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TITLE: Functional Impairments in Service Members with Normal Audiometric Thresholds

PRINCIPAL INVESTIGATOR: Douglas Brungart, Ph.D.

RECIPIENT: Henry M. Jackson Foundation for the Advancement of Military Medicine
Bethesda, MD 20817

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6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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6720-A Rockledge Dr. STE 100
Bethesda, MD 20817

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Military service is more hazardous to hearing than almost any other occupation, and both the line and medical components of the Department of Defense (DoD) have a responsibility to protect Service Members from the harmful effects of noise exposure. Despite the best efforts of a comprehensive DoD-wide hearing conservation program, hearing loss and tinnitus continue to be the most frequent permanent injuries in the military; nearly 30% of service members experience a permanent threshold shift and just over 30% report tinnitus. These problems propagate to our veteran population, resulting in almost 1.5 million veterans receiving compensation for hearing loss and tinnitus. Of further concern is the increasing incidence of Service Members reporting hearing difficulty and/or tinnitus in the presence of normal hearing. These factors could have a significant impact on readiness and resilience in the Active Duty population.

The goal of this research effort is to advance our understanding of the etiology and implications of noise- and blast-related hearing damage in our Active Duty population with normal or near-normal audiograms, and obtain normative data for tests that could be used to efficiently assess these problems in DoD Audiology Clinics. This will be accomplished by three studies. The first study will be a direct evaluation of the relationship between objectively measured noise dosimetry and subjective noise surveys. This data will be used to improve the ability to obtain reliable self-reports of noise exposure. In the second study, auditory tests that are sensitive to objective differences in performance among Service Members with normal or near-normal thresholds and varying levels of noise and blast exposure will be identified, to establish normative data in those tests that will facilitate their direct transition to clinical use. Finally, auditory and functional tests that are sensitive to differences in performance among Service Members with normal or near-normal thresholds and various levels of bothersome and non-bothersome tinnitus will be identified, and normative data will be established to facilitate direct transition to clinical use.

15. SUBJECT TERMS					
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Unclassified	Unclassified	Unclassified			

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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

The line and medical components of the Department of Defense (DoD) have a responsibility to protect Service Members from the harmful effects of noise exposure. Despite the best efforts of a comprehensive DoD-wide hearing conservation program, hearing loss and tinnitus continue to be the most frequent permanent injuries in the military; nearly 30% of Service members experience a permanent threshold shift and just over 30% report tinnitus. This study will address the current lack of knowledge regarding actual versus self-reported noise exposure and the functional impact of noise- and blast-exposure in Service members with normal hearing. This study will also address the lack of knowledge regarding the prevalence and incidence of tinnitus in military Service members as a function of noise- and blast-exposure, as well as the functional impact of tinnitus. The overarching goal of this effort is to better understand the relationship between noise exposure, blast exposure, tinnitus, and subjective and objective measures of hearing impairment in the military population with normal hearing thresholds. We believe the only way to make inferences about the complex interactions between these different factors is to collect data from a large number of volunteer participants from both military and civilian populations. This data will help us both 1) determine which standardized tests are most likely to be sensitive to the effects of blast and noise exposure; and 2) establish normative data on these standardized tests and transition the tests to the clinic for validation on individuals with clinical complaints of hearing difficulty or tinnitus.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Tinnitus, hidden hearing loss, hearing impairment, noise/blast exposure

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

- **(Year 1) Specific Aim 1:** Evaluate and Optimize Subjective Metrics for Assessing Noise History
    - **Major Task 1:** Improve our ability to obtain reliable self-reports of noise exposure by directly evaluating the relationship between objectively measured noise dosimetry and subjective noise surveys.
        - Subtask 1: Submit documents for local IRB review. Local IRBs include Walter Reed and University of Texas, Dallas.
        - Subtask 2: Design and develop infrastructure to implement objective and subjective noise measurements.
        - Sub task 3: Collect data
- **(Year 2) Specific Aim 2**: Evaluate the influence that noise and blast exposure have on the performance and subjective hearing handicap of listeners with normal hearing thresholds.

- **Major Task 2:** Identify auditory tests that are sensitive to objective differences in performance among Service Members with normal or near-normal thresholds and varying levels of noise and blast exposure, and establish normative data in those tests that will facilitate their direct transition to clinical use.
  - Subtask 1: Collect data at Walter Reed and at the UTD audiology clinic.
  - Subtask 2: Analyze and begin publish results from Aim 1.
  - Subtask 3: Begin developing infrastructure and collecting pilot data for major task 3.

- **(Year 3) Specific Aim 3**: Evaluate the non-bothersome and bothersome tinnitus in Service members
  - **Major Task 3:** Identify auditory and functional tests that are sensitive to differences in performance among Service Members with normal or near-normal thresholds and various levels of bothersome and non-bothersome tinnitus, and establish normative data in those tests that will facilitate their direct transition to clinical use.
    - Subtask 2: Collect data at Walter Reed
    - Subtask 3: Analyze and begin to publish from Aim 2
    - Subtask 4: Analyze and publish data from Aim 3

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

- Major Activities:
  - Personnel Hire: Jaclyn Schurman, Au.D. was brought onboard on 25 September 2018 to be the research audiologist on this project. Anticipated start date for the research audiologist was 1 July 2018. However, onboarding did not occur until 25 September 2018.
- Specific Aim 1 Accomplishments:
  - Subtask 1:
    - Walter Reed: IRB was submitted and approved on 1 July 2019. Data collection will occur at Quantico at The Basic School. A CRADA has been submitted to the Walter Reed and we are currently awaiting approval. The protocol will be submitted for HRPO approval in the next quarter.
    - University of Texas, Dallas: IRB was submitted and approved on 27 June 2019. The protocol will be submitted for HRPO approval in the next quarter.
    - Contractor for the Industrial site, Deanna Meinke, has not yet submitted an IRB through University of Northern Colorado. There has been much debate regarding the most appropriate local IRB to submit to for the industrial site IRB. Dr. Meinke has been given approval to work on this project through her university (University of Northern Colorado), therefore she will be submitting an IRB through that university within the next quarter.
  - Subtask 2: Design and development of the data collection procedure for the subjective survey portion of Aim 1 currently underway. There is a working demonstration of the testing procedure that will be finalized during the next quarter.

- Subtask 3: Data collection is currently underway at Quantico for the objective noise exposure portion of this study. The actual noise levels for each weapon/range are either known or currently being collected as part of a Public Health Project. The Navy & Marine Corps Public Health Center- Industrial Hygiene Department were tasked with measuring the known noise exposure levels for all ranges at Quantico and our team have been assisting in data collection. Our team has traveled to Quantico for two days of data collection on three separate ranges across multiple weapons.
    - Data collection for the subjective portion of the study at Quantico: will begin in the Fall/Winter (November/December). Data collection will occur in the last 3 weeks of the trainee's 6 month training period. Therefore, data collection cannot occur until the completion of the current training period.
- Subtask 3: University of Texas, Dallas: Data collection on the subjective and objective portions of this study will begin in the next quarter.

- Specific Aim 2 Accomplishments:
    - Major Activities: Analyzed data and submitted a manuscript from a precursor to the current study. The findings of the previous study will impact the questions asked in Aim 2 of the current study regarding temporary threshold shifts after noise exposure and hearing difficulties in the military population. The manuscript entitled "The relationship between subjective reports of temporary threshold shift and the prevalence of hearing problems in military personnel" was accepted for publication in Trends in Hearing.
    - Subtask 1:
        - Walter Reed: An amendment was submitted to a currently approved MRMC protocol include the objectives of Aim 2 of this grant. This amendment was approved on 24 May 2019. Data collection is likely to begin during the next quarter.
        - University of Texas: IRB approval was received for Aim 2. Data collection is likely to begin during the next quarter.
        - Subtask 2: Data analysis for Aim 1 has not begun.
        - Subtask 3: Meetings have occurred to plan for Aim 3.
- Specific Aim 3 Accomplishments: Meeting have occurred to plan for Aim 3 and the majority of work on this Aim will occur in year 2 and 3.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report at this time.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- Specific Aim 1:
  - Subtask 1:
    - The protocol will be submitted for HRPO approval in the next quarter.
    - University of Texas, Dallas: The protocol will be submitted for HRPO approval in the next quarter.
    - Contractor for the Industrial site, Deanna Meinke: IRB to be submitted IRB through that university within the next quarter.
  - Subtask 2: Data collection procedures to be finalized and data collection will begin in the next two quarters.

- Specific Aim 2:
    - Subtask 1: Data collection will begin for protocols will approved IRBs.
    - Subtask 2: Data analysis to begin on Aim 1 once data has been collected.
    - Subtask 3: Planning for Aim 3 will continue.

4. IMPACT: Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

No results impact to report at this time. There will be impacts to report for the next annual report as data collection and analysis begin.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

There was a delay receiving approval IRB approval through Walter Reed for Aim 1. There was a delay in IRB submission because we believed the protocol would qualify for exemption under the "Benign Environmental Manipulation" exception in the new Common Rule, which will become effective in the DoD on Jan 21, 2019. Thus, we delayed submission of our revised protocol until that date. Then, the protocol underwent major revisions before approval in July.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

There was about a three month delay in hiring the research audiologist on this project.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals.

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to report for the current grant, but the following peer-reviewed article was accepted for publication and is a precursor to Aim 2 of the current grant.

  Brungart, D. Barrett, M., Sheffield, B., Schurman, J., Ramos, L., Martorana, R., & Galloza, H. (2019). The Relationship Between Subjective Reports of Temporary Threshold Shift and the Prevalence of Hearing Problems in Military Personnel. Accepted for publication. Trends in Hearing.

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to report.

Other publications, conference papers, and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *biospecimen collections;*
  - *audio or video products;*

- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Name: Douglas Brungart, PhD
Project Role: PI
Researcher ID: NA
Nearest person month worked: 1
Contribution to Project: Principal Investigator

Name: Jaclyn Schurman, AuD
Project Role: Co-I
Researcher ID: NA
Nearest person month worked: 1
Contribution to Project: Research Audiologist

Name: Colleen LePrell, PhD
Project Role: PI at University of Texas, Dallas
Researcher ID: NA
Nearest person month worked: 1
Contribution to Project: Principal Investigator

Name: Deanna Meinke, PhD
Project Role: Contractor for Industrial Site
Researcher ID: NA
Nearest person month worked: 1
Contribution to Project: Contractor

Name: La Guinn Sherlock, AuD
Project Role: Co-I
Researcher ID: NA
Nearest person month worked: 1
Contribution to Project: Research Audiologist

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.
Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

University of Texas, Dallas (Subaward)
800 W. Campbell Road Richardson, TX 75080
Colleen LePrell, PhD

- Collaboration (e.g., partner's staff work with project staff on the project);

Contractor:
Northern Colorado
Deanna Meinke, PhD

- Collaboration (e.g., partner's staff work with project staff on the project);

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.