SUMMARY STATEMENT

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(Privileged Communication)

Release Date: **08/06/2021**
Revised Date:

Application Number: **1 R03 MH128681-01**

Principal Investigator

CHATTOPADHYAY, ISHANU

Applicant Organization: UNIVERSITY OF CHICAGO

Review Group: **NAME**
Neurological, Aging and Musculoskeletal Epidemiology Study Section

Meeting Date: **07/07/2021**
Council: **OCT 2021**
Requested Start: **12/01/2021**

RFA/PA: **PA18-399**
PCC: **82-SECH**
Dual IC(s): **HD**

Project Title: **Universal Early Screening For Autism Risk using Comorbidity Pattern Discovery in Past Medical Encounters**
SRG Action: **Impact Score:47 Percentile:42 +**
Next Steps: **Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **48-At time of award, restrictions will apply**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**
Gender: **1A-Both genders, scientifically acceptable**
Minority: **1A-Minorities and non-minorities, scientifically acceptable**
Age: **2A-Only Children, scientifically acceptable**

Project Year	Direct Costs Requested	Estimated Total Cost
1	50,000	82,000
2	50,000	82,000
TOTAL	100,000	164,000

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R03MH128681-01 Chattopadhyay, Ishanu

PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE

RESUME AND SUMMARY OF DISCUSSION: This application proposes to validate the Autism spectrum disorder (ASD) Co-morbid Risk (ACoR) score, a machine learning (ML) tool that estimates ASD risk based on comorbidity patterns from past medical encounter. The project will compare ACoR with the Modified Checklist for Autism in Toddlers, Revised, with Follow-Up (M-CHAT/F), a commonly used questionnaire-based ASD screening tool. The review panel agreed that the project addresses a significant need for improved screening tools that can more accurately diagnosis ASD earlier than current practices. The investigative team is strong with complimentary expertise in autism and machine learning. The use of only diagnostic electronic health record (EHR) codes to predict autism is innovative and plans to leverage robust data sets and supportive preliminary data are additional notable strengths. During discussion, the Committee identified issues that detract from the project's potential contribution; notably, a description of the computable phenotype for autism is insufficiently described and exclusion and inclusion criteria are poorly specified. Importantly, a lack of a gold standard diagnosis on the Autism Diagnostic Observation Schedule, second edition (ADOS-2) for children with positive ACoR but negative M-CHAT/F makes the analysis of the ACoR by itself, or jointly with M-CHAT/F, problematic. There is a human subject concern that risk to participants are insufficiently considered. Overall, there is a consensus among the review panel that the identified weaknesses reduce the potential impact of the project to moderate on research in Autism spectrum disorder.

DESCRIPTION (provided by applicant): Autism spectrum disorder (ASD) is a developmental disability associated with significant social and behavioral challenges, and there is a distinct need for tools that help identify children with ASD as early as possible. To that effect, we introduce and propose to validate the ASD Co-morbid Risk (ACoR) score in a limited clinical study. The ACoR is computed via sophisticated pattern discovery on longitudinal history of diagnostic codes for individual patients, and potentially signals a future ASD diagnosis within 16-26 months of age. Computation of ACoR requires no new blood-work, or questionnaires, and uses data already available on patient file, with no demand for any particular test or demographic information. Thus, ACoR is positioned to be a universal screening tool, that can estimate the risk of autism for all children in a pediatric facility near-instantaneously, potentially outperforming existing tools. Despite being highly heritable, our current incomplete understanding of ASD pathogenesis and the lack of reliable biomarkers hampers early detection, intervention and patient outcomes. The currently available questionnaire based screening tools suffer from vast number of false positives which create long wait-times for diagnostic evaluations. Additionally, standardized checklists are vulnerable to socio-economic and interpretational biases that disproportionately impact diagnosis in diverse communities. Borderline cases with children with average to above average cognitive abilities might be left undiagnosed till start of school, which negatively impact effectiveness of interventions. The ACoR score is designed to address the aforementioned complicated challenges of ASD screening by distilling incipient patterns predicting elevated risk from past medical history of individual patients. Thus, to compute ACoR, we operationalize a documented aspect of ASD symptomology in that it has a wide range of co-morbidities occurring at much higher rates than in the general population. In the setting of a pediatric primary care clinic at the Department of Pediatrics, University of Chicago, we plan to carry out a comparative study of ACoR with M-CHAT/F, which is the most common screening tool in current use. Via a direct comparison, we specifically aim to 1) estimate prospectively to what extent we can reduce false positives, 2) the possibility of combining the scores for significant improvements in either Positive Predictive Value or the sensitivity while not losing specificity, 3) the superior performance in ethnically and demographically diverse cohorts, and 4) shed light on the ASD pathobiology by classifying patterns of co-morbidities that map to distinct presentations. We have extensively validated our results in

retrospective studies on two independent databases of patient records with over four million children. These results indicate superior performance to existing tools, achieving out-of- sample AUC exceeding 80% for either sex from just over 2 years of age. Unlike standard machine learning applications, ACoR represents a novel screening modality for ASD, functionally independent of questionnaires, and potentially can address documented language, cultural and social barriers of the existing tools.

PUBLIC HEALTH RELEVANCE: In contrast to the current questionnaire based screening tools for autism spectrum disorders (ASD) that suffer from vast amounts of false positives, and a host of demographic, socio-economic and interpretative biases, we aim to validate the ASD Co-morbid Risk (ACoR) score, that estimates ASD risk via sophisticated pattern discovery on the longitudinal medical history of individual patients. Computation of ACoR requires no new blood-work, laboratory tests, questionnaires or psychiatric/cognitive consults, and may be carried out purely from the history of past medical encounters at no additional administrative burden or resource utilization. ACoR outperforms the current tool M-CHAT/F in preliminary studies, and on account of functional independence, the two scores may be combined to further boost performance to either boost positive predictive value up to 100% or sensitivity up to 50% with no loss in current specificity.

CRITIQUE 1

Significance: 1
Investigator(s): 2
Innovation: 2
Approach: 4
Environment: 1

Overall Impact: This is a 2-year R03 application that will develop machine learning (ML) models to diagnose autism (ASD) earlier from comorbidity patterns in EHR data. The use of only ICD9/10 codes to infer comorbidity patterns has the advantage that the algorithm, if successfully developed, can be implemented for clinical use without additional data or tests. The investigators have complementary expertise in autism, machine learning, and EHR data aspects of the proposed work. A significant weakness is the lack of a gold standard for ascertainment of autism, which tempers the enthusiasm for the proposal.

1. Significance:

Strengths

- Earlier accurate prediction of the risk of autism is a clinical challenge that if successfully tackled will have a large impact on the management of autism due to earlier interventions.
- The proposed ML algorithms will use only past history of ICD9/10 codes which makes it easy to implement as an automated screening tool for clinical use.

Weaknesses

- None noted by reviewer.

2. Investigator(s):

Strengths

- The investigators have complementary expertise in autism, machine learning, and EHR data aspects of the proposed work.

Weaknesses

- Members of the team don't appear to have worked together earlier.

3. Innovation:

Strengths

- Exploring the patterns of comorbidities in autism to characterize potential phenotypes in this heterogenous condition is novel.
- Using only diagnostic EHR codes to predict autism is moderately innovative.

Weaknesses

- None noted by reviewer.

4. Approach:

Strengths

- The study will leverage a large and diverse data set with 4M children and a second data set from University of Chicago Medical Center.
- Preliminary results for the proposed machine-learning based ACoR score are promising with AUCs between 81% - 83% for predicting ASD at 125 weeks of age. The score is also able to discriminate between ASD and other psychiatric conditions.
- The proposed ML method, hidden Markov models, and comparison of the ML method to existing M-CHAT/F tool are appropriate.
- The proposed prospective study to compare ACoR with M-CHAT/F is useful as a real-world evaluation.
- Exploring the patterns of comorbidities in autism will be useful to characterize potential phenotypes in this heterogenous condition.
- Sex as a biological variable is included.

Weaknesses

- The description of the computable phenotype for autism is insufficiently described as "one or more ICD9/10 codes". A full list of inclusion and exclusion ICD9/10 codes should be included and the performance of the set of codes should be evaluated for its ability to identify autism. See for example, Lingren T, Chen P, Bochenek J, et al. Electronic health record based algorithm to identify patients with autism spectrum disorder. PloS one. 2016 Jul 29;11(7):e0159621.
- Sample size for the University of Chicago Medical Center data set is missing.

5. Environment:

Strengths

- The environment at the University of Chicago is outstanding and has excellent computational and data resources.

Weaknesses

- None noted by reviewer

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- No concerns.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion Plans:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion Based on Age: Distribution justified scientifically
- Inclusion of only children is appropriate.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

Significance: 2
Investigator(s): 4
Innovation: 2
Approach: 6
Environment: 2

Overall Impact: This R03 proposal seeks to determine the effectiveness of the newly developed ASD Co-morbid Risk (ACoR) estimator in screening for Autism Spectrum Disorder (ASD). The ACoR uses only existing electronic medical record (EMR) data, so if successful the significance of this proposal would be high---it would mean that preliminary ASD screening could be done without any further instruments. As the ACoR has already been developed, the proposal seeks to establish the characteristics of its use in screening alongside the widespread M-CHAT/F screening tool.

Unfortunately, the approach lacks some details, such as whether the sample size is adequate, but most importantly does not include gold standard diagnosis on the ADOS-2 for children who score positively on the ACoR but not the M-CHAT/F, making the analysis of the ACoR by itself, or jointly with M-CHAT/F, problematic and the hypotheses of the proposal untestable. For these reasons, my enthusiasm is greatly diminished, and I regard the likely impact to be moderate.

1. Significance:

Strengths

- As there may be substantial benefit in early intervention for children with ASD, there is great potential in an effective ASD screening tool that simply uses EMRs but no additional instrument.
- The new EMR-based algorithm, ACoR, has shown, in retrospective study, similar overall operational characteristics to the common existing screening instrument, M-CHAT/F, but with improved positive predictive value.
- The novel ACoR, largely draws on somatic comorbities in the EMR, and so may be largely uncorrelated with the M-CHAT/F; knowing the joint characteristics of the two screeners offers the possibility of a two-stage screening with improved sensitivity and specificity.
- Establishing the sensitivity, specificity, etc., of the ACoR—separately or jointly with the M-CHAT/F—will be important if it can be adopted for widespread use

Weaknesses

- None noted by reviewer.

2. Investigator(s):

Strengths

- The PI has a background in machine learning and stochastic processes, particularly with regard to unsupervised learning algorithms.
- All but one of the rests of the 9-person research team are on the clinical side.

Weaknesses

- The PI has effort of only 0.3 clinical months, and only the TBN staff scientist has more than 0.6 clinical months of effort.
- The team would have benefitted from a consultant with expertise in the public health evaluation of screening tests.
- The PI does not appear to have much experience with human subject's research.

3. Innovation:

Strengths

- The proposal is innovative in using somatic comorbities as potential indicators of ASD.
- The use of machine learning approaches on EMRs as a screening tool for ASD is innovative as well.

Weaknesses

- None noted by reviewer.

4. Approach:

Strengths

- The investigators have already developed, tuned, and implemented the ACoR for the EMRs used in the U Chicago system.
- There will be a large number (5000/year) of children screened, of whom about 300 will be evaluated on the ADOS-2.
- Sex as a biological variable is addressed by fitting separate models by sex.

Weaknesses

- Major. Children with positive ACoR but negative M-CHAT/F will not be evaluated on the widely accepted ADOS-2 diagnostic tool. Without those children being evaluated, I do not see how the operating characteristics of the ACoR by itself can be evaluated. This is particularly troubling since a likely clinical scenario is that the ACoR would be administered first, followed the M-CHAT/F, rather than the other way around. Unfortunately, no explanation of this decision is given.
- Major. The design criticism above particularly applies to Aim 3, where the design undercuts the aim of seeing whether the ACoR outperforms M/CHAT-F in a culturally diverse population.
- Major: As the characteristics of the ACoR can only be determined conditional on a positive or marginal M-CHAT/F, Aims 1 through 3 cannot actually be achieved by this proposal.
- Moderate. There are no calculations to show whether the sample size is sufficient for Aims 3 and 4.
- Moderate. The cohort description is a little unclear. “Additional” inclusion and exclusion criteria are given, but basic inclusion and exclusion criteria are not. Is it every child at the (unnamed) primary care clinic?
- Minor. The timeline is rudimentary and does not allow for any analysis.
- Minor. Why is 65+ included in the demographic makeup of the participants? Is this not a pediatric sample?
- Minor: The human subjects table refers to 30,000 subjects while the text implies 10,000.
- Moderate: This sloppiness of some of these points (and see the human subjects concern below) could be dismissed as poor grantsmanship, but it suggests an unfamiliarity with human subject’s research.
- Minor. I found Figure 1 confusing---none of the numbers, including the number of weeks, matches the corresponding description in the main text.

5. Environment:

Strengths

- The University of Chicago and the University of Chicago Corner Children’s Hospital, including the Section of Developmental and Behavioral pediatrics, provide an excellent and supportive research environment.

Weaknesses

- None noted by reviewer.

Protections for Human Subjects:

Unacceptable Risks and/or Inadequate Protections

- The protection of human subjects' section (p53) is perfunctory and does not mention the risks of stress from false positives mentioned in the research strategy. The research plan refers to consenting patients, although the patients, being toddlers, will not be competent to consent.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion Plans:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion Based on Age: Distribution justified scientifically

- No concerns

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3

Significance: 3
Investigator(s): 2
Innovation: 2
Approach: 3
Environment: 2

Overall Impact: This proposal addresses a very significant issue in the field of autism and the overall impact is high because the research is likely to validate the ASD Co-morbid Risk (ACoR) score and compare ACoR with M-CHAT/F, which is the most common screening tool in current use. The ACoR is computed via sophisticated pattern discovery on longitudinal history of diagnostic codes for individual patients, and potentially signals a future ASD diagnosis within 16-26 months of age. Based on preliminary studies, there is strong likelihood for the project to exert a sustained and powerful influence on the autism research field.

1. Significance:

Strengths

- Development of ASD Co-morbid Risk (ACoR) score, a tool that may help identify children with ASD in the next 16-26 months.
- ACoR is associated with reduced false positive and improved positive predictive value compared to M-CHAT/F in preliminary studies, the tool may provide a better screening option.
- In addition, on account of functional independence from M-CHAT, the two scores may be combined to further boost performance to either boost positive predictive value up to 100% or sensitivity up to 50% with no loss in current specificity.

Weaknesses

- None noted by reviewer.

2. Investigator(s):

Strengths

- The PI has necessary expertise and has assembled a strong team with expertise in the key areas of the proposal.

Weaknesses

- None noted by reviewer.

3. Innovation:

Strengths

- ACoR represents a novel screening modality for ASD, functionally independent of questionnaires, and potentially can address documented language, cultural and social barriers of the existing tools.

Weaknesses

- None noted by reviewer.

4. Approach:

Strengths

- Use individual diagnostic codes already present in individual patient files formulate risk score.
- develop and validate the efficacy of machine inferred digital biomarkers for autism, mined automatically from past medical encounters.
- ACOR will be compared against M-CHAT for sensitivity and specificity.
- Validate the performance in a diverse population with range of socio-economic confounders.

Weaknesses

- None noted by reviewer.

5. Environment:

Strengths

- Strong infrastructure and facilities to complete the proposed study.

Weaknesses

- None noted by reviewer.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Inclusion Plans:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis:
- Inclusion/Exclusion Based on Age:

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: UNACCEPTABLE

The protection of human subjects from research risks is unacceptable. Members of the review panel expressed concern the risks of stress from false positives is insufficiently considered. The research plan refers to consenting patients, but toddlers will not be competent to consent.

INCLUSION OF WOMEN PLAN: ACCEPTABLE

INCLUSION OF MINORITIES PLAN: ACCEPTABLE

INCLUSION ACROSS THE LIFESPAN: ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1 R03 MH128681-01; PI Name: Chattopadhyay, Ishanu

+ Derived from the range of percentile values calculated for the study section that reviewed this application.

NIH has modified its policy regarding the receipt of resubmissions (amended applications).See Guide Notice NOT-OD-18-197 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Neurological, Aging and Musculoskeletal Epidemiology Study Section
Population Sciences and Epidemiology Integrated Review Group
CENTER FOR SCIENTIFIC REVIEW
NAME
07/07/2021 - 07/09/2021

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-14-073 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html, NOT-OD-15-106 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html, and NOT-OD-18-115 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-115.html, including removal of the application from immediate review.

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