## New Skin Prick Test Device with Improved Standardization

Identifying Social Factors Resulting in Lack of Public Awareness on Food Allergy in China

A Thesis Prospectus In STS 4500 Presented to The Faculty of the School of Engineering and Applied Science University of Virginia In Partial Fulfillment of the Requirements for the Degree Bachelor of Science in Biomedical Engineering

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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:* Food allergy (FA) prevalence is rising and has become a serious public health issue. The most severe reaction, anaphylaxis, can lead to respiratory problems and dangerous drop in blood pressure that can lead to life-threatening medical emergencies. Therefore, my technical and STS research topics focus on the sociotechnical problem related to the increased FA prevalence. Together, they aim to identify social factors that refrain appropriate public acknowledgement of and response to FA as a public health issue that affects community-level well-being and assessing technical shortcomings of current diagnostic tools, specifically Skin Prick Test (SPT) devices, that reduce FA testing accessibility or reliability. In China, the prevalence of food allergy ranged from 4.0% to 8.2%, comparable to that in the U.S., where FA affects up to 8% of children and 10% of adults. While initiatives like Food Allergy Awareness Week in the U.S. aim to promote social awareness of food allergies (FA), public awareness regarding proper FA diagnosis and management remains limited in China. This can be caused by regional variations in FA prevalence and a lack of comprehensive data on the most common allergens in addition to other compounding factors that will be later discussed.

Regarding the technical topic, SPTs are a quick, inexpensive allergy test used to detect suspected type-1 allergens such as foods, pollens, or dust mites, by inserting a small amount of allergen underneath the epidermis using a lancet (Frati et al., 2018). An allergic reaction is represented by a red welt and quantified by the wheal size characterized by a raised, white-edged area. However, SPTs face high variability in the results between operators, with contributing factors such as depth of penetration and force applied, rendering test results susceptible to false positives and negatives (Andersen et al., 2016 & Fatteh et al., 2014 & Berger, 2002). The STS approach, on the other hand, will identify social determinants in China that could lead to insufficient public

awareness on the harm of FA as a public health issue and inadequate information in food services, which affect not only the local population but also foreign visitors.

With a SPT device designed to reduce operator-dependent variabilities, they can be promoted as an inexpensive, accessible, and reliable allergy diagnostics to increase public awareness on FA and promote proper, timely management in China.

*Technical:* Imagine flipping a coin to receive the results of your allergy test—50% of the time it is a false positive. This is the reality of current SPTs – about 50% yield false positive results from excess force applied, which can also induce patient discomfort and even bleeding (Birch et al., 2023). Insufficient force, on the other hand, can cause false negatives (White, 2023). This demonstrates the limitations in reproducible results from current SPT devices when operated by different individuals on the same patient.

White (2022) pinpointed the pressure applied by the SPT operator as a variable that impacts the test results in response to histamine, a common substance used for positive control in SPTs. Although a few studies have analyzed the qualitative role of pressure in affecting SPT results by applying it to a light, moderate, or hard extent, the qualitative scale is difficult to translate into quantifiable standardization. This solidified the importance of incorporating quantitative assessment of potential operator-dependent variables. Additionally, through a literature search of publications from North America spanning 5 years that used medical subject headings focused on allergy trial keywords, Chiaranairungroj et al. (2023) found that up to 90% of practicing clinical allergists might not be objectively assessing the reproductivity of SPT results among different operators, further indicating that SPT result reproducibility has been a long-established, overlooked issue. Therefore, the technical project seeks to establish and implement

standardization in SPTs based on the different operator-dependent factors (i.e. force, angle applied, and depth of penetration).

To achieve the potential standardization, we will first identify and assess the different operator-dependent factors, specifically the independent effects of force, angle of the device, and depth of penetration. Using an Instron machine and controlling each variable, my team will quantify the amount of fluorescence-labeled allergen oil transferred onto a skin-simulating medium, a decellularized epidermis sheet, by performing an absorbance assay. The goal is to develop a relationship between each of the three variables and the amount of allergens delivered, which dictates the wheal size in a SPT and its according result for a patient.

*STS:* Through my upbringing in China and my experience while studying abroad in the U.S., I have realized that there exists a lower level of public awareness on FA in China than the U.S. as a public health concern, despite comparable FA prevalence. Feng et al. (2023) stated that the FA prevalence in China ranged from 4.0% to 8.2%, varying regionally; while FA affects up to 8% of children and 10% of adults in the U.S. Although China has carried out some research on risk assessment of allergenic foods, most studies on the prevalence of FA were restricted to specific regions. High-quality prevalence data were also limited, partly because of the absence of a standardized diagnostic protocol involving oral food challenges (OFC). Moreover, a list of priority allergenic foods based upon the actual situation of the Chinese population is not currently available (Chen & Wu, 2022). Chen and Wu's perspective helped me develop the perception that the lack of comprehensive, compelling epidemiologic studies on FA that take into account the regional differences in China might be one social reason contributing to the insufficient public acknowledgement of the severity of FA as a public health challenge nationally. My STS argument is that there is a need for identifying social determinants in China

to increase general knowledge on the prevention and control of FA from the public population to the food service industries.

The theoretical framework applied is the health impact pyramid that describes the effects of different public health interventions. It is composed of, from bottom (exerting greater impact) to top respectively, socioeconomic factors, context of health, long-lasting protective interventions, clinical interventions, and counseling and education (Frieden, 2010). My methodology will focus on the bottom two tiers of the pyramid, specifically socioeconomic factors and context for health. I plan to (1) review existing literature on the factors limiting the dissemination of public knowledge on FA, (2) compare the difference in social initiatives and community-based policies to raise FA awareness in the U.S. and China, and (3) conduct a field study to evaluate the availability of FA information on online menus at major restaurant chains in Shanghai, China, such as Pizza Hut.

In a population-based survey in Inner Mongolia, northern China, Wang et al. (2018) found a positive correlation between high socioeconomic status and FA prevalence. I rendered the result expected in that it can be attributed to the fact that individuals from higher socioeconomic groups tend to be more aware of their health and have more means in seeking medical diagnosis. Liu et al. (2024) also showed how economic development and urbanization might be responsible for the increase in allergic disorders in China. This further prompted me to argue that the different prevalence in developing FA due to socioeconomic disparities might inherently lead to an overlooked, insufficient distribution of public awareness on the potential severity of FA as a public health issue if left unresolved. While it is understandable that some populations may be less affected by FA, addressing it as a significant global public health issue requires a shared level of awareness and knowledge. This is especially important since interactions around food

often transcend socioeconomic boundaries and play a role in narrowing disparities. Lie et al. also discussed how the complex nature of Chinese cuisine could pose an additional layer of difficulty in identifying specific allergens in an allergic reaction. The complexity of ingredients intrinsic to Chinese cuisine strengthens my STS approach, examining whether food labeling and FA warnings on restaurant menus in China are optimized to enhance public awareness of FA, thereby promoting community health and well-being beyond individual-level impacts. This angle of a food service's comprehensiveness and availability in disclosing FA information constitutes the second bottom tier of the health impact pyramid, context for health. I will also compare my findings through my aforementioned STS methods with community-based policies in the U.S. that I considered relevant through literature reviews to draw inspirations on how to enhance FA public knowledge in China by refining menu designs regarding RA and reinforcing community-level initiatives. Furthermore, I am interested in comparing menus from niche, special-diet restaurants in Shanghai (e.g., vegetarian restaurants) with those from mainstream chain restaurants to explore whether the former include more FA warnings, given their focus on catering to specific dietary needs.

In addition to social determinants, government regulations can play a significant role in implementing policy changes to take effect. Feng et al. (2022) found that there was no regulation on classification and management of food allergy specially for college students besides the two national standards related to food allergen labeling in China. Given socioeconomic disparities have been identified as a cause of lack of FA social awareness in China, the college population is one that features a variety of students from different socioeconomic statuses. Therefore, the implementation of more FA regulations on subpopulations with a diverse-population profile in

order to evaluate the positive outcome is necessary and beneficial before scaling up for nationwide policy changes.

*Conclusion:* Given the high degree of variability in SPT results, it is critical to identify and quantify how different operator-dependent factors compromise the test results' reproducibility. A standardization needs to be established to increase SPT result consistency. In the STS topic, social determinants in China are analyzed that lead to a lower level of public awareness on FA as a public health issue than in the U.S. despite comparable prevalence. Socioeconomic status and the context of health, specifically a food service's clear outline of all allergens in a Chinese dish, have been underlined in various studies that are responsible for contributing to the gap between individual-level FA impact and public acknowledgement as well as knowledge on proper management through timely diagnosis. Government regulations are also called upon to focus on community-based initiatives to raise FA awareness to alleviate the public health concern in China. Understanding the current situation of FA and the shared knowledge of FA in China is deemed essential to global public health to promote early intervention and prevention techniques (Tang et al., 2019).

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