

A Novel Web-based Decision Aid Tool for Reducing COVID-19 Vaccine Hesitancy

HealthCare Innovation Grant: Preliminary Grant

Principal Investigators

Ambar Kulshreshtha, MD, PhD (Corresponding PI)

Assistant Professor
Department of Family and Preventive Medicine

Email: akulshr@emory.edu

Emily Wall, PhD (Co-PI)

Assistant Professor
Computer Science Department
Emory University

Email: Emily.wall@emory.edu

Co-Investigator(s):

Shivani A. Patel, PhD

Rollins Assistant Professor
Hubert Department of Global Health
Emory Rollins School of Public Health

Email: s.a.patel@emory.edu

Zanthia Wiley, MD

Associate Professor
Division of Infectious Diseases
Department of Medicine, Emory University

Email: zwiley@emory.edu

Belinda Adeje, RN, MBA

Senior Nurse Manager
Clinical Services & Operations, Emory Healthcare
East Cobb Internal Medicine, Marietta, Family Medicine Dunwoody

Emory Belinda.adjei-stewart@emoryhealthcare.org

Piyush Kumar, PhD

Associate Professor of Marketing, Terry College of Business,
University of Georgia

Email: pkumar@terry.uga.edu

Significance and goals

While public health measures including mask wearing and social distancing are known to be effective in decreasing transmission against COVID-19, effective vaccines are critical to reduce disease spread, severe complications, and death. In December 2020, the FDA (Food and Drug Administration) provided emergency use authorization for the Moderna and Pfizer COVID-19 vaccines to prevent SARS-Cov-2 infection. These vaccines are about 95% effective in large placebo-controlled phase 3 trials. Despite free and easier access to COVID-19 vaccine, and extensive media campaigns, immunization rates remain unacceptably low, and glaring disparities persist. Vaccine hesitancy is defined as “delays in acceptance or refusal of vaccination despite availability of vaccination services” (McDonald, 2015), and is in part due to concerns around safety and potential side effects of vaccination among the public. **Georgia ranks at 48th in the country with respect to vaccination, and 40% of its residents are still unvaccinated** (CDC, November 2021). With the rapid spread of the **Omicron variant**, it is likely that more boosters will be needed in future. Interventions to address vaccine hesitancy are critically needed for public safety, schools to safely remain reopen, and overall economic activity.

Vaccine hesitancy in part emerges from decisional conflict or uncertainty regarding the best alternative when making choices about vaccination. The **decisional conflict regarding the vaccine and boosters stems in part from an incorrect assessment of the potential risks of COVID-19 infection versus the potential risks from the vaccine and boosters**. It also arises from modifiable factors such as a lack of knowledge regarding safety, misperceptions about COVID-19, perceived personal risk, unclear values, and lack of support and resources. Effective communication (e.g. using internet and social media) can lead to behavior change and can increase the effectiveness and change in public perception about a controversial issue. To the extent that perceived advantages outweigh the disadvantages, individuals are more likely to make an informed decision regarding the vaccine (move from precontemplation to contemplation) and follow-through on taking the vaccine. Several of these problems may be alleviated by **tailored health communication** regarding the advantages and disadvantages of the COVID-19 vaccines based on individualized risk-benefit assessment. A decision aid is a tool that can help individuals understand their options objectively and assess the risks and benefits of a particular intervention (such as medication, behavior, vaccination). Several studies have shown that using a decision aid-based non-directive educational approach can help individuals reach a decision by alleviating their ambivalence and eliciting a desired behavior change. We propose to develop and evaluate a **simple, personalized, data-driven, visual decision aid** for tailored health communication around the COVID-19 vaccine and need for boosters. Our proposed aims are to:

AIM 1: Identification and synthesis of quantitative data points regarding COVID-19 vaccine risks and benefits by demographic group and health condition to develop algorithms for the decision aid.

AIM 2A: Develop a visual decision aid for the public that is designed to influence vaccination behavior through providing scientific and quantitative data to inform individual beliefs about pros (e.g., benefits of the vaccine) and cons (e.g. risk of side effects) through the algorithms developed in Aim 1. **AIM 2B:** Conduct formative research to evaluate multiple presentations of the visual decision aid to identify the most effective approach to provide clear communication and influence vaccine decision making.

AIM 3: Evaluate the effectiveness of the prototype visual decision aid through a randomized pilot trial of 20 unvaccinated patients within Emory Healthcare. *Hypothesis:* The visual decision aid will improve patient understanding of risks and benefits of the COVID-19 vaccine, resulting in reduced vaccine hesitancy.

Innovation

We propose a novel, public facing, web-based tool that will deploy a decision aid and can be used by people in US and globally. Currently there is no known objective educational or decision aid tool to help people understand the risks/benefits of COVID19 vaccination and booster doses. By creating a novel, reliable, effective, and easy-to-use website for the general population, health care providers, and policy makers, it will be readily available to guide their decision making. It will provide personalized risk assessment for all age-groups (including children) about the risks/benefits of COVID19 vaccination, boosters, and give people the benefit of choice and agency. It will be **patient-centered and personalized** for individual risk assessment regarding COVID19 and will have a direct-to-consumer interface for wider dissemination, can be especially useful for targeting people who seek healthcare less often. (e.g., young adults). Another unique feature of our decision aid will be that it incorporates **evidence and research from multiple disciplines** including

epidemiology, behavioral psychology, and marketing. For example, to avoid making vaccination as an extreme option, our decision aid tool will present a **three-tier final option** (rather than two-option) choice, to allow people to get the vaccine now, defer for a later date, or avoid it completely (Wood S, et al NEJM, 2021). The tool will also be **dynamic and updated regularly** as more data is available regarding risks of new COVID-19 variants, vaccine trials in children <5 years, and other population subgroups, and community prevalence of COVID19. Finally, **the visual and graphical format** of the decision aid will allow the website to better inform patient-physician discussions on this topic and can be readily used among non-English speaking populations.

This decision aid tool for COVID19 vaccine would be the first of its kind, easy-to-use, dynamic and interactive website (with some elements modeled after popular decision aid tools such as the <https://carethatfits.org/>; <https://statindecisionaid.mayoclinic.org/>). We plan to integrate this tool to the existing Emory COVID-19 Health Equity Dashboard (emory.covid19.edu). The **COVID-19 Health Equity Dashboard** was created by this team including **Dr. Emily Wall and Dr. Shivani Patel** to track and disseminate epidemiologic data regarding the US pandemic within social context across US counties. The dashboard has become a widely used tool by decision makers, the public, and academics, and has been featured by the CDC Covid Tracker and several media outlets such as NPR, Science Magazine, and CNN. The dashboard was built by an interdisciplinary team of researchers and students at Emory University and draws on several publicly available data sources. The vaccine decision aid will be placed in the public domain through creating a dedicated page within the dashboard. We anticipate this to be a widely accessed resource that can be promoted through several community-facing projects designed to improve vaccine uptake across the state and nation. Our COVID-19 vaccine decision aid will be further assessed in larger clinical trials regarding the degree to which it can help improve vaccination rates globally.

Nature of the collaboration

This project represents a collaboration among a team of inter-disciplinary experts based at School of Medicine (SOM), the Rollins School of Public Health (RSPH), Emory College of Arts and Sciences, Emory Healthcare, and other collaborators in Georgia State and Georgia Tech to apply complementary knowledge and research methods for solving the complex problem of vaccine hesitancy. **Dr. Ambar Kulshreshtha** is a physician-epidemiologist at Emory, who has been the PI for several pilot studies looking at web-based approaches of delivering interventions in primary care for patients with cognitive impairment, diabetes, and heart failure. He has led recent studies on COVID vaccine hesitancy across all major health care systems in Georgia. **Dr. Emily Wall** is an Assistant Professor in the **Computer Science** department at Emory University. Her research focuses on **data visualization**. Along with collaborators at Georgia Tech she develops computational approaches to characterize human decision making and designs and implements visualizations to better support decision making. **Dr. Shivani A Patel** is a social epidemiologist at RSPH who leads the Emory COVID-19 Health Equity Dashboard and has studied health equity and dimensions of the vaccination rollout. She will provide expertise in disparities populations, health communication to the public, and integration of the tool with the COVID-19 Health Equity Dashboard. **Dr. Zanthia Wiley** is an Infectious Disease specialist at Emory SOM and will contribute to the development of the algorithms as well as recruiting patients for the evaluation of the tool. **Belinda Stewart** is an RN at Emory Healthcare and has leadership roles in minority and immigrant communities in Atlanta. She has been active in campaigns to improve vaccination rates in her community. **Dr. Piyush Kumar**, Professor of Marketing at the Terry College of Business will help identify potential commercial partners and devise the marketing and distribution plan for the vaccine decision aid.

Approach

AIM 1: Identification and synthesis of quantitative data points regarding COVID-19 vaccine risks and benefits by demographic group and health condition to develop algorithms for the decision aid. (months 1-2)

An Emory SOM research assistant with statistical background, in under the supervision of Dr. Kulshreshtha, will conduct a systematic review of published studies on COVID-19 vaccine risk factors as well as the potential benefits under various scenarios of the prevalence of the disease. Results will be used for comparison against an individual's characteristics to build the decision aid tool for computing an individual's risk and benefits.

Data sources include (1) COVID-19 vaccine manufacturers, (2) post-marketing surveillance regarding rates of side effects seen, and (3) FDA reports on the efficacy of approved vaccines and (4) data on the community prevalence of the disease and adverse health consequences. These data sources are publicly available.

Following the discovery phase and the acquisition of the data, the individual sources will be cross-validated, cleaned, and curated into a live common source. Statistical analyses will include developing a personalized data-based model for COVID-19 risk estimation (e.g. <https://covid19risktools.com:8443/riskcalculator>) as well as the estimation of risk from alternative vaccines. The predicted output of this conditional statistical analysis will be used to design the interactive decision aid for helping individuals assess their own risk levels based on simple parameters that they will input on the public user interface.

AIM 2A: Develop a visual decision aid for the public that is designed to influence vaccination behavior through providing scientific and quantitative data to inform individual beliefs about pros (e.g., benefits of the vaccine) and cons (e.g. risk of side effects) through the algorithms developed in Aim 1. **AIM 2B:** Conduct formative research to evaluate multiple presentations of the visual decision aid to identify the most effective approach to provide clear communication and influence personalized vaccine decision making.

2A. Decision Aid Design & Development (months 1-8): An Emory Computer Science student, in collaboration with Dr. Emily Wall, will design and develop an interactive decision aid informed by (1) research in cognitive science and decision making on the design of effective decision aids and (2) principles of effective communication through data visualization. Following a user-centered design process, the decision aid will be shaped by formative feedback from stakeholders including epidemiologists, doctors, public health experts, and end-users. The decision aid will be developed as an innovative new feature in the ecosystem of Emory’s COVID-19 Health Equity Dashboard [1] under the existing webspace (<https://covid19.emory.edu>). The decision aid will be developed in JavaScript using well-known open-source libraries (e.g., React JS) for front-end development. The vaccination decision aid will be promoted alongside the vaccine related resources already housed within the dashboard (e.g., <https://covid19.emory.edu/vaccine-tracker>). The decision aid will involve several informational and personalized interactive components, including modules containing (1) information about risks and complications of COVID-19, (2) personalized risk assessment calculator, (3) information about COVID-19 vaccines approved for use in the US, (4) advantages and disadvantages of vaccination, and (5) a map-based tool to locate vaccine availability. These modules will be developed in parallel, beginning immediately and continuing through July. Each module will be instrumented to collect anonymized interaction logs to support future research on the effectiveness of the decision aid. After the initial launch of the decision aid, additional data about vaccines approved globally will be integrated.

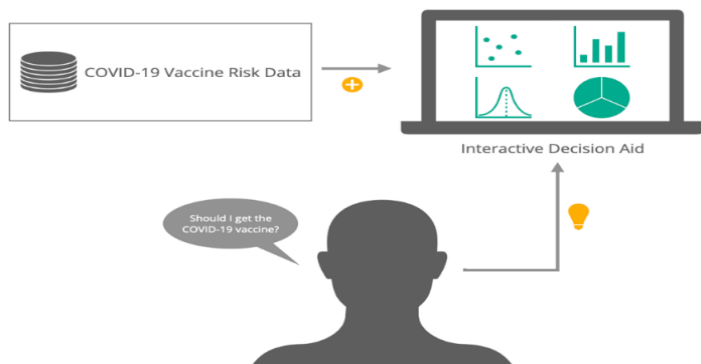


Figure 1: Interactive Decision Aid for COVID19 vaccine and booster decisions

Table 1: Modules that will be incorporated into the COVID19 decision aid along with the types of information contained in each component.

COVID-19 Decision AID Tool Component	Topic Covered
Information about COVID-19 and Risk of complications	- Clinical Features of COVID19, How COVID19 differs from Flu, Cold and Allergies. - Risk of hospitalizations, Complications, and Deaths based on data from current variants in the community.
Personalized Risk Assessment (Risk prediction algorithm)	- Age, Race, Risk factors, and contraindications
Information about COVID-19 Vaccine (Pfizer, Moderna, J&J)	- How the vaccine works, effectiveness, rates of adverse effects

Advantages of getting vaccinated	- Protection of family members, friends, workplace, potential of ending the pandemic
Disadvantages of getting vaccinated	- Potential for fever, myalgia, and risk of adverse events such as clots
Where to get the vaccine	- Information regarding vaccine availability based on residence

2B. Formative Feedback on Decision Aid Visualizations (months 3-8): The initial design and deployment of the decision aid will be driven by formative user feedback. After the deployment of the decision aid, additional evaluations will take place to inform future iterations. We will conduct crowdsourced user studies, e.g., via Amazon Mechanical Turk, to assess learnability and ease of use of the decision aid. We will conduct additional user studies in-lab to collect qualitative feedback on the usefulness, navigability, and completeness of the decision aid to impact users' behaviors around personal vaccine decisions. This will be led by Dr. Patel.

AIM 3: Evaluate the effectiveness of the prototype visual decision aid through a randomized trial study of 20 unvaccinated patients within Emory Healthcare. Hypothesis: The visual decision aid will improve patient understanding of risks and benefits of the COVID-19 vaccine (months 8-11)

The purpose of this randomized pilot is to determine whether a patient centered/tailored visual decision aid tool can increase confidence regarding vaccination among people who are undecided or decline to use COVID19 vaccine. We seek to assess if the visual decision aid affects the intent of a person to be immunized or not. We will recruit up to 20 patients at Emory Primary Care clinics who self-identify as not having received the COVID-19 vaccine and are vaccine hesitant under the supervision of Drs. Kulshreshtha and Wiley. We will examine their perceived risk, perceived benefit, and level of hesitancy before and after exposure to the visual decision aid. The pilot study focuses on English-speakers for feasibility of completion within the one year timeframe. Statistical analysis (led by Patel) will estimate post-intervention between group differences and within-person change pre- and post-intervention.

Table 2. Decision aid evaluation trial design

Recruitment: The site for the pilot clinical intervention will be at Emory primary care clinics. Patients who are seen in regular clinic will be asked regarding COVID19 vaccination status and will be approached later via letter or phone call from the investigator team with a description of the study. Based on evidence-based recruitment strategies, we will take additional steps to enroll 50% minority men and women. CONSORT guidelines will inform procedures. At the first screening contact, participants will give verbal informed consent and will be interviewed by a study staff to determine eligibility. If patients are deemed eligible, they will complete written informed consent.
Setting: Emory Primary Care Clinics
Randomization: Assignments to the two groups will be based on a random number sequence.
Inclusion Criteria: (1) EHC patients >18 years old who have not received the COVID-19 vaccine. (2) English speaking. Exclusion criteria: (1) Contraindication to get the vaccine such as allergy to any of the vaccine components. (2) Unable to consent because of medical conditions (such as dementia)
Intervention: Patient-centered and tailored Decision aid tool to help vaccine hesitant participant decide regarding the COVID19 vaccine administered in the clinic waiting room. Control: Standard CDC information booklet (https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html)
Outcomes: Survey-based assessment of decisional knowledge, decisional conflict and values choice concordance about COVID19 vaccine (Decisional Conflict Scale), and self-reported vaccination status at one-month. Measurement: Knowledge and intention outcomes will be assessed immediately following use of the tool (primary) and by online surveys 1 week and 1 month after using the decision aid (secondary). Online survey of self-reported vaccination status at one month after the intervention (secondary).

Impact: Effective interventions are necessary to engage stakeholders to address misinformation regarding COVID19 vaccines. This will be the first decision aid for COVID19 vaccine and will present vaccination pros and cons in a simple, transparent, and evidence-based manner. If pilot findings indicate effectiveness of the decision tool, we will apply for grants to conduct a randomized controlled trial to adapt the tool for culturally (rural and urban) and linguistically (such as Spanish language) diverse populations and evaluate its impact on vaccination uptake. Future funding will be sought from PCORI (Patient Centered Outcomes Research Institute), NIH (National Institute of Health), and private foundations such as the Gates foundations. In addition, the tools and collaborations will be expanded to other health outcomes where there are large gaps in the uptake of evidence-based therapies among the public.

Timeline

The timeline for this project has been extensively discussed and deemed feasible given the team’s prior experience and the urgency to develop a tool for this complex problem.

Months →	1 st	2 nd	3 rd	4 th	5 th	6 th	7 th
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Project plan and milestones

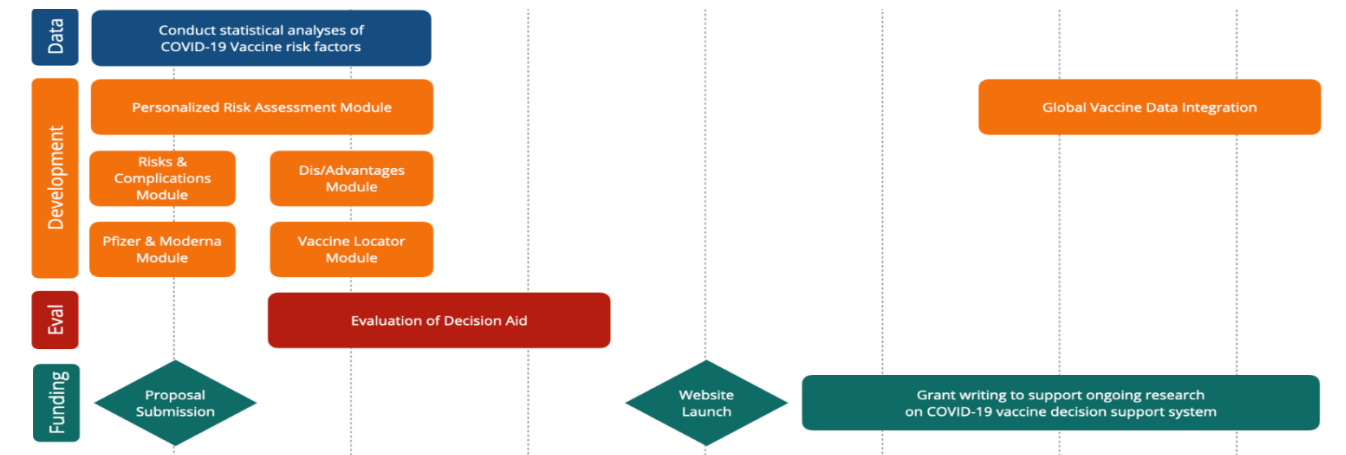


Figure 2: A timeline of the proposed development activities.

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