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Pursuing a "normal" life of food: Families' experiences of pediatric food allergy clinical trials

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ABSTRACT

Although food allergies have been on the rise over the past twenty years, there are currently just two products approved by the United States Food and Drug Administration (US FDA) for this condition, and one treats peanut allergy only. For families seeking medical intervention for their children's food allergies, many turn to clinical trials, which have proliferated in the last decade. Indeed, the entry of the pharmaceutical industry and the availability of clinical trials are rapidly reshaping the food allergy landscape. As a result, many families now perceive clinical trials as a way to "do something" other than merely avoiding the foods to which their children are allergic. Based on ethnographic research, including 124 semi-structured interviews with families and other key stakeholders, this article describes parents' and children's experiences in these clinical trials. It describes how the families that pursue clinical trials for their children's food allergies are typically affluent, and the "normal" life they hope to achieve for their children reflects idealized and privileged notions of normalcy. Analyzing my findings through the lens of stratified biomedicalization, I argue that affluent parents willingly accept a form of biomedicalization of their children that involves exceptional, and sometimes traumatic, clinical trial experiences as they pursue the elusive normal life and future they envision for them.

1. Introduction

Food allergy is a condition in which a person's immune system mistakenly views an otherwise harmless food as a threat and triggers what could become a potentially life-threatening reaction (Nettleton et al., 2009). Food allergy diagnoses have increased dramatically since the 1980s (Smith, 2018; Waggoner, 2013), and an estimated 5.6 million (1 in 13) children in the United States (US) have a food allergy, with nearly half being allergic to multiple foods (Gupta et al., 2019). With the increasing prevalence of food allergy, it has not only been deemed an important public health concern but also a commercially attractive area for pharmaceutical and biotechnology investment (Nadeau and Barnett, 2020; Smith, 2018). Indeed, the peanut allergy treatment "market" alone has an estimated value of $4.5 billion annually (Pharmaceutical Technology, 2018). As a result, food allergy treatment has become a major area of pediatric research and product development. In addition to increased private investment, the National Institutes of Health (NIH) expanded research funding for food allergy from $5 million in 2000 to nearly $500 million in 2022 (NIH RePORTER, 9/14/24).

Clinical research on food allergy has already started to pay dividends. Since 2020, two products have received approval by the US Food and Drug Administration (FDA) to treat food allergy. The first was Palforzia, which treats peanut allergy through an exposure therapy model in which increasingly larger doses of a pharmaceutical-grade peanut powder aim to decrease patients' risk of reaction in the case of an accidental exposure (Nadeau and Barnett, 2020). Palforzia was approved for children aged 4–17 in February 2020 and later approved for children aged 1–3 in July 2024. The second drug approval was for a new indication of Xolair (omalizumab), a monoclonal antibody that has been on the market since 2003 to treat asthma. In February 2024, Xolair received approval as a food allergy treatment for patients aged 1 and up. Xolair also offers protection from a severe food reaction, but it does so not by desensitizing the patient to their allergen but by interrupting the immune system's response to the food.

For any drug to receive FDA approval, participants are needed for clinical trials to test its safety and efficacy. In food allergy, those participants are typically children. This article explores the motivations and experiences of families that enrolled a child in a food allergy trial,

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including the Palforzia and Xolair trials. Drawing on ethnographic research, including 124 semi-structured interviews with key stakeholders, this article illustrates that the predominantly affluent families pursuing food allergy trials are in search of what they perceive as a normal life for their children. As the data from this study will show, this sought-after "normal" life reflects a highly privileged one. At the same time, in seeking normalcy for their children, these families give their children an extraordinary experience in clinical trials—one with potentially severe and traumatizing harms. Analyzing my findings through the lens of stratified biomedicalization, I argue that affluent parents willingly accept this form of biomedicalization of their children as they pursue the elusive normal life and future they envision for them. This study contributes to conceptualizations of stratified biomedicalization (Clarke et al., 2003, 2010), in particular, not only by showing how clinical trials can enforce social inequalities but also by emphasizing the embodied labor, including child labor, that biomedicalization requires of those who have the means to pursue it.

2. Background

2.1. Food allergy, health disparities, and everyday life

Food allergy substantially impacts families, and concerns about patients' and families' quality of life, not preventing deaths, have been central to arguments for the need for food allergy treatments (Cook, 2023; Pitchforth et al., 2011; Warren et al., 2021). Deaths caused by food allergy are extremely rare (Anagnostou et al., 2022), but parents often hold exaggerated views of the risk (DunnGalvin et al., 2009). These unrealistic risk perceptions, coupled with a lack of "responsible sociality," or ethic of care from unaffected people, to protect those with food allergies (DeSoucey and Waggoner, 2022), compel families to avoid the risks that others present to their children in schools, airplanes, sports stadiums, and other semi-public spaces (DeSoucey and Waggoner, 2022; Smith, 2018). Following food allergy diagnosis, many families severely restrict their activities, including avoiding restaurants, travel, and socializing with other families (Herbert et al., 2016), and much of the labor and anxiety associated with managing children's food allergies falls on mothers (DunnGalvin et al., 2006; Glabau, 2022; VanderKaay, 2016).

Allergy has been seen as a disease of affluence, one that primarily occupies the "White, worried, and well" (MacPhail, 2023), hiding substantial health disparities associated with the condition (Tepler et al., 2022). Indeed, one stereotypical image associated with food allergies is the highly neurotic "food allergy mom" who is White, often does not work outside the home, and whose life and identity revolve around her child's (or children's) food allergies (Glabau, 2022). Despite this image, US prevalence data suggest that Black children have a higher risk of developing food allergies compared to non-Hispanic White children (Gupta et al., 2019). Black and Hispanic children also have higher rates of being seen in an emergency department for food-induced anaphylaxis (Warren et al., 2020), which may result from low-income families' limited access to expensive allergen-free foods and epinephrine auto-injectors (Minaker et al., 2014). Thus, food allergy, as with most healthcare concerns, is characterized by health disparities that stem primarily from social and economic inequalities (Dehbozorgi et al., 2024).

Until 2020, the only FDA-approved food allergy treatments were epinephrine products (e.g., EpiPen) that are used to stop an allergic reaction after it has been triggered. As rescue medications, these products are essential tools for managing food allergies, but they do not treat the underlying condition itself, frustrating many parents who want a disease-modifying treatment instead. The allergy field has started to shift from an avoidance to exposure model of managing food allergy through therapies that require patients to consume small amounts of their allergen (Nairn, 2023), but in the US, clinical trials have been a primary way for parents to "do something" about their children's food allergies beyond avoiding the allergens and carrying epinephrine.

2.2. Food allergy clinical trial risks and benefits

All clinical trials include risks and burdens. In food allergy trials, the study intervention might be a daily dose of food allergen with its concomitant risk of anaphylaxis (Nadeau and Barnett, 2020), or the study intervention might be regular injections of a monoclonal antibody that carries increased risk of infections (Casale et al., 2024). However, many parents also perceive receiving a placebo as a risk because all their time, energy, and hope is invested in a clinical trial that will have no individual benefit to their child (Greenberg et al., 2018). In that vein, food allergy trials typically require a substantial number of study visits. Because these occur during conventional business hours, caregivers might have to take (paid or unpaid) time off from work and the child might have to miss a few hours or a day of school (Nadeau and Barnett, 2020). These are not inconsequential burdens, as will be seen below.

One of the largest risks associated with food allergy trials is the double-blind, placebo-controlled oral food challenge ("food challenge" hereafter) (Plaut et al., 2009). Because current food allergy testing is highly inaccurate (Kerr et al., 2009), the food challenge is seen as the gold standard test to confirm an allergy because patients are exposed to increasing doses of a suspected food allergen to determine whether and at what dose a reaction occurs (Nadeau and Barnett, 2020). In addition to proving children are truly allergic to the food (or multiple foods) as the basis for their study enrollment, the food challenge also generates baseline data about the threshold at which the child reacts to the allergen, which can then be compared to subsequent food challenge results (i.e., after receiving the investigational drug or placebo). In the clinical trial setting, the risks of food challenges are reduced because participants are closely monitored (Plaut et al., 2009). However, participants must have a "qualifying" reaction, which may mean that investigators have to push dosing beyond the first signs of a reaction (e.g., itchy throat, flushing) and may even induce anaphylaxis. Children routinely need epinephrine at the end of a food challenge, either to help quickly reverse a mild reaction that may intensify or to treat a severe reaction that has occurred (Noone et al., 2015).

Parents or caregivers consent or provide permission for their children to enroll in food allergy trials for the perceived benefits despite the risks. An early study on why parents enrolled their children in a peanut allergy trial revealed that they were often influenced by an exaggerated view of the likelihood of their child dying from accidental exposure to peanut (DunnGalvin et al., 2009). In this context, many parents are desperate for any protection a clinical intervention might provide. To date, none of the therapies in clinical trials have been or promise to be curative. The benefits offered to families tend to reflect the goal of "bite-proof" protection in which the treatment would raise the child's threshold of reacting and/or minimize the severity of a reaction that occurs in the context of accidental exposure (Dantzer et al., 2023). This is a far cry from curing the allergy, but many parents and investigators expect that this physiological benefit to the child will lead to a better quality of life because of diminished anxiety about accidental exposure on the part of both the child and parents (Nadeau and Barnett, 2020). However, the published literature has not been grounded in the lived experiences of families that struggle with managing their children's food allergies to show how such experiences shape their perceptions of benefit and risk when pursuing treatments for their children.

2.3. Biomedicalization and pharmaceuticalization

The pharmaceutical industry and the availability of clinical trials are reshaping the food allergy landscape. In the process, food allergies have become an important contemporary example of medicalization in action. Despite the possibility of a severe reaction, having a food allergy is not hazardous to one's health provided one avoids ingesting the allergenic food; in this way, the condition itself is not harmful or progressive,

unlike asthma, diabetes, cancer, and other illnesses. Medicalization describes the process by which normal human experiences or conditions become incorporated into medical practice and defined as disease (Conrad, 2007). For food allergies, the medical management of the condition by allergists, including the diagnostic apparatuses and prescriptions for epinephrine are clear signs of medicalization (Kerr et al., 2009).

Food allergies are also paradigmatically an example of what Clarke and colleagues (2003) refer to as *biomedicalization*, or the "Biomedical TechnoService Complex, Inc.," in which medicine and health care have become profit-generating industries that essentially sell products and services to patients via physicians. Unlike medicalization, there is a shift away from treating disease to enhancing health. This trend is evinced by treatments targeting risk rather than disease (Clarke et al., 2003). Take, for example, the highly ubiquitous drugs that are prescribed to "treat" patients' high levels of cholesterol, but the value of this treatment paradigm hinges on reducing risk to those patients (who may otherwise be healthy) of having a heart attack or stroke (Greene, 2007). The newly approved food allergy treatments and those in clinical trials are similarly given to (otherwise typically healthy) children to reduce their risk of anaphylaxis should they accidently consume their allergen. Likewise, these risk-reducing treatments have no set endpoint; they are interventions that are effectively "drugs for life" (cf. Dumit, 2012) that children must continue taking to maintain any benefit.

This risk-based therapeutic orientation is not problematic in and of itself, but it could be used to justify treating children who are unlikely to benefit. Specifically, clinical research has suggested that greater rates of food desensitization are achieved when therapies are started younger (Jones et al., 2022). In this way, a 2-year-old may benefit more than a 12-year-old who may benefit more than a 30-year-old. This raises questions not only about when starting a treatment is most appropriate but also about when starting a treatment might *not* be justified because of a potential lack of expected benefit. Yet, food allergy treatments have the potential to become another example of how ever increasingly healthy patients are advised to take a medical treatment (Barbee et al., 2018; Greene, 2007; Marshall, 2002), even when individual children may not benefit and may also be at greater risk from the therapy than just practicing avoidance.

Food allergy treatments create new health risks to and high cost for the patients and/or healthcare system in exchange for these uncertain or limited therapeutic benefits (cf. Light, 2010). In the case of Palforzia for peanut allergy, treatment can and does cause the very reactions it is prescribed to treat (Chu et al., 2019). Moreover, when peanut powder is an FDA-approved drug, it comes with a corresponding price tag. Writing about Palforzia, James Hamblin (2019) noted, "The U.S. health-care system found a way to make peanuts cost $4,200," and after FDA approval, the cost jumped up to $11,000 for a year's treatment (Guiao and Ogurchak, 2020).

The availability and cost of medical treatments contribute to stratified biomedicalization (Clarke et al., 2003). In the US context of neoliberal health care, the effects of biomedicalization on different populations are also critically important. Biomedicalization contributes directly to some of the health disparities in food allergy described above. The cost of the two approved drugs for food allergy is extremely high, and patients have different levels of access and out-of-pocket expenses for treatment based on their health insurance programs, including private payers as well as government ones like Medicaid (Bjelac et al., 2023). Additionally, the time and structure of clinical trials put such opportunities out of reach of many families because they do not live near participating research centers or because they cannot afford or have the flexibility to attend the required study visits. Given that clinical research for food allergies has accelerated over the past decade, it is critically important to understand the implications of biomedicalization for families that seek food allergy treatment.

3. Methods

This article draws on data collected as part of a larger ethnographic study of food allergy trials conducted at three US food allergy research centers—one in the Northeast, one in the Southeast, and one in the West. I came to this research as a social scientist with expertise in clinical trials (Fisher, 2009, 2020), and I was drawn to the topic of pediatric food allergy trials because of media coverage of early trial results. However, I had no expertise in or direct personal connection to the topic of food allergy when I began the research. I conducted field work from January 2020 to February 2024. From March 2020 through March 2021, all field work was virtual due to the Covid-19 pandemic, which meant that I was primarily interacting with investigators at my field sites rather than families. In April 2021, I recommenced in-person observations. In total, I spent over 300 h in the three food allergy research clinics, over 100 h attending in-person and virtual meetings, and over 100 h conducting telephone or Zoom interviews with stakeholders. The study was reviewed and approved by the University of North Carolina Biomedical Institutional Review Board.

With the permission of the clinical research teams (who had provided prior consent to participate in my study), I approached specific families who had clinical trial appointments (screening or study visits) when I was in one of the research clinics. I gave all families a detailed information sheet about the study and answered any questions about the study they had. In explaining the study to them, I informed them about who I was and why I was doing the study, including my independence from the research site and clinical trial in which they were participating. When providing this information, I spoke both to the parent(s) and child, conveying to the child in particular what it would mean to be observed during their clinical trial visit. All parents provided explicit verbal consent to participate and completed a demographic questionnaire. After the parent consented, I also got the child's verbal assent to observe their clinic visit. Each time I encountered a family that had already enrolled in my study, I reminded them who I was and got their permission to observe these subsequent clinical trial visits. Across the three field sites, I enrolled 50 families. There were some families that I met a single time and others that I observed the majority of their subsequent study visits over a period of 18 months.

The demographic breakdown of the families in my study reflected who was enrolled in food allergy trials at these three centers. Although the three clinics were located in metropolitan areas with substantial socioeconomic diversity, the families in the clinical trials did not represent this regional diversity. From the 50 families I enrolled, there were 67 parents in my study. Some of the 34 paired parents (i.e., part of 17 families) attended study visits together, but what was more typical was to meet paired parents separately as some shared the responsibility of bringing their child to those study visits. The majority of parents were women/mothers (n = 45; 67.2 %). None, to my knowledge, were same-sex couples, and at least one couple was divorced. Of the 50 children included in the study, 12 (24 %) were adolescents between the ages of 12 and 17, and the other children ranged in age from 1 to 11. The gender split among children was nearly even, with 27 (54 %) of them being boys and the other 23 (46 %) girls. Only 3 parents (4.5 %) identified as Hispanic or Latinx, 5 parents (7.5 %) identified as Black or African American, 1 parent (1.5 %) identified as multiracial, and 9 parents (13.4 %) identified as Asian. Two parents declined to provide information about their racial or ethnic identity. The remaining 47 parents (70.1 %) identified as non-Hispanic White. Parents provided demographic information for their children. There were 8 children (16 %) who were multiracial, a higher percentage than among parents. I did not collect formal data about socioeconomic status, but many parents were highly educated, with many working in health care as physicians or nurses, and many, as will be developed below, described themselves as privileged and financially secure.

I began conducting interviews in June 2021 only after I had more in-depth familiarity with how the clinical trials operated and the types of

experiences the families—and investigators—had. Most often, I conducted interviews by telephone with one of the parents and, when applicable, any adolescents who were willing to be interviewed. I interviewed 47 parents and 9 adolescents. Less relevant to the current article, I also interviewed 8 adults with food allergies who were enrolled in clinical trials, 41 food allergy investigators (i.e., doctors, nurses, and other staff), 10 pharmaceutical company representatives, 5 patient advocates, and 4 representatives of the FDA or FDA advisory boards, for a total of 124 interviews. All interviews were transcribed verbatim before being coded following the methods of abductive analysis (Tavory and Timmermans, 2014). To ensure the rigor of the project during data collection and analysis, I followed the norms of ethnography by focusing on writing highly detailed fieldnotes during and immediately after each observation period; interpreting what informants said in the broader context of their lives; and triangulating data from fieldnotes, interviews, and the food allergy literature; member checking interpretations of my findings as I identified important themes; and sustaining a prolonged engagement in the research field that spanned multiple clinical trials and three trial sites (Patton, 2015). All participant names used in this article are pseudonyms.

4. Findings

When I interacted with parents and children during their study visits, we often talked about the clinical trial itself, the procedures they were there for that day, and how things were generally going in the trial. Those interactions were part of my observations of the clinical trials—my opportunity to see how oral food challenges went in practice; how other study procedures, such as blood draws, injections, and skin prick tests, were conducted; and how the research team interacted with study participants and their caregivers. It was in interviews where I gained insights into how food allergies affected these families. Parents often situated their decision to enroll in a clinical trial in the everyday reality of raising a child with food allergies and their desire for a normal life for their child. This desire for normalcy can be seen as *normalizing* their pursuit of a biomedical intervention despite its risks. Drawing on data from my observations and interviews, this section details my findings about (1) parents' motivations and hopes for their child's clinical trial participation and (2) parents' doubts about the potential negative effects of the trial experiences on their child.

4.1. Parents' motivations and hopes

Each parent I interviewed shared with me the extent to which their child's, or in some cases, children's food allergies had deeply affected every aspect of their life. From their own homes to school to socializing with extended family and friends, food allergy was a central part of the decisions they made about what they did and where they would go. While this might seem hyperbolic, parents had this experience because food, they found, is everywhere, which meant that the danger to their child was also everywhere. I illustrate here how navigating this social world with either no risk or less risk was often at the heart of why they had enrolled their child in a clinical trial.

Many parents had not realized how central food was to social life until their child's food allergy manifested. Becky, mother of a 5-year-old boy with peanut, milk, and egg allergies, commented, "I think it's hard to explain to people, unless you have a child with food allergies, the way it feels. Most people are going to react like my coworkers. Most people are going to be like, 'Well, it's food allergies. Don't eat it. And it'll be fine.' And it's just not like that. You realize [as a food allergy parent] how much food is integrated into our society and our events and celebrations." Likewise, Brian, a father of a 6-year-old daughter who was allergic to peanut, egg, milk, and tree nuts, said, "[I]t's more than just the medical aspect. There's a whole sociological effect. I mean so much of our culture is based around food. The ability to sit down and eat with people and experience food." In this way, parents felt like their children were not just missing out on specific foods, but they were also missing out on critical aspects of socializing and being part of a community. Some parents associated this most strongly with their ethnic identity or heritage. Other parents talked about how their kids' friends or classmates would tease (or even taunt) their children for not being able to eat typical American staples, such as peanut butter and jelly (PB&J) sandwiches, pizza, or many desserts. As a result of these and other experiences, parents talked about how important it was to them that they minimize how much their child might be missing out on because of their food allergy.

Enter clinical trials. As part of the information parents received during the consent process for the clinical trials, they were told that there should be no expectation that their child's food allergy would be cured. However, parents often distinguished their expectations from their hopes for how the clinical trial might benefit their child. This was the case for Isabel, mother to a 3-year-old boy with allergies to peanut, tree nuts, and egg:

> It's just my pipe dream, I think, that something will work and actually cure his allergies. … I think the point [of the trial] is if [the treatment] lets you live your life, which [my husband], again tries to tell me, "That's really great if you can be in the world and eat a peanut and not go to the hospital; it's a huge success." Whereas I think I'm still hopeful like, "Oh, but maybe there's something else that can really make him not allergic, and he can eat a peanut butter and jelly sandwich and be like a normal kid."

In a similar vein, Veena spoke about her hope for the clinical trial that one of her two children with multiple food allergies was enrolled in:

> We didn't take them to any restaurants. … And so, it was just like, "Oh, we can go out to eat [if the treatment works]!" … And then my husband would be like, "How is that your goal? You really wanted just to go out to eat. That's what you're hoping for?" Meaning, that's so silly. … Everyone else gets to do it, why can't I? … So, that's what I just put all my life's hopes and dreams in, like, "I want to just go to Europe. I want to travel with her."

Isabel and Veena illustrate the gendered component to how parents' motivations for a biomedical intervention might vary. In both quotes, the women recount how their own views conflict with those of their husbands, whom they both perceive as disparaging their hopes for their child as too ambitious.

There is also an important element of privilege that is inflected in many parents' goals for their children. Veena jumps from her more mundane desire for the family to eat in restaurants to the more privileged wish to travel to Europe, which is something out of reach in her mind not because of financial resources but because of her daughter's food allergies. Another example of this came up in how Linda described her decision to enroll in a trial her 1-year-old son with allergies to egg, milk, sesame, peanut, and other legumes:

> I just ultimately decided that for us, with what he has going on and with the reactions he was having, the benefit hopefully will outweigh the cost and that we're going to do anything we can to, like I said, set him up to have the best life. So that if he wants to travel to far remote places, he can hopefully eat the foods there or not have to be stressed about going out to a restaurant to eat with a date or all of these things that just are normal, everyday things that, I think, people who don't have food allergies … just totally take for granted how much goes into thinking about all of that stuff.

Linda's vision of the "best life" for her son is one in which he can safely travel the world. Like, Veena and Isabel, concern for the quotidian is simultaneously present; she wants him to be able to date and do other social activities "normally," and she is willing to try to set him up for that normal life even in his infancy.

What is analytically interesting about these narratives is how quickly parents' worries about their children's risk of missing out jumps from

core experiences of sociality to very privileged activities with little consideration of where normal may begin and end. This is likely a reflection of the socioeconomic privilege that allows them to pursue clinical trials in the first place. Notably, most of the parents were keenly aware of this privilege. For example, Amy—mom to an 8-year-old son who was allergic to peanut, tree nuts, egg, barley, and wheat—made the decision to quit her 60-h-a-week, corporate job to be the person who could bring Shane to his study visits. She explained, "We made a big family choice to do this. Not all families can do that. If I was still working all the time, it would be a huge burden, because it's not something I'd want the nanny doing; this is something a parent has to be doing. … That's why we made that decision." Amy and her husband had the financial resources to continue to thrive without her six-figure salary, and the decision was reached not just because someone had to be available for study visits, but because she viewed it as something she, as Shane's mother, and not hired help should be involved in every step of the way.

Other parents engaged in similar self-comparisons to express their privilege or luck to have the time and resources for this opportunity for their child. Isabel was a consultant, worked part-time, and controlled her own schedule. She contrasted her situation to most other families, saying,

> I think it's totally untenable for a working mom, or a family with two working parents, or a single mom, or a single dad, or anything. You couldn't [do the trial]. I call [the clinical trial] my part-time job bordering on my full-time job. … I think about that all the time. If I were a mom that was just trying to help my kid and had a job, not even in McDonald's, but any regular job where you have to be there, you just wouldn't be able to take off even close to the amount of time that it's taken. So, I just feel really grateful, and it's just unfortunate for those who can't take the time.

Not all the parents I met were affluent, but all at least had the flexibility to ensure that a parent (usually the mother) could attend the frequent study visits. Those with fewer resources also described receiving financial support from their parents or friends to remove some of the economic barriers (e.g., gas, hotel) to their child's participation in the clinical trial. Nonetheless, these acknowledgments of privilege did not seem to extend to awareness of how privilege directly influenced their hopes for their child's clinical trial participation. This may reflect how stratified biomedicalization is experienced on the ground, wherein parents were cognizant of their privilege of access but much less aware of the way privilege was built into how they defined the normalcy they were seeking for their child.

4.2. Parents' doubts about the trial experience

Parents' visions of a normal life for their children were trained exclusively on experiences outside of the food allergy trials in which they were enrolled. However, many expressed anxieties or doubts about the means to that end. Specifically, they perceived what children must endure to take part in these clinical trials as potentially traumatizing. From my observations of study visits and what biomedicalization of these children involved, I can attest to seeing both ends of the spectrum—children shaking with terror when it was time for a blood draw or injection and children thrilled to be given popsicles, toys to play with, and TV or movies to watch after their procedures were done. Not infrequently, I witnessed kids who experienced this entire spectrum in a single visit. Many parents mindfully observed their children in and outside of the research clinic to gauge the psychological harm the study might be doing to their child.

I was present on the day that Veena, one of the mothers quoted above, brought her 5-year-old daughter Dahlia to what unexpectedly turned out to be her last study visit. Dahlia was there to receive a higher dose of the study drug, an oral immunotherapy that was a mixture of three of her food allergens in powder form. The protocol for the day was for Dahlia to be given the new dose, be observed for 1 h, then sent home with packets of this higher dose to take daily. About 45 min after consuming the powder, Dahlia said her stomach was hurting and her throat was a little sore. The study nurse instructed Dahlia to tell her if/when her symptoms got worse. About 5 min later, Dahlia started coughing and her lips became very pale. Another study nurse took Dahlia's blood pressure. It was 78/45, quite low even for a child. The study nurses and physician on call decided that they needed to administer epinephrine immediately. Hearing this, Dahlia panicked. While she shrieked with tears flowing down her face, all three members of the study team restrained her on Veena's lap to do the injection. Within minutes, Dahlia's blood pressure returned to normal, and she said her stomachache was gone. Because of her reaction, Dahlia had to be observed for another 2 h by the study team before being allowed to go home; they set her up on an exam table with some blankets where she could watch TV and rest. Dahlia was withdrawn and quiet for the rest of the study visit.

I followed up with Veena about a week later by phone. By that point, she had been informed that Dahlia had to be withdrawn from the study for her safety. Veena was tearful about this outcome, feeling as though the clinical trial had been helping her daughter up until that last visit. The bright side she found, however, was that Dahlia would not be subjected to further injections. Beside epinephrine, Dahlia had been receiving injections of what was either an investigational drug or placebo for most of the trial. Veena declared,

> She hates, oh my gosh- … Well, you saw her during the epi. That's how she was at every [injection visit] every two weeks. Screaming, bloody mess. You just needed three nurses—she's 28 pounds—you needed three nurses to hold her. It doesn't make any sense. And she just screamed and screamed and screamed. … She never got used to it. There was not a time where they were like, "Oh, she got used to it. She knows what's coming." She just hates, hates, hates, hates shots.

At least half of the children I met were similarly fearful of injections. Experiences like this made many of the parents worry about the implications for their child's future health care. For some parents, they did see evidence that the clinical trial experiences were spilling over into their child's routine care. After the last study visit for their clinical trial, Lisa reflected on her 5-year-old daughter Molly's experiences:

> It was hard when we had to do blood work and I had to hold her down. She screamed because she didn't want to have blood work done. That was tough, because it's like, I knew I had to-, we had to do it. But it's also in the back of my head, "Are we going to traumatize her, where she's never going to want to go to a doctor again?"

Explaining her worry about this, Lisa continued,

> Molly gets nervous when we have to go to the dentist or just routine wellness visits. Because she's like, "Are there shots? Do I have to eat goo [i.e., the food challenge paste]? Do I have to do this?" So, it does cause her some anxiety, because all of her [medical] experiences have been at the study. And I do wonder down the road, is this just giving her some kind of complex with doctor's offices?

Kids like Molly understandably associate these frightening procedures with all health care, so they carry that anxiety with them to other providers.

Despite all the invasive procedures, other children did not appear scarred. For example, 3-year-old Tiffany had such dramatic meltdowns for each injection or blood draw that during one of her study visits, a study nurse, in an unguarded moment of judging Tiffany's parents, asked me rhetorically, "At what point do you say enough is enough?" However, Tiffany's father gushed about how she wanted to be a doctor when she grows up because of the trial. Likewise, 8-year-old Shane regularly played clinical trial at home by giving his parents and brother "injections" and doing "blood draws"; his mother Amy imagined how he would go into medicine and perhaps become an allergist in the future.

For them, not only was the clinical trial not causing any lasting harm to their child, but it was also potentially opening a career pathway for them—another unexplored facet of the experience of biomedicalization for children and perhaps also representative of their class privilege.

Other parents consoled themselves about the distressing study visits by noting that their child never resisted attending the next appointment. One such parent was Jessica, mother to two children with food allergies, who enrolled her 6-year-old son in a clinical trial:

> The other thing is, I think, in some respects, it's given him a greater degree of comfort with medical caregivers and procedures. … You were there for his hard day. He had the skin prick test, which he hates. For him, that's the worst part. … They basically poke his arm with a toothpick three times [i.e., to see if he will react to the allergen], and then it starts itching uncontrollably. … Then, he had a blood draw, and it was a lot of blood; they took several vials. And then, [for the food challenge] he had to eat all the goo, which is disgusting. And then, he felt sick. And then, he got an epi shot. And then, he still didn't feel great for a little while after that. And so, it was a hard day.

After enumerating the ways in which the study visit had been difficult for Connor, Jessica continued,

> And yet, the next day, I had to take him back. And when we got out of the car at the building, he was just skipping ahead of me, just happy as he could be to be there. It would've been very understandable for him to be crying and saying, "I don't want to go there again." But he's still happy and resilient and glad to see people and talkative. And to some extent, I think some of these procedures and the poking and prodding has helped to make him more resilient.

For Jessica, she relied on her son's disposition about going to the clinic to reassure her that no lasting harm and possibly some psychological benefit in the form of resiliency would result. While most parents did not frame the experience as psychologically beneficial, they noted how much their children loved the study team and how willing they were to attend visits, though it bears noting that these visits almost universally included bribery in the form of toys or special treats the children would receive from their parents afterwards.

Despite parents' worries about how the clinical trial experiences might affect their children, they never discussed it as the extraordinary experience it was. Instead, those biomedicalizing experiences were seen as traumatizing in a more bracketed way, with the effects limited to the medical realm. Only one mother connected the dots between the normalcy she was seeking for her son and the effects of the clinical trial on him. In that instance, 15-year-old Cody was withdrawn from the clinical trial because, like Dahlia, he started having severe anaphylactic reactions to the treatment (which, at that point in the trial, was not a drug but carefully measured amounts of peanut, milk, and egg products consumed daily). However, unlike Dahlia, his anxiety about needing to eat these foods daily and the risk of reacting led to anorexia, severe depression, and suicidal ideation. Fearing for Cody's life and wellbeing, his parents and the study team agreed that it was not in his best interest to continue in the clinical trial. In a second interview I conducted with his mother Katie, she observed,

> And I think the whole point of doing this study was to try to give him some normalcy. And I just don't know if maybe I had the wrong idea of what normal is, because … it's all relative, what's normal to him. I was thinking what's normal to the world and what will make him feel normal, but maybe in doing that, I pushed him to a place that was not normal, and he couldn't handle it.

5. Discussion

What does it mean for parents to use clinical trials as a means to pursue a normal life for their children with food allergies? In part, it means that they have a higher tolerance for the risks and harms to which their children are exposed in a clinical trial compared to their tolerance for the risks and harms of navigating life with a food allergy. Avoidance is difficult, as has been well documented in the literature (Glabau, 2022), but the families that have enrolled their children in clinical trials are not doing so just to keep their kids safe. They have already been successful at doing that through the restrictions they observe, which is why their motivations target the restrictions themselves.

Children's enrollment in food allergy trials can and should be seen as an example of stratified biomedicalization. The vast majority of the families that are involved in these trials are affluent, regardless of their racial or ethnic background. Instead of the "White, worried, and well" that MacPhail (2023) has associated with allergies, food allergy trials attract a similar "3Ws"—the *wealthy*, worried, and well. On one hand, the poor and less affluent are denied the potential benefit of expensive and time-consuming treatments that might put them at less risk of allergic reactions. Yet, on the other, stratification in the context of food allergy is more than a question of cost or simple access to medication or clinical trials. Biomedicalization enables (or is hoped to enable) class privilege to which parents feel their children are entitled but has been denied or hampered by the food allergy. Since biomedicalization targets enhancement of health and risk reduction, these therapies have value beyond their specific use. Clarke and colleagues (2003) write,

> Where medicalization practices seemed driven by desires for normalization and rationalization through homogeneity, techniques of stratified biomedicalization additionally accomplish desired tailor-made differences. … Such customization is often part of the commodification and fetishization of health products and services common in the biomedicalization era, wherein health products and services become revered, valued, and imbued with social import that has little to do with their use value or physical properties. (181)

In food allergy, desire for normalcy appears to drive parents' interest in clinical trials for their children, but the outcome is not simply medicalization. It is also biomedicalization because the normalcy desired is not physical normalcy; it is social and relational. Food is central to everyday life, including the formation of cultural identities, such as when foods ground people in their ethnic heritage (Ku et al., 2013; Tompkins, 2012). This was striking not just for ethnic identities, but also for "fitting in" to mainstream culture when foods symbolize what it means to be an "American kid" (Best, 2017) who can eat typical American foods. Seeking treatment for food allergies cannot be read as a simple desire for children not to be at risk from their food allergies, but instead it should be seen as a more nuanced desire for those children, and their families by proxy, not to have to live restricted lives, especially when their class privilege creates expectations for no such restrictions.

Although parents are motivated by visions of "normalcy" when they enroll their children in food allergy trials, I have shown how the experience of clinical trials is far from normal. Parents do not narrate the experience this way, but there is a stark contrast between their hopes for what the clinical trial can achieve for their child versus the reality of what that child must endure as a trial participant. Cooper and Waldby (2014) have developed a framework to understand clinical trial participation as "clinical labor." Their articulation of clinical labor is conceptualized in terms of the postindustrial, post-Fordist, flexible economies that disadvantage low-wage workers and drive them to participate in clinical trials or surrogacy markets (see also Fisher, 2020; Vora, 2013). However, the embodied labor of children is central to food allergy trials. Such labor is burdensome, psychologically taxing, and too often physically harmful to the child for limited benefits. Recall that, to date, no child has been cured of their food allergy through these clinical trials, so the hoped-for benefit for which the child labors remains just that rather than a reality for the child and their parents. This type of labor is also a key part of biomedicalization. Clarke and colleagues (2010) do not refer to it as "labor" per se, but they emphasize that biomedicalization "demands of patients, consumers, and patient groups

that we become more knowledgeable and responsible—essentially more 'scientized'—vis-a-vis biomedicine" (16). How better to achieve this in food allergy than through the clinical labor of research participation or even through treatment with these products when they are on the market?

6. Conclusion

In analyzing children's participation in food allergy trials through the lens of stratified biomedicalization, I neither want to diminish the risk that some children face of having a life-threatening reaction when they are exposed to their food allergens nor the benefit that safe and effective treatments would provide to children. The goal here is to understand sociologically the dynamics of children's participation in clinical trials when the motivations parents have fail to line up with the reality of what children experience. Affluent parents' fears of possible social harms for their children, including their inability to exercise their financial and cultural privilege, drives them to accept biomedical harms. By attending to the biomedicalization of food allergies, an otherwise invisible aspect of stratification can come into focus. Under its logics, affluent parents rationalize the exceptional, and sometimes traumatic, clinical trial experience their children undergo to justify the elusive normal life they envision for those children.

Ethics approval

The study was reviewed and approved by the Biomedical Institutional Review Board at the University of North Carolina at Chapel Hill. Full approval was received on April 13, 2020 under application number 20–0567.

Declaration of competing interest

I have no conflicts of interest to declare.

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Data availability

The data that have been used are confidential.

References

Anagnostou, A., Sharma, V., Herbert, L., Turner, P.J., 2022. Fatal food anaphylaxis: Distinguishing fact from fiction. J. Allergy Clin. Immunol. Pract. 10, 11–17.
Barbee, H., Moloney, M.E., Konrad, T.R., 2018. Selling slumber: American neoliberalism and the medicalization of sleeplessness. Sociol. Compass 12, e12622.
Best, A.L., 2017. Fast-food Kids: French Fries, Lunch Lines, and Social Ties. New York University Press, New York.
Bjelac, J., Shaker, M., Greenhawt, M., Kodish, E., 2023. Viewing pediatric food oral immunotherapy through an ethical lens: a narrative systematic review. J. Allergy Clin. Immunol. Pract. 11, 1914–1925.
Casale, T.B., Fiocchi, A., Greenhawt, M., 2024. A practical guide for implementing omalizumab therapy for food allergy. J. Allergy Clin. Immunol. 153, 1510–1517.
Chu, D.K., Wood, R.A., French, S., Fiocchi, A., Jordana, M., Waserman, S., et al., 2019. Oral immunotherapy for peanut allergy (PACE): a systematic review and meta-analysis of efficacy and safety. Lancet 393, 2222–2232.
Clarke, A.E., Shim, J.K., Mamo, L., Fosket, J.R., Fishman, J.R., 2003. Biomedicalization: technoscientific transformations of health, illness, and U.S. biomedicine. Am. Sociol. Rev. 68, 161–194.
Clarke, A.E., Shim, J.K., Mamo, L., Fosket, J.R., Fishman, J.R., 2010. Biomedicalization: a theoretical and substantive introduction. In: Clarke, A.E., Mamo, L., Fosket, J.R., Fishman, J.R., Shim, J.K. (Eds.), Biomedicalization: Technoscience, Health, and Illness in the U.S. Duke University Press, Durham, NC.
Conrad, P., 2007. The Medicalization of Society: on the Transformation of Human Conditions into Treatable Disorders. Johns Hopkins University Press, Baltimore, MD.
Cook, E.E., 2023. Anthropological and sociological perspectives on food allergy. Clin. Exp. Allergy 53, 989–1003.
Cooper, M., Waldby, C., 2014. Clinical Labor: Tissue Donors and Research Subjects in the Global Bioeconomy. Duke University Press, Durham, NC.
Dantzer, J.A., Kim, E.H., Chinthrajah, R.S., Wood, R.A., 2023. Treatment for food allergy: current status and unmet needs. J. Allergy Clin. Immunol. 151, 1–14.
Dehbozorgi, S., Ramsey, N., Lee, A.S.E., Coleman, A., Varshney, P., Davis, C.M., 2024. Addressing health equity in food allergy. J. Allergy Clin. Immunol. Pract. 12, 570–577.
DeSoucey, M., Waggoner, M.R., 2022. Another person's peril: peanut allergy, risk perceptions, and responsible sociality. Am. Sociol. Rev. 87, 50–79.
Dumit, J., 2012. Drugs for Life: How Pharmaceutical Companies Define Our Health. Duke University Press, Durham, NC.
DunnGalvin, A., Chang, W.C., Laubach, S., Steele, P.H., Dubois, A.E.J., Burks, A.W., et al., 2009. Profiling families enrolled in food allergy immunotherapy studies. Pediatrics 124, e503–e509.
DunnGalvin, A., Hourihane, J.O.B., Frewer, L., Knibb, R., Oude Elberink, J., Klinge, I., 2006. Incorporating a gender dimension in food allergy research: a review. Allergy 61, 1336–1343.
Fisher, J.A., 2009. Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials. Rutgers University Press, New Brunswick, NJ.
Fisher, J.A., 2020. Adverse Events: Race, Inequality, and the Testing of New Pharmaceuticals. New York University Press, New York.
Glabau, D., 2022. Food Allergy Advocacy: Parenting and the Politics of Care. University of Minnesota Press, Minneapolis.
Greenberg, R.G., Gamel, B., Bloom, D., Bradley, J., Jafri, H.S., Hinton, D., et al., 2018. Parents' perceived obstacles to pediatric clinical trial participation: findings from the Clinical Trials Transformation Initiative. Contemp. Clin. Trials Commun. 9, 33–39.
Greene, J.A., 2007. Prescribing by Numbers: Drugs and the Definition of Disease. Johns Hopkins University Press, Baltimore, MD.
Guiao, E., Ogurchak, J., 2020. Clinical insights: Palforzia is the first FDA-approved treatment of peanut allergy. Pharmacy Times. https://www.pharmacytimes.com/view/clinical-insights-palforzia-is-the-first-fda-approved-treatment-of-peanut-allergy. (Accessed 23 March 2025).
Gupta, R.S., Warren, C.M., Smith, B.M., Blumenstock, J.A., Jiang, J., Davis, M.M., et al., 2019. The public health impact of parent-reported childhood food allergies in the United States. Pediatrics 142, e20181235.
Hamblin, J., 2019. The U.S. health-care system found a way to make peanuts cost $4,200. The Atlantic. https://www.theatlantic.com/health/archive/2019/09/dangers-peanut-allergy-drug/597997/. (Accessed 23 March 2025).
Herbert, L., Shemesh, E., Bender, B., 2016. Clinical management of psychosocial concerns related to food allergy. J. Allergy Clin. Immunol. Pract. 4, 205–213.
Jones, S.M., Kim, E.H., Nadeau, K.C., Nowak-Wegrzyn, A., Wood, R.A., Sampson, H.A., et al., 2022. Efficacy and safety of oral immunotherapy in children aged 1–3 years with peanut allergy (the Immune Tolerance Network IMPACT trial): a randomised placebo-controlled study. Lancet 399, 359–371.
Kerr, A., Woods, B., Nettleton, S., Burrows, R., 2009. Testing for food intolerance: new markets in the age of biocapital. BioSocieties 4, 3–24.
Ku, R.J.-S., Manalansan, M.F., Mannur, A., 2013. Eating Asian America: A Food Studies Reader. New York University Press, New York.
Light, D. (Ed.), 2010. The Risks of Prescription Drugs. Columbia University Press, New York.
MacPhail, T., 2023. Allergic: Our Irritated Bodies in a Changing World. Random House, New York.
Marshall, B.L., 2002. "Hard science": gendered constructions of sexual dysfunction in the "Viagra Age". Sexualities 5, 131–158.
Minaker, L.M., Elliott, S.J., Clarke, A., 2014. Exploring low-income families' financial barriers to food allergy management and treatment. J. Allergy 2014.
Nadeau, K., Barnett, S., 2020. The End of Food Allergy: the First Program to Prevent and Reverse a 21st Century Epidemic. Avery (an imprint of Penguin Random House), New York.
Nairn, S.A., 2023. Passive tolerance and productive uncertainties in food allergy immunotherapy biomedical practices. Sociol. Health Illness 45, 989–1007.
Nettleton, S., Woods, B., Burrows, R., Kerr, A., 2009. Food allergy and food intolerance: towards a sociological agenda. Health 13, 647–664.
Noone, S., Ross, J., Sampson, H.A., Wang, J., 2015. Epinephrine use in positive oral food challenges performed as a screening test for food allergy therapy trials. J. Allergy Clin. Immunol. Pract. 3, 424–428.
Patton, M.Q., 2015. Qualitative Research and Evaluation Methods. Sage Publications, Thousand Oaks, CA.
Pitchforth, E., Weaver, S., Willars, J., Wawrzkowicz, E., Luyt, D., Dixon-Woods, M., 2011. A qualitative study of families of a child with a nut allergy. Chron. Illness 7, 255–266.
Plaut, M., Sawyer, R.T., Fenton, M.J., 2009. Summary of the 2008 National Institute of Allergy and Infectious Diseases-US Food and Drug Administration workshop on food allergy clinical trial design. J. Allergy Clin. Immunol. 124, 671-678 e671.
Smith, M., 2018. Another Person's Poison: A History of Food Allergy. Columbia University Press, New York.
Tavory, I., Timmermans, S., 2014. Abductive Analysis: Theorizing Qualitative Research. University of Chicago Press, Chicago.
Tepler, E., Wong, K.H., Soffer, G.K., 2022. Health disparities in pediatric food allergy. Ann. Allergy Asthma Immunol. 129, 417–423.
Tompkins, K.W., 2012. Racial Indigestion: Eating Bodies in the 19th Century. New York University Press, New York.
VanderKaay, S., 2016. Mothers of children with food allergy: a discourse analysis of occupational identities. J. Occup. Sci. 23, 217–233.
Vora, K., 2013. Potential, risk, and return in transnational Indian gestational surrogacy. Curr. Anthropol. 54, S97–S106.

Waggoner, M.R., 2013. Parsing the peanut panic: the social life of a contested food allergy epidemic. Soc. Sci. Med. 90, 49–55.
Warren, C., Dyer, A., Lombard, L., Dunn-Galvin, A., Gupta, R., 2021. The psychosocial burden of food allergy among adults: a US population-based study. J. Allergy Clin. Immunol. Pract. 9, 2452–2460.
Warren, C.M., Jiang, J., Gupta, R.S., 2020. Epidemiology and burden of food allergy. Curr. Allergy Asthma Rep. 20, 6.