regularly completed, while the acute hospital and the outpatient rehabilitation forms were sparsely collected. The first was probably because rehabilitation issues were not sufficiently prioritized in the acute care setting, the second because it was consistently reported that the protocol took too long to be routinely applied in physiatrists' outpatient visits. Indeed, it's feasibility had been verified, but only for the inpatient rehabilitation form[10,11]. Another emerging issue was that, in line with the most recent literature, it became necessary to review and update some assessment tools. Thus, in 2019, the SIMFER appointed a working group (WG) to provide a revised, updated version. The aim of this study is to describe and discuss the updated version: PMIC2020.

Materials and methods

The WG was appointed in July 2019 by the coordinator of the Stroke Section of the SIMFER, and involved 12 experts: the whole board of the SIMFER Stroke section plus 4 specialists (3 physiatrists and one neurologist), with at least 10 years of experience in stroke rehabilitation; two experts, SP and MF, had also been involved in the original PMIC national project steering committee. The WG operated by collegial meetings and email communications. The WG started with a critical revision of the PMIC, both from the literature and from direct extensive clinical experience by most group members[10,11,12]. To the purpose of updating the PMIC, a search for national guidelines specifically focused on stroke was performed on July 2019 in PubMed (https://www.ncbi.nlm.nih.gov/pubmed), and Guideline International Network (www.g-i-n.net). The search algorithm used for PubMed was ("stroke rehabilitation"[MeSH Terms] OR ("stroke"[All Fields] AND "rehabilitation"[All Fields]) OR "stroke rehabilitation"[All Fields]) AND (Practice Guideline[ptyp]) and was adapted for the other database. Besides the Italian SPREAD Guidelines[6], two American, 2 Canadian, and 2 British Stroke Rehabilitation Guidelines[5, 13, 14, 15, 16], were identified, that were shared and discussed by the WG.

Through the collegial discussion on the PMIC's main critical issues, the WG reached an agreement on the objectives of the revision. Several intermediate drafts of the PMIC2020 were proposed, reaching a consensus in case of conflicting opinions by voting. The final version of PMIC2020 was therefore edited, including both the form and all the information on the adopted tools.

The reference framework was intended to maintain adherence to the International Classification of Functioning, Disability and Health of the World Health Organization (https://www.cdc.gov/ nchs/data/icd/icfoverview_finalforwho10sept.pdf) conceptual model of Functioning, thus the selected variables/tools covered the following domains:

structures and functions, activity, participation, contextual factors. We also made reference to the critical Areas for the development of the Individual Rehabilitation Plan, as described by Basaglia[17]: clinical stability, basic vital functions, communication/relation, emotional/affective and cognitive/behavioral, sensory motor function, mobility and transfer, activities of daily living, adaptation and social reintegration.

The PMIC2020 aims to provide each individual physiatrist and rehabilitation team a uniform tool for the assessment of the patient with stroke in the various stages of disease, from acute hospital care, to community rehabilitation.

In line with the PMIC previous version[10], the protocol requires the collection of a series of clinical-functional variables, for a comprehensive, though minimal, multidimensional assessment of rehabilitation needs, outcomes, and prognostic factors of stroke patients addressing rehabilitation services. In reviewing the variables, we aimed to maintain the comprehensive minimal assessment feasible, by giving our preference to rapidly administered tools, and searching for informative variables that could be easily and reliably collected in all rehabilitation settings, including outpatient routine physiatrist's assessment; further, we searched a high standard of validity, identifying internationally recommended, validated tools, and adopting, when possible, their Italian validated version.

Results

The PMIC2020 requires the recording of a minimum set of variables/tools presented in a 1 single-sheet form, printed on both sides (Figures 1). Compared to the previous version, providing 3 separate forms for the different phases of rehabilitation, the current protocol is a single-sheet form, including 2 sections:

1) demographic and anamnestic information, to be collected at the first contact with the person with stroke, regardless of the assessment setting;

2) clinical data and assessment tools, that can be used in the different phases of the disease, and in the different settings in which the interventions are carried out; this section should be re-assessed, every time it is deemed necessary for patient's monitoring.

According to the ICF model, the following domains were explored as following (newly introduced variables and tools in bold):

Contextual factors: Education, profession, **mother tongue**, family and caregiver support, **certification of disability**, current housing, architectural barriers.

Structures and functions: affected side; stroke etiology and classification (Oxfordshire Community Stroke Project - OCSP for ischemic stroke); thrombolysis/thrombectomy procedures; obesity: Body Mass Index (BMI) >30; **malnutrition BMI<18,5**; breathing; deglutition; urinary and fecal continence; pain: **Numeric Rating Scale (NRS)-pain**[18] substituted the VAS[19] and the **Pain Assessment in Advanced Dementia Scale (PAINAD)**[20] to assess pain in the non-verbal patient; spasticity: recorded for each articular district included in the **Modified Ashworth Scale (MAS)**[21]; trunk control: Trunk Control Test (TCT)[22]; motricity: Motricity Index (MI)[23]; cognitive status: Mini Mental State Examination (MMSE)[24]; neurological impairment: **National Institute of Health Stroke Scale (NIH-SS)**[25], substituted the Canadian Neurological Scale[26]; **Mood: Adequate / Deflected /Not evaluable**.

Activities: anamnestic and current modified RANKIN Score[27]; Lower limb performance (and frailty): **Short Physical Performance Battery (SFBP)**[28]; Ambulation: Functional Ambulation Classification (FAC)[29]; **basic Activities of Daily living: Modified Barthel Index** (**MBI**)[30] substituted Barthel Index[31].

Participation: ambulation/mobility: Walking Handicap Scale (WHS)[32]; **involvement in community, instrumental and leisure activities: Frenchay Acitivities Index (FAI)**[33].

A detailed description of each tool administration in Italian language can be found online (https://springerhealthcare.it/mr/numero/volume-34-n-2-giugno-2020/).

Discussion

The PMIC project was started to provide Italian physiatrists with a common ground for the assessment of persons with stroke at any given time after the onset. Although diffusely implemented, the PMIC failed to reach the objective of becoming a common reference frame throughout Italy, and each Italian rehabilitation facility still assesses stroke patients at different stages and with different methods. Probably, one reason may be due to the fragmentary nature of our health system, where every region and sometimes every local health authority states own requirements and guidelines. In this sense, the need of a National Rehabilitation Stroke Registry for evaluating stroke rehabilitation outcomes and allowing quality benchmarking of different rehabilitation models across Italian regions is stronger than ever[9].

As the SIMFER Stroke Board recognized that some critical issues of the PMIC had emerged, the appointed WG for PMIC2020 agreed to address a series of the PMIC's critical issues and re-propose an updated tool as a possibly reference for this highly needed Italian Rehabilitation Stroke Registry. The sparse collection of data on the post-acute phase was addressed by proposing a single form, aimed at providing a coherent description of patient's abilities and needs throughout the continuum of the whole rehabilitation path, and by removing or substituting some time-requiring and/or possibly redundant information; we also chose to further simplify the PMIC2020 by removing the synthetic description of the Individual Rehabilitation Plan (IRP), as exceeding the purpose of a minimal assessment tool. Finally, some tools that had become obsolete, according to the latest literature revision, were substituted.

In the PMIC2020, contextual factors are collected in the first section of the protocol, along with pathological anamnestic and general information; if the assessment will be informatized, these data could be collected only at the first access, and updated only as needed, thus speeding up the assessment process. Information was re-arranged and simplified to include education (years), profession (unemployed vs student/employed), mother tongue, family and caregiver support, certification of disability, previous and current housing, architectural barriers.

Structures and functions maintained the information already required in the PMIC as to stroke affected side, etiology and classification (OCSP for ischemic stroke)[34], thrombolysis/ thrombectomy. Malnutrition is recognized as a serious clinical risk factor, requiring systematic screening assessment and care, but in rehabilitation practice this rarely happens, also because of the lack of simple diagnostic criteria. Indeed, in the previous PMIC, malnutrition had not been considered among assessed variables, although a record of patient's weight and height was required. The European Society of Clinical Nutrition and Metabolism[35] recently provided a consensus-based minimum set of criteria for the diagnosis of malnutrition to be applied independent of clinical setting and etiology, identifying a cut off for low BMI (<18.5 kg/m2) as a criterion for the diagnosis of malnutrition. Therefore, the WG unanimously choose to adopt this definition to score malnutrition as well as the BMI>30 as a cut off for obesity in the PMIC 2020[35].

As to pain, Stroke survivors often experience pain, either of mechanical, neuropathic or mixed origin. Regardless of the cause, this symptom can burden quality of life for both patient and caregiver. In Italy the law N. 38/2010 *("Disposizioni per garantire l'accesso alle cure palliative e alla terapia del dolore"*, GU n. 65, 19 March 2010) guarantees the right of having pain daily measured in clinical settings and of receiving proper care for it, but this is often difficult to achieve for stroke patients especially for aphasic and or non-

collaborative patients. The PMIC included the VAS[19], but this tool is complex to score, as it requires the measuring of the intercept line drawn by the patient to score pain intensity on a 10 centimeter segment, representing the visual analogue of pain intensity from 0 to 10, and also to administer, since drawing the line requires both cognitive (at least comprehension) and motor abilities, and this led to a sparse collection of the pain assessment. To overcome this issue the NRS PAIN substituted the VAS; the NRS simply requires patients to state presence and severity of their current pain, from 0 (no pain) to 10 (most excruciating pain)[18]. This however still excluded non-verbal and non-collaborative patients, who can be a relevant share of stroke survivors, especially in the acute phase. A recent systematic review on the incidence and prevalence of pain-in aphasic patients after stroke, underlined the difficulty of identifying pain in these patients and concluded that a reliable and valid instrument is not available for them[36]. Thus, the WG agreed on adopting the PAINAD for pain assessment in non-verbal patients, an observation-based tool originally developed to measure pain in non-verbal demented patients, as it is both quick and easy to administer[20], and has recently proved good psychometric qualities in neurology patients unable to self-report pain[37]. As to motor impairment, we maintained the TCT for assessing trunk control, and the Motricity Index, which remained the only tool assessing motricity in upper and lower limb, as prospective studies confirmed a high predictive power of both tools for functional recovery and home discharge.[38,39] As manual dexterity is briefly assessed in the MI, the Nine Hole Peg Test for finger dexterity[40] was no more proposed, since its "optional" nature led to its sparse administration when PMIC was applied to clinical practice.

Another critical issue of the PMIC was the sparse collection of the spasticity assessment by the MAS[21] reported by the WG members who routinely used the PMIC. To maintain the minimal information about spasticity, the group chose to allow the simple yes/no

record of spasticity for each articular district included in the MAS, though recommending the MAS administration whenever possible.

Cognitive Impairments can precede, but also be a direct consequence of Stroke; cognitive status influences the outcome of rehabilitation and should be accurately assessed providing a qualitative and quantitative report of patient's problems and needs. For the PMIC2020's purposes, only a cognitive screening was possible. Since 2008, many other screening tools have been recommended for stroke patients. The WG focused on the MoCA[41] and the OCS[42]. Compared to the MMSE[24] the OCS allows screening of executive functions, and the separate evaluation of cognitive domains can be performed and scored even when a full assessment is not possible (for instance in aphasic patients). However, a recent review comparing the accuracy of cognitive and mood assessment in stroke survivors[43], found that, despite the large number of potentially available tools, only Folstein Mini-Mental State Examination and MoCA have enough literature to allow meta-analysis. Finally, the MMSE has become part of current physiatric comprehensive assessment, independent from the disease[44]. A recent review comparing MoCA, OCS and MMSE concluded that compared to MMSE, MoCA is extremely sensitive but has poor specificity, while MMSE has satisfactory sensitivity and specificity, and that MMSE required far less time to complete administration (<10' on average) than the other 2 tests[45]. Thus, after extensive discussion, the majority of the WG agreed on maintaining MMSE as a first screening tool, while suggesting to provide a separate assessment of executive functions or full administration of the OCS, when possible, and employing additional specific tests (as recommended by AHA/ASA and SPREAD Clinical Practice Guideline)[5,6] only as a second level assessment.

As a partial exception to the rule of choosing the most quick and easy to administer tool, all group members agreed on substituting the previous choice of the Canadian

Neurological Scale[26] to assess neurological severity with the National Institutes of Health Stroke Scale[25]. Indeed, although the two scales are highly related to each another, the NIH-SS is now the most diffuse scale not only in stroke clinical trials, but also in clinical practice, while the CNS is almost obsolete, at least in Italy. The NIH-SS indeed provides a deeper assessment of stroke-related impairment, including screening of level of consciousness, cognitive and communication abilities, sensory and visual as well as motor and coordination impairment[46]. The NIH-SS extensive use in the past decades proved its accurate predictive value as to clinical and functional outcome of stroke survivors[47]. NIHSS administration needs some specific training, but the Campus Biomedico has recently provided the possibility of achieving free online training, exam and certification in italian (https://secure.trainingcampus.net/UAS/Modules/TREES/windex.aspx). Further, as the NIHSS is invariably used in all neurological acute settings including stroke units, at least in Italy, its choice allows also a common language with the acute phase specialists and maintain the same assessment to monitor patients' progresses through time.

Another relevant predictor of rehabilitation outcome that had not been included in the PMIC was mood: depression is a common and serious complication after stroke, yet often is not detected or inadequately treated: nearly 30% of stroke patients develop depression, in the early stage or later after stroke; depression predicts functional recovery and burdens quality of life, but still many patients go undiagnosed and treatment is not constantly provided in common clinical practice[48]. The WG considered and discussed depression screening tools proposed by international and national Guidelines, but their administration time was unanimously deemed too long for the PMIC2020 purposes. Thus, the WG agreed on simply requiring a definition of Mood as Adequate / Deflected /Not evaluable, based on the physiatrist's anamnestic and direct assessment. Although this may provide limited information, the introduction of the requirement to systematically check and assess

depression may by itself increase the physiatrist's awareness of this dimension when assessing stroke survivors.

As to Activity, the anamnestic modified Rankin Score was maintained, and the current modified Rankin score (MRS) introduced[27], although it is strongly correlated with the more detailed, also included Modified Barthel Index[30]. This choice was to provide a common language with the acute care setting, where the MRS is invariable used to assess this dimension. The original Barthel Index[31] was substituted by the Modified Barthel Index (MBI) in the version provided by Shah et al[30], as the latter allows more discriminant levels to quantify the need for help and provides an accurate description of the abilities required to classify each score in any single level. Since some Italian regions still require the BI, it is possible to transcode the MBI score into the BI score[49]. The MBI can be scored by observing the patient performance (recommended in the inpatient and home settings) and by recording the patient's and/or caregiver's report (allowed for outpatient assessment)[30]. Although a stroke patient may recover full independence in the basic ADL considered in the MBI, his/her motor abilities may still be impaired, and this may be a risk factor to develop further disability; persons at high risk of developing (or worsening) ADL disability have been defined as frail[50]. Thus, we substituted the Tinetti assessment[51] of balance with the Short Physical Performance Battery (SPPB)[28], including a measure of standing balance, of the time needed to raise up and sit on a chair (5 times, arms crossed), and to walk 4 meters on an even, flat surface. The SPPB has not been specifically validated for stroke patients, but it was extensively used to evaluate lower limb motor performance in community older persons including stroke survivors[52].

The assessment of Participation takes on an important role in the multidimensional bio-psycho-social approach to stroke survivors, as highlighted in the reference model of the ICF. The Frenchay Activity Index (FAI)[33] has been introduced in the PMIC2020 to

integrate the Walking Handicap Scale (WHS)[32] as a measure participation. The FAI is made up of 15 questions that investigate the frequency with which domestic activity, leisure and outdoor activities are practiced in the last 3 and 6 months before the questionnaire administration, patients are stratified into 3 groups according to the degree of activity. The WHS allows the assessment of ambulatory performance in the form of an interview and investigates the journey in the domestic and community context; for each item, it is specified if the person is able to walk independently or if he/she needs assistance. For both questionnaires, it is important to record an anamnestic assessment (past 3 and 6 months before stroke), to be compared to current participation levels achieved by the patient.

Beyond synthetizing the PMIC2020 in a single form, designed to monitor all phases of the patient's rehabilitation pathway, and providing this critical re-organization and update of the assessment tools, other interventions have been promoted by the WG and by the SIMFER to address the critical issues of the previous PMIC. First, a multicentric feasibility study is being carried out by the WG, to verify the accessibility of all required information, as well as the time required for the administration of each single tool. This will allow to improve the protocol's feasibility, if necessary, and thus, possibly, facilitate its adoption in all rehabilitation settings. Second, to promote a more widespread diffusion of the PMIC2020 throughout Italy, the PMIC2020 has been presented at the SIMFER National Congress 2020, and a Webinar on its administration has been produced and made freely available on the internet to all SIMFER members. The WG has also proposed a 10-18 (one day module) theoretic and practical course on the PMIC2020 administration, that, according to the SIMFER regulations, can be provided wherever required in Italy by the local regional sections. Finally, through the Stroke Section, the SIMFER is taking direct contact with all the regional secretaries and the directors of the specialization school in

physical and rehabilitation medicine, to inform them about the contents and purposes of this initiative, and involve them in the dissemination of the PMIC2020 contents among the regional members and the students.

Conclusions

The PMIC2020 provides an updated tool for the multidimensional rehabilitation assessment of the stroke patient, at any stage of the rehabilitation pathway. It aims to identify a minimum set of variables, describing patient's clinical and functional profile, rehabilitation needs and outcomes across different rehabilitation settings and facilities, and to promote the adoption of a common reference tool for stroke rehabilitation assessment throughout Italy, possibly providing ground for a highly needed Italian Stroke Registry. The dissemination and implementation of PMIC2020 on a large scale will allow further research on its feasibility at different times from stroke onset and in different stroke rehabilitation settings.

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Notes

Titles of figures

Figure 1 — *PMIC2020 Form (single - sheet, printed on both sides)*

FIG. 1