STANDARDIZING THE ALLERGY SKIN PRICK TEST

ACCESSIBILITY OF ALLERGY TESTING FOR LOW-INCOME FAMILIES

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

For my capstone project, I am working to create a device and/or protocol that standardizes the allergy skin prick test, or SPT. Currently, there is no definitive method followed to conduct an allergy skin prick test, which involves dipping a lancet into allergen oil and scratching the surface of the skin to introduce allergen to the body in order to detect a reaction via swelling and/or a red flare (*Position Paper: Allergen Standardization and Skin Tests - Dreborg - 1993 - Allergy - Wiley Online Library*, n.d.). Skin prick tests face a large amount of variation between operators, with factors such as depth of penetration, force of penetration, and proximity to other test sites being some of the controllable factors. In addition, there is no quantifiable and reliable method to interpret the results. Thus, results can vary from patient to patient for the same allergen, and can even vary for the same patient based solely on how the test was conducted.

I am working on the topic of standardizing allergy testing protocols for allergy patients because I want to find out how standardizing this technology will affect accessibility across various demographics, including lower income families. I want to determine whether current technologies are accessible, and whether or not standardizing allergy testing will increase accessibility, or alternatively make it harder to access for families in need. This is important because testing for allergies is critical during the earliest years of life in order to prevent serious allergic reactions during childhood (Høst et al., 2003). Since current allergy testing protocols are not standardized, every hospital has a different way of testing for allergies and thus results vary from one hospital to the next. As an outcome, patients and families cannot get second opinions to inform their financial decisions, which becomes a struggle for lower income families.

As biomedical engineers, we create technology for the health and wellness of humans, and it is our responsibility to make these technologies accessible to those who need it in terms of cost as well as availability (Masum et al., 2013). Conducting this research for testing protocols and technology will allow us to understand the current limitations of existing technologies, including accessibility, and thus allow us to create a new technology for allergy testing that is both standardized and accessible to those who need it.

Challenges in Standardizing the Allergy Skin Prick Test

The allergy skin prick test is neither standardized in application nor result interpretation. In terms of application, there are a variety of factors that influence how the skin prick test is conducted (*Position Paper: Allergen Standardization and Skin Tests - Dreborg - 1993 - Allergy - Wiley Online Library*, n.d.). The general method is to dip a device into allergen oil then prick the skin. There are several different devices with different strengths and weaknesses currently used to conduct an allergy test. The main current devices are the lancet needle, which is a handheld metal stick with a small metal needle at the end, the lancet stallerpoint, which is a handheld plastic stick with a metal needle at the end, and the greer pick, which is another handheld plastic stick with several sharp plastic prongs at the end. All of these devices are single use and handheld, making for easy access and minimal setup. The lancet needle is appealing for its ability to be used at several different angles, while the lancet stallerpoint can only be applied straight down on the skin. Both of these devices also have a natural stopping point that prevents the needle from entering the skin too deeply. The greer pick is attractive for its method of scratching rather than pricking the skin. However, none of these advantages are consistent per application. The force and angle with which the needle is applied, the depth at which the needle

enters the skin, and the site of the test are all at the discretion of the nurse who is conducting the test (Høst et al., 2003). In addition, proximity of tests to each other can cause a larger reaction than would occur if they were spaced farther apart.

In terms of result interpretation, results can vary anywhere from redness in the area of application to a large raised welt or bump on the skin. Results are interpreted by the nurse who conducts the test, who assesses the presence and size of the bump to determine if it is within the range to consider the patient allergic to the tested allergen. This process is arbitrary and there is no reliable or quantifiable way to interpret the results, leading to a variety of diagnoses across nurses and hospitals conducting the same test, including false positives and negatives (Roberts et al., 2016). In addition, the allergen oils used for allergy tests are also not standardized, meaning that some allergen oils could be stronger than others and induce a stronger allergic reaction (Høst et al., 2003; *Reliability of Allergy Skin Testing - ClinicalKey*, n.d.). Along with these post-test considerations, there are a few pretest factors that can affect result interpretation, such as ethnicity, age, environmental factors, and coexisting clinical diseases (Gergen et al., 1987). These factors can affect the way someone reacts to an allergy test, making it important for nurses to consider these variables when interpreting the results of an allergy skin prick test, but there currently is no way to incorporate these pretest probabilities into result interpretation.

These inconsistencies amongst application and result interpretation make the test unreliable and thus skin prick allergy testing is not an effective nor efficient way to test for allergies. The most accurate way to test for allergies is through an immunoglobulin E blood test, also called an IgE test, which tests the amount of immune response for different allergens; however, this method can take several weeks to yield results, whereas an SPT takes less than an hour. In addition, there is a poor to moderate agreement between the two tests, highlighting the

unreliability of SPTs (Schoos et al., 2015). Thus, there is a need for a reliable and efficient device or protocol to standardize the allergy skin prick test, which is the exact goal of my capstone project.

Designing Accessible Allergy Testing for Low-Income Families

Accessibility is an important factor to consider when designing new technologies. Thus, the purpose of this project is to conduct research for test protocols and technology in order to understand the limitations of current technologies, and specifically focus on accessibility across low-income families. Low-income families with allergies already have difficulty when it comes to allergy management, and the last thing they need is an unreliable, expensive allergy test (Hill et al., 2004). Therefore it is important to create and standardize an affordable test and/or method, especially for low-income families.

The main cost-burdens families face due to having food allergies include lost labor productivity, out-of-pocket costs, and opportunity costs, whether it be for choosing one testing protocol over another or for allergy test expenses that could have been spent elsewhere. In terms of low-income families, they may have poorer access to anaphylaxis treatment and may therefore be at a higher risk of allergy-related harms. Some documented harmful patient habits regarding avoidance of allergy-related costs were keeping expired epinephrine pens or using benadryl and other over the counter medicines to treat an allergic reaction, which highlights the need for affordability in allergy tests (Hill et al., 2004). Allergists' interpretation of results is also extremely important for patients, both financially and personally, since patients often change their diet and/or lifestyle based on the allergist's opinions and direction, which can lead to higher health care costs if misdiagnosed (*Unnecessary Food Allergy Testing by Primary Care Providers*

- *ClinicalKey*, n.d.). The food allergy field is an area with many opportunities for shared decision-making between patients and allergists. Since patients need to obtain the necessary information and understanding of existing options from the allergist, and allergists need to understand where their patient is coming from and their needs, preferences, and values, it is critical that an accurate and reliable allergy skin prick test protocol is devised (*Shared Decision-Making in Food Allergy - ClinicalKey*, n.d.).

In order to analyze the implementation of a new technology, and the current problem itself, an experimental design approach will be taken to compare current methods to the new technology. Nurses, medical technicians, and allergists who are involved in administering the skin prick test will conduct this experiment on a diverse sample of patients across different demographics, including varying age groups, ethnicities, environmental factors, coexisting clinical diseases, and socioeconomic backgrounds. The several different aforementioned types of allergy devices will be tested for consistency and patient response, and the results will be compared across different healthcare providers to assess variability in interpretation.

In terms of assessing accessibility, especially amongst low-income families, data will be gathered on the cost and time associated with current methods of allergy testing, such as the cost of an allergy test itself, allergy medications, and/or preventative measures. Once the new device is implemented amongst a sample, these metrics will be measured again to determine if there was a difference in affordability and overall decrease in allergy related expenses. In addition, healthcare providers and patients will be surveyed on perceived accessibility issues, focusing on socioeconomic barriers such as costs and insurance coverage. This data will be used to create several refining iterations of the device and/or protocol that combat financial obstacles in order

to develop a practical version of the device and/or protocol that is affordable and accessible to low-income families.

Conclusion

There is a lack of affordable and effective health technologies that address key health needs and concerns in the developing world. It is our job as engineers to create technology for the health and wellness of humans, while also making it affordable and accessible. Implementing this research regarding testing protocols and technology will allow us to understand the current limitations of existing technologies, including accessibility amongst low-income families, and thus allow us to create a new and revised, standardized technology for allergy testing.

As an outcome of my capstone project, I expect the new device developed to be reliable, easy to administer, and capable of producing consistent results that are accurately interpreted. Less false positives and negatives as well as a decrease in misdiagnosis are both intended outcomes of the new device and/or protocol. In addition, I expect the device to be cost effective to produce and have long term financial effects such that low-income families are able to afford the technology. Along with the physical device and/or protocol reducing cost burdens on low-income families, I also expect the accuracy and reliability of the test to lead to lower overall allergy related costs.

In conclusion, by addressing both the technological limitations and accessibility challenges of current allergy technologies, this capstone project aims to create a standardized, cost-effective allergy device and/or protocol that improves diagnostic accuracy, reduces healthcare costs, and ensures better access for low-income families.

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