The national institute of health toolbox

Madhuri Khilari, Sunil K. Narayan

Department of Neurology, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India

For correspondence:
Dr. Sunil K. Narayan, Department of Neurology, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India.
E-mail: sunil.narayan@jipmer.edu.in

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Prologue

National Institutes of Health (NIH) toolbox, with the blue print designed in 2004, and the detailed format for assessment published in 2013 has been introduced for uniform assessment of behavioral and neurological functions and aimed at the use in longitudinal epidemiologic studies and prevention or intervention trials for people aged 3-85. The toolbox is intended to be brief, comprehensive and validated state-of-the-art computer administered tests to cover the full range of normal functions. These methodologically sound constructs are available royalty free. The NIH toolbox assessment center is a free, online research management tool that allows a library of patient reported and examiner-administered instruments.[1] This critical appraisal aims at familiarizing readers with the NIH toolbox and appraising its practicability and its implications in the Indian context.

Core Domains: The NIH toolbox is a multidimensional kit designed on four core domains: Emotion, cognition, motor, and sensory-which in turn include multiple subcomponents, six unique sensory teams and supplementary measures comprising of questionnaires. The emotional subset includes administration of a questionnaire to cover subcomponents of positive and negative affect, stress and coping, social relationships. Assessment of cognition comprises of executive function, episodic memory, language, processing speed, attention and working memory. Motor domain encompasses endurance, strength, dexterity, locomotion and balance, whereas the sensory evaluation embraces the traditional domains of olfaction, taste, vision, audition, vestibular balance and somatosensation, all maintaining core features of brevity of assessment and ease of administration.

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Development of the NIH tool box: This colossal work has spawned from a methodological investigation in two phases, a first phase consisting of data collection and soliciting information from domain area experts from diverse multidisciplinary clinical and research communities and reviewing existing literature, with compilation of data toward the development of the toolbox and a second phase, which comprised of pilot testing and of testing applicability in diverse settings. During its development, further constructs were incorporated based on criteria like inter-rater reliability, responsiveness to real change, stability over time and also having equivalent translation into Spanish, along with a rational idea of providing lifespan coverage of the construct.[2] The toolbox also addresses the pediatric, geriatric, culturally distinct, and also disabled populations.[3] The declared aims include facilitating longitudinal assessment of neurological and behavioral functions with a validated, quantified, objective and computerized tool. There is also a bold new initiative in clinical neuroscience arena, incorporating a novel and easy set of measures to examine the impact of perturbations in non-neurological systems, on brain functions.[4] The toolbox consists of different constructs and comprises scoring in the individual items A commendable aspect of scoring of all the test items is their basis on Item Response Theory (IRT).[5] Parameters have also been assessed with the traditional classic test theory. Traditional psychometric methods rely on reliability, validity, and responsiveness of the tests and postulate the observed score as integration of a true score and an error score.[6] In contrast, the IRT embraces the concept of prediction of statistical and psychometric properties of a test so that the probability of any response of an examinee to an item may be predicted even if similar examinees have never taken similar items before. In short, it involves predictions about how people would behave in the real world and a representation of how an ability or skill of an examinee determines his or her response to an item.[7] Most of the constructs in the toolbox except for the motor and sensory evaluation are bolstered up by their evaluation based on the IRT. For each of the data, the constructs were analyzed to create population and age based norms of the instruments and the former have been designed to be modifiable in the

future if needed, without affecting the validity of previously collected data. The NIH toolbox was not hypothesized as an understudy for the detailed assessment of behavioral domain or its subdomains and does not target disease outcomes as they are conventionally done.[2] In the rest of the article, we would strive to acquaint the readers with the constructs of NIH tool box and deliberate on each of them separately.

Cognitive Battery

Cognition assessment in NIH toolbox is through a computerized battery. Computerized assessment may be uniquely suited to early detection of changes in cognition in the elderly. Several advantages have been cited for computer based tests including coverage of a wider range of abilities; minimization of floor and ceiling effects; a standardized format and a precise record of accuracy and speed of response with a level of sensitivity not possible in standard administrations.[8] The battery has been endorsed for pediatric age group (from 3 years) to 85 years of age with reasonable test-retest reliability as well as adequate convergent and divergent validity.[9] The constructs have been affirmed as brief, accessible, and psychometrically sound.[10] Each of the constructs has been defined and procedures to administer them explained along with the videos.[1,10] This toolbox assesses executive function, episodic memory, language, processing speed, working memory and attention as the most important constructs in use in day-to-day life, schooling and at work. An integrated attention network test based on modification of Erikson Flanker test was used, designed to test attention based on three networks of anatomical areas that carry out the functions of orienting, alerting and executive control (including conflict monitoring).[11] Flanker inhibitory control and attention test has been used as a marker of visuospatial inhibitory attention. (Flanker test is mentioned in NIH toolbox as the NIH-TB Flanker Inhibitory Control and Attention Test). Eriksen Flanker paradigm has also been used in studies for tracking the recovery of visuospatial attention deficits in mild traumatic brain injury patients. The list sorting test serves to assess the working memory and has been adapted from the Spanish and English Neuropsychological Assessment Scales (SENAS) that were created to provide psychometrically equivalent measures of multiple cognitive abilities in older English-and Spanish-speakers.[12] Dimensional change card sort test interrogates the executive function and assesses chiefly the set-shifting component, which is the cognitive flexibility to switch attention between one task and another. It has been widely used and is an established measure of executive function across a wide age range and assesses the development of these functions in children too.[13] Episodic memory is tested, using the picture sequencing memory test. It includes reproduction of multiple sequences in an order from a representation of the event in the absence of ongoing perceptual support. Its incorporation into the assessment of children has been based on previous appraisal of nonverbal memory recall in children.[14] The tools designed for language were the oral reading recognition test and the NIH toolbox picture vocabulary test. Reading has been included also as an overall estimate of general intelligence and has been used to determine the premorbid intelligence measured by the ability to read irregular words from the American version of the Nelson Adult Reading Test (AMNART).[15] Processing speed is assessed with the pattern comparison speed test and draws its origin from the Salthouse's pattern comparison task.[16]

Emotion Assessment

Emotion team identified four central subdomains: Negative affect, psychological wellbeing, stress and self-efficacy, and social relationships. Emotional assessment is based on the Watson and Clark paradigm where they had used two broad dimensions of negative and positive affect for testing emotions. According to this paradigm, negative affects have been hierarchically arranged into a Negative factor affect dimension, which can be due to depression or anxiety as they share general negative affect, and a higher order Positive affect, which has stronger negative association with depression than anxiety. They had proposed a structure with four first-order factors (Fear, Sadness, Guilt and Hostility) and one second-order factor (Negative Affect). In the NIH toolbox, Assessment of negative affect included second order factor (general distress) assessment and first order factors for assessment of anger, fear, and sadness.[17] Psychological wellbeing assesses eudemonic (psychological well-being) and hedonic (subjective wellbeing) measures.[18] Measurement tools were developed from large pools of questions in the form of item banks. For young children (3-12 years) proxy instruments were used and self-report instruments targeted more than 8 years of age.[5] The measures of emotional health concepts were also analyzed using IRT and classic test theory. However, the authors have stated several limitations on the emotional assessment toolbox, including modest convergent validity, weak psychometric properties, and as for indicators of child's emotional health, reliance on informant's data.

Sensory Assessment

Assessment of six domains is included here, consisting of gustation, olfaction, vision, vestibular system, audition and somatosensation/pain.

Gustation assessment

The toolbox uses two measures, for adult and pediatric population, respectively. In the latter group, assessment is by sucrose preference test alone whereas for the former, additionally the regional taste intensity test using general Labeled Magnitude Scale-placing the label "strongest imaginable sensation of any kind" at the top.[19] It also has a whole mouth perception analog where sucrose preference is used for ages 5-85 years and bitter taste assessment in those 12-85 years of age.

Olfaction assessment

Olfaction is assessed by two versions of odor identification test, first being the brief smell identification test, using standardized odor stimuli in a scratch-and-sniff format, based on the San Diego odor identification test,[20] which takes only <5 min for administration where 8 everyday food or household items are presented for sniffing in opaque plastic jars, where participants have to match five (for children) or nine (for adults) odours to pictures representing the odor source, The second, University of Pennsylvania's smell identification test[21] uses the microencapsulated scratch and sniff odors.

Vision assessment

Of the several components of vision, toolbox focusses on acuity of vision, due to its vital functional role and ease of assessment. The computerized static visual acuity test, based on Electronic Early Treatment of Diabetic Retinopathy Study (E-ETDRS) protocol and Amblyopia Treatment Study (ATS-HOTV) protocol, is administered with the former designed for children younger than 7 years of age and the latter for 5-12-year-old using the individual letters H,O,T and V presented as optotypes for visual acuity testing.[22] The ETDRS chart uses letters of equal recognition difficulty and uses the log of the minimal angle of resolution and has significant advantages over the old Snellen-type charts.[23] The toolbox also includes a supplemental measure called vision-related quality of life survey, which is a 53-item questionnaire on aspects like color vision and problems such as blurriness, headache and vision while performing different activities and in different intensities of illumination.[24]

Vestibular assessment

Vestibular assessment follows the static visual acuity test and is carried out by Dynamic Visual Acuity (DVA) and balance accelerometry measures, both being brief (taking <5 min), of low cost and suitable for wide range of 3 to 85 years of age.[25] Accelerometry offers a practical low cost method of objectively monitoring human movements and has been used to monitor a range of different movements, including gait, sit-to-stand transfers, postural sway and falls. These tests have been adapted from a sequence of six tests assessing the effect of sensory integration on balance, utilizing visual and surface support conditions.[26]

Audition

Audition is tested using an automated procedure with pure-tone thresholds as the main tool, based on the Hughson-Westlake method, where the minimum audibility is measured by progressively increasing the stimulus intensity.[27 There are also supplemental auditory measures in the form of tympanometry, speech perception in noise (words-in-noise test) and self-assessment of hearing impairment using a handicap inventory (for > 18 years age groups).[28]

Somatosensation and pain assessment

This section includes evaluation of kinesthesia, tactile discrimination and pain. These elements are measured respectively with the brief kinesthesia test, Tactile Discrimination Test (TDT), and a questionnaire for pain. A separate Patient-Reported Outcomes Measurement Information System (PROMIS) pediatric pain interference test has been used in children aged 8 to 17 years. The brief kinesthesia test is adapted from Ayre's sensory integration and praxis tests that provide insight into the underlying sensory processing and praxis abilities of children. TDT originally used by Carey, uses finely graded plastic surfaces marked by ridges at customary spatial intervals for measurement of tactile discrimination.[29] Pain evaluation comprises of a brief self-report measure of pain intensity and pain interference using a 0 to 10 numerical rating scale for measuring intensity (of experienced pain from no pain (0) to extreme pain (10) and a six-item patient reported outcome measurement information system for measuring the pain interference-, a measure of the functional consequence and disability resulting from pain. The latter's counterpart in children comprises of an eight-item scale as a supplemental measure.

Motor Assessment

This assesses multiple inputs and systems including neuromuscular, neurosensory, musculoskeletal, and cardiopulmonary systems. Subdomains assessed are dexterity, upper-extremity strength, balance, gait (locomotion) and endurance, using the nine-hole peg board test, grip dynamometry, standing balance test, 4-m walk test and 2-min walk test respectively. A pioneering and important measure added to the motor evaluation is endurance, which is to be tested at the end of other motor subdomains.

Readers can find a further expatiation of the aforementioned constructs in the NIH toolbox supplement (www.nihtoolbox.org and www.assessementcenter.net).

Discussion

The NIH toolbox constructs have been based on profound evaluation and validation by more than 250 scientists from around 100 academic institutions establishing a collaborative framework[30] involving several committees, domain teams, and working groups.

A major advantage of the toolbox is lack of intellectual property constraints. All the constructs are available on the website royalty free and needs minimal equipment set up.

The toolbox calls attention to standardized quantification using methodized constructs, computerized administration and scoring, validated questionnaires and standardized gadgets such as those used for audiometry, DVA and muscle power testing.

Expectedly, these constructs shall establish uniformity among the measures used for the neurological and behavioral functions worldwide, and shall augment the opportunities for comparison and consolidation of data of studies across the world.

A commendable aspect is the representation of pediatric subjects and validation of constructs for their age through a large undertaking. The factor structures of both young and older children conform to expectations regarding the development of specialization of skills and speech and corresponding findings from the neuroimaging literature on specificity of activation (as opposed to more global activation) during the assessment of cognitive tasks.[9]

These constructs have been designed to be brief and yet comprehensive to take a maximum of 2 h and even less so for children, with about 30 min for administration of individual domain batteries.[31]

However, as mentioned previously, these constructs are not a substitute for a detailed clinical evaluation nor are they meant for differentiation of normal from diseased states. Also it is not

clear to what extent the constructs can be used, for an evaluation of baseline disease status to monitor the disease progression needs to be elucidated. They best serve as quantification measures of normal functions in interventional and preventive longitudinal epidemiological studies.

The sequence of administration of these tests does not appear to be clear. We consider evaluation of cognition and emotional status preceding the other measures, paramount in order to make out if the patient would comprehend the nature of further tests. Assessment of the motor system should be preceded by sensory constructs like vestibular system which, in turn, be preceded by assessment of the static visual acuity.

Needless to say, deficits in primary constructs will make tests in higher mental functions such as gnosis and praxis impractical. One also needs to respect the fact that such disorders of higher mental functions can also sometime interfere with assessment of other cognitive as well as non-cognitive neurological domains.

A prime concern for us is the applicability of the toolbox in the Indian context. Transfer of western cognitive instruments to a nonwestern scenario requires a careful analysis of its appropriateness in the latter context. Adaptation in response to language, culture and theory might need modification of the construct. Familiarity to and being comfortable with the tools used, as well as, a basic level of education is mandatory for a subject to undergo these tests. Adaptation of these constructs to the Indian constructs would need *a priori* (judgmental procedures) and *a posteriori* procedures (statistical methods) to avoid the bias that can get introduced in assessment of cognitive performance. *A priori* procedures are applied before the instrument is administered to examine the cultural suitability of translations and adaptations of instruments, such as quality checks of translations, examinations of the adequacy of pictorial stimuli, and pilot studies to determine whether test instructions and items are interpreted as intended. *A posteriori* procedures are applied to the data obtained with the instrument like statistical methods to reduce the bias. Bias in the cross-cultural research could be in the form of construct, method and item bias which come in the way of adoption of the tests in our context.[32, 33]

Attempts have been made in India for adaptation of several cognitive tests, validated for normal individuals and even for pathological states, meant mainly for clinical use, but not for longitudinal epidemiological studies, unlike the NIH toolbox. An extensive search of literature shows endeavors to adapt the screening tests like Mini-Mental State Examination (MMSE) in several languages such as Hindi,[34] Bengali, Guajarati, Marathi,[35] Malayalam,[36] Kannada, Kashmiri,[37] Dogri, Bhamouri,[38] and Urdu. The adaptations in original MMSE include adjusting for orientation to current year, attention subtest by substituting WORLD by naming days of the week or months of calendar backwards, writing subtest by an oral task, construction tasks by simpler ones, attempts at modification of word list for learning, recall and recognition and simplifying command tasks using more familiar words. Certain commonly applied batteries like clock drawing test were initially substituted by a human face drawing though this too had confronted difficulties. Verbal fluency tests had also encountered hurdles due, partly to poor literacy of subjects and hence been adapted by retaining only the category fluency and negating the letter fluency test.[39] A pilot study applying the modified Hindi MMSE based on Indo US Cross National Epidemiology Study and a systematically translated Hindi version MMSE gave conflicting results in illiterate elderly subjects emphasizing a need for a well validated test in that subgroup.[40] The National Institute of Mental health and Neurosciences (NIMHANS) neuropsychological battery for the elderly was validated in identifying early dementia.[41] A comprehensive Hindi cognitive screening test battery, the Mattis Dementia Rating Scale (HMDRS) based on a Consortium to Establish Registry for Alzheimer's Disease has been developed for Hindi-speaking, semi-literate and illiterate population of rural northern India [42]. 11-item scale for assessing dementia in rural illiterate population has also been validated.[43] A Kolkata cognitive screening battery has been validated for the urban population of 50 to 95 years of age in the city of Kolkata, categorizing each subject into age groups based on total number of years of their education (illiterate, primary education, high school, graduation, and above) and lowest 10th percentile score was used as a cutoff for significantly impaired population.[44] The paradigm of superior performance of multi-linguals on executive-attention network test addressed in literature bears particular relevance in India. Adaptation of yet another tool, Cognistat, in Indian context has been validated in head injury patients and highlights the importance of detailed evaluation of the spoken language and quantification of abnormalities, and culturally relevant changes assembled by bilingual psychologists.[45] Cognitive tests for children have also been adapted. The American Kaufman assessment battery for children (second edition) has been adapted for the 6-10 years old Kannada speaking children of low socioeconomic status in Bangalore, South India. Fewer attempts have been made for adaptation for other domains of examination.[46,47] Notable is an other aphasia battery adapted in various Indian languages (Telugu,[48] Bangla,[49] Malayalam,[50] Kannada,[51] and for children[52]).

In India a low cost testing system for standing balance has been used for assessment of psychomotor symptoms using a Wii Balance Board using variety of loads at different places and load sensors at legs to measure weight, all interfaced with computers and using Bluetooth, that can be adapted into Indian toolbox.[53] There are other tests like the Indian Smell Identification test, which has been tried using commonly available odorants, making it cheap, convenient, and acceptable. The latter has been usefully tested in idiopathic Parkinson's disease patients.[54]

A uniformly applicable Indian neurological toolbox is still a bit too far to materialise. However, the above mentioned tools could provide inputs for the underpinnings. However, tools for assessment of somatosensory, motor, hearing, gustation and vision for the Indian subjects along the new directions of NIH tool kit remains largely unavailable and need to be explored, where the NIH tool box applications reveals inadequacies to adapt to our populations.

Conclusion

The NIH toolbox is a radical and practical step in rationalizing the scientific comparability of data in neurological and

behavioral examination throughout the world and potentially has far-reaching implications across different age groups and populations, though currently its applicability appears hinged across the American and Spanish subpopulations. Its utilisation in Indian as well as global contexts will need significant work of dedicated working groups for translation into different languages and adaptation to suit, cultural, educational and occupational diversity of the populations, but this should be a worthwhile exercise.

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