Scoping Review Protocol

Title: Uses of NIH Toolbox in Clinical Samples: A Scoping Review

Review question(s)
In what clinical populations (i.e., populations defined by a clinical diagnosis) is the NIH Toolbox being used in research?

a. For what purpose (outcome measure, covariate, eligibility screener, validation measure, etc.) is the NIH Toolbox being used in these studies?

b. Who is/what research teams are using the NIH Toolbox with clinical populations (multi-institutional, departmental, database/registry, hospital/community collaboration, etc.)?

We will include all types of clinical populations seen in any setting as long as the study sample is or could be defined by an ICD code.

Searches

- PubMed MEDLINE
- PsycINFO
- ClinicalTrials.gov
- EMBASE
- ProQuest Dissertations & Theses Global

Searches were restricted to research made available after 2008. Conference proceedings, dissertations, and other gray literature were included in the search. There were no language restrictions.

The references from included articles will be reviewed to identify additional records.

Search Strategy (provide one, if available):

The following search strategy was used in PubMed MEDLINE:

<table>
<thead>
<tr>
<th>Query</th>
<th>Terms</th>
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<tbody>
<tr>
<td>1</td>
<td>NIHTB[tiab] OR NIH TB[tiab]</td>
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</table>
Types of study to be included
We will include any type of original research (e.g., cohort study, RCT, case control study, case series/report). We will not include meta-analyses, systematic reviews, or editorials/opinions.

Condition or domain being studied
Applications of NIH Toolbox with clinical samples.

Participants/population
Individuals with any clinical diagnosis (i.e., identifiable by an ICD-10 code) seen in any setting (e.g., inpatients, outpatients, community health clinics, primary care). We will not restrict based on sex or other participant characteristics.

Interventions/Exposures
Any test included within the NIH Toolbox.

Comparator/control
Not applicable.

Context
We will exclude documents reporting on uses of NIH Toolbox in healthy or normative samples.

Main outcomes
No studies will be excluded based upon study outcome.

Data extraction (selection and coding)
CM and RF collaboratively identified and refined search terms. After final search terms were defined, CM developed search strings and carried out searches in PubMed, EMBASE, PsycINFO, ProQuest, and ClinicalTrials.gov.

To pilot test and calibrate the search protocol, 70 titles were selected for initial screening by all reviewers. All reviewers then met as a group to discuss the titles and resolve conflicts. All other titles/abstracts will be screened for inclusion by no less than two reviewers using the screening tool Rayyan. Throughout the review process, authors will include articles that discuss, or might
discuss, use of a test included in the NIH Toolbox and in which participants can be defined using an ICD-10 code. Conflicts at each stage of the review process will be resolved by discussion among the two reviewers who screened the relevant title. If a conflict cannot be resolved through discussion among the two original reviewers, a third reviewer will screen the record to resolve the disagreement.

Data will be extracted from included studies using a pre-defined data extraction sheet, initially developed by RF and iteratively refined based on full-team feedback.

We plan to extract the following information from included records:
- Type of investigational team (e.g., multi-institutional, departmental, database/registry, hospital/community collaboration, etc.)
- Types of participants/patients (e.g., cancer, neurologic, etc.)
- Number of participants
- Participant age (mean or median)
- Funding source (NIH, foundation, none, etc.)
- NIH Toolbox domains used (Cognition, Emotion, Motor, Sensation)
- NIH Toolbox assessments used
- Type of variable: outcome, inclusion/exclusion criteria, validation, covariate, etc.
- Mean/median scores on NIH Toolbox assessments
- Study design
- Journal impact factor
- Year of publication

**Strategy for data charting**
We will conduct a narrative charting of the literature.

**Charting of subgroups or subsets**
If there are adequate studies, we will discuss the state of the literature within and across different clinical conditions.

**Risk of bias (quality) assessment**
We will not review risk of bias or quality of assessment.

**Dissemination plans**
We plan to present this work at conferences and in manuscript form.

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**Type and method of review**
Scoping review

**Anticipated or actual start date**
June 9, 2020

**Anticipated completion date**
January 1, 2021

**Funding sources/sponsors**
This project is funded in part with Federal funds from the National Institute on Aging under grant number U2CAG057441, and The Environmental Influences on Child Health Outcomes (ECHO) program, Office of the Director, NIH, under award number U24OD023319.

**Conflicts of interest**
Dr. Richard Gershon previously served as the Principal Investigator for development of the NIH Toolbox under contract number HHS-N-260-2006-00007-C from the Blueprint for Neuroscience Research, NIH.

**Language**
English

**Country**
United States

**Subject index terms status**
In progress

**Subject index terms**
International Classification of Diseases, data collection, cognition, emotions, sensation, motor skills

Stage of review
In progress

Date of registration in DigitalHub
September 24, 2020

Stage of review at time of this submission

<table>
<thead>
<tr>
<th>Stage of review at time of this submission</th>
<th>Started</th>
<th>Completed</th>
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<tbody>
<tr>
<td>Preliminary searches</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Piloting of the study selection process</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Formal screening of search results against eligibility criteria</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Data extraction</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Data synthesis</td>
<td>No</td>
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