Summary

Background: Exertional Heat Illness (EHI) occurs when individuals are exercising in hot and/or humid conditions and their body systems are unable to regulate the increased temperature. While many studies have been done on athletes which have informed the creation of protective guidelines, such guidelines regarding rest and hydration as well as temperature cutoffs for participation do not exist for participants in marching bands (MB). This is because the true nature of heat stress on these individuals is unknown.

Objectives: To quantify the incidence of EHI in Marching Band participants (MBP) and understand the influence of various factors on core body temperature in this population. This line of investigation will inform the development of tailored safety protocols, based on evidence, to reduce the occurrence of EHI among marching band members. Success will be measured by identification of risk factors that influence the response to heat and the subsequent national adoption of interventions to mitigate these risk factors into national safety guidelines for marching band participants.

Design: Multicenter, prospective quantitative, observational study

Settings: We will recruit approximately 800 students/Faculty NFHS Member High Schools, with broad geographic representation from 8 Sections of the country, as determined by the NFHS. Temperature and data points will be accumulated for 2 weeks. Recruitment will start in June and will end in October, In most states, there is a moratorium where football practice cannot start until August 1; therefore, from June through July, there will not be any football players to serve as controls.

Participants: Participants will be identified via an informational flyer through the NFHS. The Band Director, Coach, Team Leader/Captain, Athletic Trainer, or other Assistant will be invited to participate to record environmental conditions (ambient and surface) as well as students dress code for each day. Faculty will also be responsible for receipt and return of the box containing all the individual study "KITS" for student participation. Up to 100 students from each high school, 90 MB participants and 10 football players, as available, to serve as controls and allow for comparisons from the same school.

Consent: Oral consent will be obtained by Faculty via zoom/teams session once participating schools have been identified. Student/Parent Consent will be obtained electronically via QR code printed on the informational flyer that will be handed out by consented Faculty prior to the marching band/football season. The flyer will also contain dates for 2 optional zoom sessions to answer questions prior to participation.

Data collection plan: A novel, wearable core temperature measurement device, the OMNI 555, will be used on the MB participants and football players and will collect biophysiological data. Band Director, Coach, Team Leader/Captain, Athletic Trainer, or other Assistant will record environmental conditions (ambient and surface) as well as dress code for participation each day. Demographic data for each participant (in an anonymous, HIPAA compliant fashion) will be obtained at the beginning of the season and daily symptom assessments will be obtained from participants.

Data analyses: Key informant data points will be obtained via Qualtrics. Survey data will be tabulated and summarized using descriptive (frequency, percent, mean, standard deviation, range) and inferential statistics (Chi-square tests, T-tests). Surveillance data will be analyzed to assess the EHI/EHS frequency and incidence rate and 95% confidence intervals.

Anticipated results: Information gained from the study will allow the research team and the NFHS Foundation to inform the creation of safety protocols for MB participants. This comprehensive study will build the evidence base for the creation of national programs to protect MB participants and can inform regional variations.

Potential stakeholder impact: This project commits to a proactive engagement strategy with stakeholders, including regular updates and feedback sessions with school officials, band directors, and student representatives. This collaborative approach ensures that the research

remains grounded in the practical realities of marching band participation and facilitates the smooth implementation of research findings into practice.

Protocol

This multi-center, prospective study will utilize quantitative methods to evaluate the effect of heat on marching band participants, and when possible, will compare this against football players. Football players are currently protected by acclimatization policies which do not apply to marching band participants.

Research protection: The Mayo Clinic IRB committee will approve prior to the study.

Enrollment: There will be a call for NFHS member public schools to participate led by the state association as well as Performing Arts Leadership of the NFHS. A Band Director, Coach, Team Leader/Captain, Athletic Trainer, or other Assistant that expresses interest will be orally consented via zoom/teams session to receive the Students study kit and collect practice information and daily weather data. A maximum of 100 students, 90 MB participants from each section will be recruited and a maximum of 10 football players from the same school will be recruited.

The study team will identify 1-2 schools from each section. Each rotation will last 2 weeks.

Marching band participants will demonstrate equity among sex and gender and we will aim to recruit a broad range of instruments.

Timing of recruitment:

Example Rounds (Section number in Parenthesis)

1. June 17-July 1: Texas (6) - all 50 in one state or 25 in Texas and 25 in Arizona (7)
   Return to RST for download of data, and cleaning, re-package and prep for shipment
2. July 8-22: Florida (3) 25 and maybe 2 or 4 (Indiana or virginia)
   Return to RST for download of data, and cleaning, re-package and prep for shipment
3. July 15-July 29:: Minnesota (5) 25 and (8) Oregon or Montana (25 units)
   Return to RST for download of data, and cleaning, re-package and prep for shipment
4. Aug 5 - Aug 19: Sections to be named
   Return to RST for download of data, and cleaning, re-package and prep for shipment
5. August 26-Sept 9: Sections to be named
   Return to RST for download of data, and cleaning, re-package and prep for shipment
6. Sept 16 - Sept 30: Sections to be named
   Return to RST for download of data, and cleaning, re-package and prep for shipment
7. Oct 7 - Oct 21: Sections to be named
   Return to RST for download of data, and cleaning, re-package and prep for shipment

Data collection plan:
The Mayo Clinic Department of Emergency Medicine research team will create the Qualtrics surveys which will be completed by the team and by the individuals participating in the study.

Technology
The Mayo Clinic Special Purpose Processor Development Group (SPPDG) is a division of the Mayo Clinic Department of Physiology & Biomedical Engineering and have focused on the development of robust, mission flexible and scalable wearables to monitor biophysiologic vital signs with complete end-to-end communication solutions for the US Government. Dr. Russi and the Department of Emergency Medicine have partnered with SPPDG to deploy and test these remote monitoring solutions in our ambulances and helicopters. The team has a platform of technologies available and will provide either a chest mounted or wrist mounted wearable. All devices transmit data (heart rate [HR], heart rate variability [HRV], geolocation, accelerometer and temperature) real-time via low-energy bluetooth, wifi or LoRA (Long Range) or store data locally for asynchronous download via uniquely designed charging / docking stations. In addition, the wearables have a built in accelerometer to detect motion or “wobble.” If participants are not moving but have a “wobble” this could indicate symptoms related to EHI. All combined, the data can be used to demonstrate the ability to monitor subjects and use those data to develop early machine learning models predicting impending EHI.

Data from devices used at high schools in Rochester, MN will be synchronized to Mayo Clinic servers via LoRA radio transmission to area regional towers, all other regions will require the schools to ship the wearables back for data download to Mayo Clinic servers.

All devices and communication technology are developed and manufactured at Mayo Clinic.

Data analyses:

Core temperature, vital signs, ecg tracings, and gyroscopic analysis will be summarized across individual practice sessions for each participant using medians and maximums. These values will be compared across risk factors for EHI such as practice surface, instrument, participant gender, geographic zone, and costume type using univariable Kruskal-Wallis tests.

The primary outcome for this study will be participants' time at risk for EHI. For each study participant, time at risk for EHI will be calculated as the time spent with core temperature exceeding 101 degrees or the reporting of symptoms of heat exhaustion.

The effect of EHI risk factors on participants' time at risk will be assessed using regression. The regression models will be both univariable and multivariable, adjusted for other risk factors and potential confounders. The time at risk will also be compared between MB and football participants using similar regression models.

Dissemination / implementation plans:

The findings from our study will be disseminated through a comprehensive multi-channel strategy designed to reach diverse stakeholders and maximize impact. Our dissemination efforts will include:

1. Academic Conferences: Presenting results at leading academic conferences, such as the NATA, to engage researchers and practitioners in relevant fields. We will also consider broadening our reach to include officials who are in the vicinity of marching band activity.
2. Peer-Reviewed Publications: Submitting manuscripts to high-impact, peer-reviewed journals to ensure rigorous evaluation and wide dissemination within the scientific community.
3. Workshops with Educational Institutions: Conducting workshops and seminars at schools, universities, and other educational institutions to directly reach educators, students, and administrators.
4. National Conferences for Performing Arts: Sharing findings at national conferences focused on performing arts to engage a broader audience involved in the marching band and performing arts communities.
5. Partnership with External Organizations: Collaborating with organizations such as the National Federation of State High School Associations (NFHS), marching band associations, and healthcare organizations to amplify our outreach efforts and influence policy and practice.

Additionally, we will create a concise, 1-page summary of the study results to be distributed to all participating schools. This summary will include key findings, practical recommendations, and an invitation for schools to provide feedback on the results. The collected feedback will be compiled and shared with the NFHS to inform their guidelines and protocols.

This multi-faceted dissemination strategy ensures that our findings reach a wide audience, including educators, healthcare professionals, performing arts professionals, and policy-makers, thereby maximizing the study's impact on enhancing safety protocols for marching band participants.

THE KIT
Protocol for Participant Enrollment and Study Participation:

1. Receipt of Study Kit:
  - Upon receiving the study kit, carefully check the contents to ensure everything is included as listed:
    - QR code for consent form for both student and parent/guardian (done once)
    - Flyer detailing study information, objectives, and contact details. (See Appendix 1)
    - QR code to Initial demographic intake form (done once) (See survey 4.0)
    - OMNI 555 device.
    - Stickers.
    - Chest strap.
    - QR code for daily post-session questionnaire (daily) (See Survey 3.0)
-QR code for Band Director or Drum Major surveys (initial and daily - See Surveys 1.0 and 2.0)

2. Consent and Enrollment:
  - Scan the QR code provided in the kit to access the consent form.
  - Ensure both the student and their parent/guardian thoroughly read and understand the consent form.
  - Complete the consent form online, providing accurate information and signatures where required.
  - Submit the consent form electronically.

3. Demographic Intake Form:
  - Fill out the demographic intake form with accurate details as requested. (Individual - See Survey 4.0, School - See Survey 1.0)
  - Ensure all fields are completed correctly.
  - If there are any questions or concerns about the form, contact the study coordinator for assistance.

4. OMNI 555 Setup:
  - Carefully unpack the OMNI 555 device from the kit.
  - Follow the instructions provided in the user manual or any accompanying materials to set up the device.

5. Chest Strap Application or Sticker:
  - Apply the chest strap according to the instructions provided or the stickers provided..
  - Ensure it fits comfortably and securely for accurate data collection during sessions.

6. Study Participation:
  - Engage in the designated study activities as instructed by the study protocol.
  - Wear the OMNI 555 device and chest strap during every marching band/football session for 2 weeks.
  - Adhere to any guidelines provided for data collection and recording.

7. Daily Post-Session Questionnaire:
  - Scan the QR code provided for the daily post-session questionnaire. (Individual - see Survey 3.0, School Band director or Football Coach - See survey 2.0)
  - Complete the questionnaire honestly and thoroughly after each session.
  - Ensure responses are accurate and reflective of your experience during the session.

8. Contact Information:
  - Save the contact details provided in the study flyer for any queries or assistance needed during the study period.

- Reach out to the study coordinator or designated contact person for any concerns or issues encountered during participation.

9. Compliance and Follow-up:
- Adhere to the study protocol and guidelines throughout the study period.
- Complete all required activities and questionnaires in a timely manner.
- Notify the study coordinator of any changes in contact information or circumstances that may affect participation.

10. Conclusion:
- Thank you for your participation in the study. Your contribution is valuable in advancing research in this field.
- If there are any additional instructions or updates provided during the course of the study, please follow them accordingly.

By following this protocol, participants can ensure smooth enrollment, participation, and contribution to the study.

Survey 1.0 Collected after obtaining oral/verbal consent

Preseason school and practice and weather information (Completed by Band Director, Team Leader/Captain, Athletic Trainer, or other Assistant)
Address of school
Presence of Wet Bulb Globe Test (WBGT)
Primary contact name
Do you have a heat illness policy for Marching Band/Football Team?
If yes, email it to Raukar.Neha@Mayo.EDU with your school name

Survey 2.0

Daily Practice Information (Completed by Band Director, Team Leader/Captain, Athletic Trainer, or other Assistant)
Surface conditions for practice (grass, turf, asphalt, other)
Temperature of surface - if available
Practice schedule - start and end time
Water break time and length
Presence of an athletic trainer
Timing of practice
Wet Bulb Globe Test (WBGT) reading - if available
Dress code for practice that day
Material of attire (cotton, wool, etc) (if known)

QR Code Here

Survey 3.0

Daily student tracker (Completed by Student)

Device # assigned to the student (student will have the same device through their participation)

What time was practice today?

How much sleep did you have the night before? (hours)

How do you feel prior to the start of practice? (0-5 sliding scale - 0 - I felt great, 5-I felt terrible)

If anything above a 0: Did you feel ill before practice? If yes: nausea, lightheadedness, fatigue, did you pass out, did you feel like you were going to pass out, other?

Did you have any of the following symptoms **after** practice? (drop list)

Headache, nausea, lightheadedness, fatigue, did you pass out, did you feel like you were going to pass out?

if yes to any above: Did you need to sit out of practice?

if yes to any above: Did you need to seek medical care?

Urgent care, emergency department, ambulance

If you completed practice, how did you feel once practice was over? (0-5 sliding scale - 0 - I felt great, 5-I felt terrible)

How hard was this practice? 1-5 sliding scale

How much water did you consume during practice?

Soda?

Gatorade?

(show them pics of water bottles - a standard 16 ounce water bottle and the green Gatorade bottle)

What did you drink: water, soda, sports drink (Gatorade, Powerade), energy drink (Celsius, Bubbl'r), coffee, other

QR Code Here

Survey 4.0

Preseason Participant Background / Demographic Data (Completed by Student only once)

Biological Sex (man/woman) /Gender (male, female, other: write it in)

Past medical history (check box) - anxiety, depression, hypertension, other

Medication/Supplement list (include list of medications, supplements) - will be a check box for medications of interest including NSAIDS, anti-anxiety/ADHD/ADD medications, diuretics, OCP, other

Height of student

Weight of student

What Instrument(s) do you play

QR Code Here