

Community Perspectives on Emergency Department Use and Care for American Indian Children

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Abstract Emergency department (ED) utilization by American Indian (AI) children is among the highest in the nation. Numerous health disparities have been well documented in AI children, but limited information is available on parental experiences of care for AI children in the ED. Our objective was to understand parental attitudes towards ED care for AI children. Focus groups were held with AI parents/caregivers at five sites in the Upper Midwest. Traditional content analysis was used to identify themes. A total of 70 parents participated in ten focus groups. Three main themes were identified: healthcare environment, access to care, and interaction with providers. Healthcare environment

issues included availability of specialists, wait times, and child-friendly areas. Transportation and financial considerations were major topics in access to care. Issues in interaction with providers included discrimination, stereotyping, and trust. This is one of the first studies to assess parent perspectives on ED use for AI children. Obtaining parental perspectives on ED experiences is critical to improve patient care and provide important information for ED providers.

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Abbreviations

ED Emergency Department

AI American Indian

IHS Indian Health Services

SES Socioeconomic Status

Health disparities abound in American Indian (AI) children that could have an impact on the usage pattern of EDs, including a higher burden of chronic disease, substance abuse disorders, and injuries compared with non-Hispanic white children [1]. Enhancing and possibly contributing to these disparities include lack of access to quality healthcare for AI children. Previous studies have identified barriers to healthcare access, such as poverty, lack of insurance, limited providers in rural areas, and inadequate funding of Indian Health Services [2–5]. These barriers may result in increased use of emergency departments (ED) for care and contribute to unsatisfactory interaction with healthcare professionals [2, 6–8].

Discrimination or perceived discrimination may also be a threat to quality healthcare for AI children visiting the ED as it has been seen in adults [9, 10]. Little research has been done in



this area for AI children, but one study found that AI parents were 25 times more likely to perceive racial discrimination in healthcare overall for their child compared with non-Hispanic white parents [8]. Cultural and religious considerations are also important and, in the same study, AI parents were more likely to feel that the providers neither understood their culture nor respected their religious beliefs [8]. In the frenetic pace of the ED, other possible factors contributing to discrimination or perceived discrimination are overcrowding and implicit bias. Overcrowding could affect treatment received and may increase differential treatment by reducing empathy toward disadvantaged groups [11]. Implicit bias has also been shown to be present within the ED setting for AI children and may lead to differential care, especially in the face of a busy ED [12].

Currently, there are no studies that discuss AI perspectives on pediatric emergency care, and there are few studies with AIs that have obtained community and parental perspectives on the availability and quality of care received for their children. Given the inherent barriers to establishing trust for any race or culture in an emergency setting, including lack of prior relationship and available clinician time, it is especially important to identify parental experiences and community attitudes toward the ED [13]. The aim of our study was to evaluate community and parental perspectives on their experience of healthcare within EDs with the ultimate goal of using the data to inform the development of interventions to improve quality care for AI children in the ED.

Methods

For this study, we utilized qualitative research methods to better understand community perspectives on ED use and care for AI children. A total of ten focus groups (two at each study site) were conducted at five sites in the Upper Midwest. Study sites included a large metropolitan area, two mid-size cities, and two smaller rural areas near AI reservation communities. Our aim was to include 6–8 participants in each group to facilitate discussion. Prior to conducting this study, all study procedures were reviewed and approved by the relevant institutional review boards and tribal communities. These procedures were in accordance with ethical standard of all institutions participating in this study. All participants were at least 18 years of age. The criterion to participate was to be a parent or other caregiver (hereafter referred to as parent) of an AI child under the age of 18 and to have taken a child to an ED within the last year. All participants in the study provided informed consent.

Focus group questions were developed by research team members with training in qualitative research methods and developing focus group questions for AI communities (Table 1). The questions were reviewed by other team members including an AI cultural liaison. All study team members

agreed on the final focus group protocol. Focus group questions were framed to gain insight on experiences within the healthcare system. The initial questions were broad in scope, asking about general healthcare options and experiences in the community and surrounding areas. Throughout the discussion, the questions became more specific to utilizing the ED and available resources and services specific to children. Participants were also asked about possible interventions that would improve care in the ED.

We collaborated with six EDs in our five sites (one location in a large metropolitan area had two EDs, but we only held one set of focus groups). The population of interest for our study was those who would be likely to go to one of our six EDs. Participants were recruited through flyers, community connections, and word of mouth within the catchment areas of our six EDs. Although our recruitment did not result in a representative sample of all possible parents in the catchment area, we used a variety of recruitment strategies to attempt to reach all possible participants. The specific locations and the time of day the focus groups were held likely had an impact on the individuals who participated due to transportation, working hours, child care availability, and familiarity with the location. We worked to overcome some of these barriers by holding groups at different times and at convenient locations.

The focus groups were held in a private room at a local community building, conference site, or library. Each participant was compensated with a meal and a \$25 gift card for their time and involvement in the focus group. All focus groups were audio recorded and transcribed verbatim. Consent was obtained from each individual by a study team member when the participant arrived and prior to participating in the focus groups. This involved a conversation about the study, what to expect during the group, and how the data would be used. Any names mentioned were excluded to maintain the confidentiality of the participants. Trained facilitators led the focus groups with a co-facilitator present to take notes.

The transcriptions were reviewed and analyzed through traditional content analysis. Themes were identified based on the data in the transcripts. Two members of the study team (WJP and JNR) met to identify and draft a list of themes and then met with the entire study team during the initial analysis process to discuss the list of potential codes and structure to ensure that different perspectives were included in determining the structure of the data. Once the codebook was developed and code definitions were set, the same two team members coded the transcript to identify if the coding process was being applied correctly. We also utilized Cohen's kappa to determine inter-rater reliability for the full coding sample. Each independent coder was given the same randomly selected 300 lines from the transcripts to code based on the final codebook. Our Cohen's kappa value was .74 and interpreted as "substantial" (.60–.80) using the benchmarks set by Landis and Koch [14]. Final analysis of the data included assessment



Table 1 Focus group questions

General healthcare options questions	ED specific questions
Where do you get information or ask questions when your child is sick or injured?	Describe any experiences you have had taking your child to an emergency department when he or she is sick or injured.
2. Where do you usually take your child for healthcare?	2. What aspects of an emergency department do you like for your child's care?
3. Where do you usually take your child for healthcare?	3. What aspects of an emergency department do you dislike for your child's care?
4. What do you dislike about your current healthcare options for your child?	4. What are some things that could be improved in the emergency department that would help your child?
5. What unique barriers do you feel that American Indians in your community face in receiving good health care for their children?	5. Is there anything that you would like to add?

of themes identified. Some themes that had initially been divided were combined into one overall topic. NVivo 10 software was used for content analysis (NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 10, 2012).

Results

A total of 70 parents participated in the focus groups. Participants were primarily AI (although all were parents/ caregivers of an AI child) with an average participant age of 38.3 (Table 2). The data was coded into three primary themes: (1) healthcare environment, (2) access to healthcare, and (3) interactions between providers and patients. Each theme was further divided into barriers, facilitators, and recommendations. Depending on each individual's experience, some aspects of care could be described both as a barrier and a facilitator. For example, in some facilities, there was a noted lack of child-friendly areas but, at other facilities, child-friendly areas were available and helped to facilitate a good healthcare experience. Recommendations were provided by parents based on what they thought would improve the overall healthcare experience for their child. There were some differences in content of the focus groups by site representing local issues. For example, one site talked specifically about the lack of dental care availability while another site talked about interactions with other healthcare facilities. The major themes were common across all sites, but some themes had different focus areas at different sites which are detailed below.

Healthcare Environment Parents talked about the overall healthcare environment for their child, including availability of care and physical features of the facility. This included both healthcare facilities in general as well as EDs. This theme helped in understanding the current state of the healthcare environment and how that might influence use of the ED. Barriers for the availability of care included difficulty in

obtaining appointments and referrals and long wait times. Long wait times primarily referred to the ED and parents felt that, even for urgent visits, the wait time was excessive. One parent said "they told me I had to wait 'cause there was six or eight people ahead of me but my daughters temperature kept getting higher and higher." Parents also described medical facilities where there were few child-friendly areas and a lack of specialty providers. An example quote from one parent was "when you go in the emergency room, there's nothing really for little kids." This was true for ED facilities as well as other healthcare facilities in their communities. Lack of pediatricians overall and especially in the ED was noted by many parents, as was the lack of mental healthcare providers both on an emergency and continuing basis. One parent commented, "Well then there should be a pediatrician down there. Okay. Because that's what they specialize in, is working with children. I mean there's a difference from somebody that works with children and somebody that, you know, works with adults." As highlighted in Table 3, various solutions were given to improve child-friendly areas. EDs in some

Table 2 Demographics of focus group participants

Characteristics		Frequency (%)
Race	American Indian alone	59 (84.3%)
	American Indian and other	7 (10.0%)
	White alone	3 (4.3%)
	Missing	1
Ethnicity	Hispanic	2 (2.9%)
	Non-Hispanic	68 (97.1%)
Age	Mean (Std)	38.3 (13.8)
	Missing	6
Site	Site 1 (urban)	11 (15.7%)
	Site 2 (rural)	17 (24.3%)
	Site 3 (urban)	10 (14.3%)
	Site 4 (rural)	16 (22.9%)
	Site 5 (urban)	16 (22.9%)



 Table 3
 Characteristic quotes for each theme

Theme	Barriers	Facilitators	Recommendations
Healthcare environment	"a doctor somewhere, they wouldn't see you unless you have a referral from down here. I think that's wrong, if it's an emergency it should be ok." "Yep, and you'll sit in-in, they'll get you in a room and you think, "Okay, I'm almost done." - *Interrupts* And then you sit there for another hour or two And you sit there and sit there and you open the door, "Is anybody here?" - You have no idea what they're doing." "One of the other things that has really affected my family I, I have, um, a couple of children that have mental illness and um, this community has very, very, very limited ability to deal with children with mental illness. You know, to be able to even to get in to see psychiatrist is weeks and months."	"And then even if it's like early hours, early in the morning, they have a pharmacy like right there that's accessible. " "it's nice that they have like a little play area and like T.V. that the kids like to watch and then-then I think that's nice for them you know to get em like if they're cryin you know get em away fromget their attention to be on something else." "They [emergency departments] have a bigger um, variety of technology, as such as you know, you can get MRIs, CAT scans, for your kids, you can get better use of these things. Um, like I said, like you can get a lot of more, a lot of more results of, um, strep, and all these, like mono, and all these other things like that, that a lot faster"	"Yeah. And like a room where the kids can go, with the carpet. Toys or something. You know just make it more kid friendly for them." "Maybe making the appointment for us, when we leave so it's already set up, and we don't have to worry"
Access	"When you're poor, you don't have options. When you are poor here, and you're American Indian, you have even fewer options." "And then you have to be hitch hiking home even at midnight. <i>Laughter</i> . Which is not a good deal."	"Then I think the other thing to um is you know whether they have Medicaid card. Yep. Okay. If they have Medicaid card you pretty much (can go anywhere) probably can go anywhere" "like welfare system I know they help with bus cards and then like some insurances they offer you the rides, like they have insurance programs down here where you call your insuranceum couple days ahead of time, set up this ride and there goes your ride, Okay, which is pretty reliable to me I use it quite a lot."	"Maybe a bus system at night, like some of the big cities. I lived in Utah for a year, and their bus system ran on all of their main roads, but they didn't close down until, I think, midnight." "I think it starts at the top though, with policy. Because I know things cost money, and I'm well aware of that. But at the same time, there's like an invisible line with the haves and the have nots, and for the have nots, the world is really hard. There just has to be a place where there is free healthcare. There has to be some place, somehow."
Interactions between parents and healthcare providers	"I was like okay and that is why we left cause we felt like we wasn't important enough." "And attitudes and comments is another one. Like you can't tell me that, 'Oh, I wouldn't have brought my kid.' Of course you wouldn't, you're a doctor. You already know that. I don't know that, that's why I'm here." "A couple of my kids are darker complected. So I always make sure that somebody goes with them when they take their kids in, because I've seen them being treated differently."	"well for me, my experience is that they made my child a priority." "The receptionists up there are pretty welcoming. They're kind of like, 'Whatchya [sic] need? What's going on?' They get your information right away."	"Reassuring parents while you're in the waiting room, like give 'em [sic] some checkup times or go check on them and the child." "Well, it would be nice if there were more Native Americans, especially nurses."

communities were more child-friendly than in others. Additional facilitators related to the healthcare environment included increased use of technology through connections to medical records at other facilities, access to specialized medical equipment and tests, and setting up referrals during a visit.

The availability of medical technology was especially common as a reason to go to the ED instead of other healthcare facilities. Parents noted that all of these could be done in the ED in one visit without referrals which were otherwise sometimes challenging to obtain and resulted in multiple visits and



missed time from work and school. One parent said, "They have a bigger um, variety of technology, as such as you know, you can get MRIs, CAT scans, for your kids, you can get better use of these things. Um, like I said, like you can get a lot of more, a lot of more results of strep, and all these, like mono, and all these other things like that, that a lot faster."

Overall, parents wanted a child-friendly environment that was welcoming, had short wait times, access to specialty providers, and assistance in seeking additional care. Parents are looking for a one-stop shop to provide all care needed to their child without having to set up multiple appointments with different providers at different facilities. One parent mentioned, "And like I said the ER is better equipped, for a lot of things." Additional characteristic quotes for this theme are presented in Table 3. Comments at different sites were similar with more specialty care needed in pediatrics in rural communities and in mental health services in others (Table 4).

Access Access to care was a broad theme overall and parents talked about reasons they might use the ED and access issues surrounding emergency care. Parents brought up issues around access to medical care, especially primary and urgent care. Also discussed were some instances in which the only option for care was the ED because the child could not be guaranteed to be seen at an urgent care center or parents could not afford the insurance co-pay. A comment on getting a clinic appointment was, "And then I called community clinic to get her in and that was...*sighs* ridiculous. I mean that was just, they were book solid forever. And this child is experiencing pain every day." Prescribed medication and other medical tests were expensive and also seen as a barrier to accessing healthcare. Some parents were not able to get all the medication or referrals their child needed due to limitations with economic resources and insurance coverage. One parent stated, "And now he hasn't been on medication for two months, hmm, cause medication is 20-30 bucks a month, for each of my boys. And I cannot pay that much ... Well...so it is...that is the scary part ... what to do." Lack of transportation was also a barrier, but some programs were identified that overcame this barrier, such as public transit with extended hours or community health representatives providing transportation. However, where there were transport systems, there were comments that it was still not enough to meet the needs, "We have ah, we have the CHR services and that's a greatly needed over abused program, it's so needed ... if they could expand that service or come up with another one it's, it's really needed bad, badly." Having Medicaid for their child(ren) was viewed as a benefit and allowed parents to obtain better care for their child. Recommendations included longer hours for bus systems and universal healthcare to ensure that all are provided with needed care. See Table 3 for additional specific quotes.

There were specific site differences in this theme based on location (Table 4). Within the large metropolitan site, more options for care were available and accessing care seemed to be less of an issue, but still some comments about lacking transportation were made. However, in rural areas, access was a huge issue based on a lack of care providers, large geographic distances, and limited transportation. In midsized cities, there were more choices, but comments indicated that access was limited due to insurance and financial barriers. Transportation was also mentioned as an issue in mid-sized cities.

Interaction Between Patients and Providers Parents talked a great deal about their positive and negative interactions with providers. Within this category, sub-themes included provider-patient/parent communication, education for the provider on common health conditions within the community, cultural competence of the provider, inequity in receipt of care, parental education/knowledge on caring for a sick/injured child, and general medical care received. Barriers involved perceived negative attitudes, disrespect, and stereotyping by care providers. Parents felt that their children were treated differently based on their race/skin color. There was also a feeling of accusation, for example, providers believed that parents were only there to obtain drugs for themselves or had abused their child(ren). One parent said, "it's just like they'll look at it and they'll look at you like, well what you want for a pain pill... like-like he wanted pain pills. You know and it's not what we're there for." Facilitators of positive interactions included the provider treating the child as a priority and providing an explanation of what was happening while care was being provided. A positive experience was detailed by one parent, "They were really attentive to my daughter when we took her in and um, they kind of made her feel comfortable. They gave her a teddy bear and everything to make her feel good. So we had a good experience there." Education and cultural competence training for providers was recommended, as was better communication about wait times and information about prescription drugs. An example of this from one parent was, "But I think it's policy at the top, because how can you change somebody's attitude about Native Americans. You know all it does it just creates backlash so that prejudice stuff is like I don't even know how to begin to change that. I just all my life I've tried to...figure out a way for my children to be free of that, but they've experienced it now, you know. And like she said, when you fight-when you're treated like that in front of your kids, you fight harder cause you don't want them to see you like you know walk away defeated by just. So it's like and then that fighting creates more of it." Finally, parents recommended increasing the number of AI nurses and physicians as they would be more comfortable with an AI healthcare provider. Table 3 highlights some more quotes from this specific theme.



Table 4 Characteristic quotes for site similarities and differences

Theme	Rural	Mid-sized	Large metro area
Healthcare environment	"Cause I think, a few times we had pediatricians here and then they leave and then we do not have anybody. And now we end up with the PAs, and some of them are just here to pay back the money they owe and they're just practicing on us."	"so we really need more mental health services for children in this community."	"they have walk ins available, umm. Same day appointments," "Psychiatric. Psychiatric care? Therapy. Okay, there's not enough therapy is what you're saying? No, there's not."
Access	"And then families have to travel to be with their loved ones, when therethere's that kind of an emergency and it causes a hardship. And a lot of times we don't have cars to go, you know, any distance. We can get around here, but we don't always have transportation to make it to somewhere else." "We have a PHS that lives here, but you have toshe's only PHS from 8-4:30. *laughs* So if we could have a doctor that could even possibly come over after 4:30."	"I think transportation is another huge issue (oh big time) (yes it is) because you know if your relying on the bus you know forget it. That night that I had to go to the emergency room, I didn't have a way to get home and so it cost me 20 bucks (umhm) just to get a cab home and you know, luckily I had that money on me (yeah) otherwise I don't even know how we would of even gotten home, it was like after midnight and I didn't want call anybody and wake em up to come and it was a snowy night and it's we, our community really needs a better, uh, bus service that goes through to the evening, weekends." "Yeah, you'd be shocked how many people try to self-diagnose because, because of no health insurance and things in that nature, no transportation,	"I would have to say like transportation iss-issues would be with like parents not having enough funds" "like welfare system I know they help with bus cards and then like some insurances they offer you the rides, like they have insurance programs down here where you call your insuranceum couple days ahead of time, set up this ride and there goes your ride, Okay, which is pretty reliable to me I use it quite a lot."
Interactions between parents and healthcare providers	"They have a pain committee, pain whatever pain pill committee and you don't know whose on there and then the ones that they choose that the committee selects you see them all, you hear them all, you know, doing exactly what they think the ones that aren't good enough to get 'em or aren't trusted enough to. I don't know, it's kind of like the color of your skin too, the darker you are the more apt you are to abuse, misuse." "Well and everythingyou know, they didn't understanduhh weather. Which makes them angry. They don't understand a lot of the-the culture, the dynamics, and you know it's just a lot of negativity and"	things like that." "But ifit-it is an attitude and it is a really uncomfortable um situation all around. And I think-I think it's real. I don't think it's just in people's minds. Or people's, you know, perception." "Umm just last week I kinda cancelled out going to them. I was denied being seen because of the twenty dollarco-fee, co-pay, co-pay that they wanted. They denied me because I didn't have the twenty bucks." "I think the cultural sensitivity is a really good idea. I mean not even just for our culture, but this city has got a lot of different cultures, lots of cultures. And so I mean I don't want to make it seem like for myself, I'm just worried about me me me, our race I mean whatever, our culture but everybody's"	"They're judgmental, sometimes they're judgmental you know, you don't know where we came from or our background so why do you look at us the way that you do, or you know look at our children as you knowwe're abusing them or we're neglecting them, because we don't havethe right clothes or the right shoes, or we don't look a professional way, likethey don't understand where we come from so" "I don't think they're as culturally sensitive to our traditions, like about ten years ago, it-it's it was really hard to[inaudible] if you had alike a severe medicalemergency in the hospital stay, it was hard to burn sage and hang up eagle feathers and things and we had to getand if you didn't accept their clergy or their whatever and we did our ways, it was like well "What are you doing?", Mhmm, well we don't go that way, we a different-different way."

Comments about discrimination and stereotypes were prevalent at all sites, but sites had different experiences (Table 4). For example, at one rural site, there were a lot of comments about using the ED to obtain pain

medication that were not as common at other sites. The same site also had more comments about specific racial discrimination and discussed being treated differently based on skin color or looking "more native". Another



mid-sized city site talked some about racial discrimination, but more about socioeconomic status (SES) discrimination and bias. This site also had several comments about being stereotyped as alcohol abusers. The other sites all mentioned racial discrimination and discrimination based on SES and insurance along with stereotypes. Cultural training was suggested at all sites, but some sites were noted for allowing traditional ceremonies within the hospital which was more common at hospitals that served a larger proportion of AI patients.

Discussion

In this study, we identified themes that are important to parents in healthcare for their children, especially in their experiences with emergency care. Parents sometimes struggled for access to quality care for their children and were limited by transportation and cost concerns. Positive interactions with healthcare providers were essential, including checking on patients when visits were lengthy, having a compassionate attitude toward the patient and family, especially the child, and ensuring that the providers were familiar with the patient's culture. A final theme was the environment in which the care was provided including appointment and referral availability, providing a child-friendly environment, and having clean and welcoming facilities.

These themes and concerns are not that different from the concerns of all parents wanting to obtain quality healthcare for their children, but may be more important due to the health disparities and access to care issues within many AI communities. While there are few studies on perceptions of care for AI children, several studies focused on the adult population, either in general or for specific diseases or conditions [15–19]. Most of these studies focused on the patient-provider relationship and found that one of the most important aspects is trust between the provider and patient. This was seen in our study as well. Parents wanted someone who was nonjudgmental and attentive to their child's needs, and felt that this was not always provided in an emergency setting.

Culturally competent healthcare builds communication and trust, thereby enhancing patient adherence to medical instructions and ultimately improving health outcomes [20]. Healthcare providers, like other individuals, are likely influenced by implicit biases and broader social trends [12]. Several studies have shown that minority patients are often assigned less urgent emergency severity index scores, tend to wait longer, and are less likely to receive opioids [21–23]. Furthermore, among adults seen in the Veterans Affairs ED, minority patients appeared to receive lower-prioritized care compared with non-Hispanic whites [23]. Other studies have shown that minority children are

less likely to receive pain medications in the ED, suggesting reduced trust of patients by the healthcare provider [21].

Along with patient-provider-interactions, healthcare access was reported as a substantial barrier to satisfactory ED care. In one study, access issues persisted among AI children, with lower rates of a medical home and of receiving all needed medical care [24]. Furthermore, AIs have the highest percent of uninsured individuals under age 65 (21.5%) [25]. Participants in our study stated similar issues, including not being able to afford co-pays and other healthcare-associated costs.

Little data exists on the healthcare environment and its effects on AI children in the ED. One contributing factor is that many Indian Health Service (IHS) facilities are understaffed and underfunded, which contribute to longer wait times and insufficient referrals. One study found that physicians providing care at IHS facilities reported inadequate access to specialists (29%) and high-quality imaging services (32%) [26]. This was consistent with our study, in which participants indicated difficulty in obtaining referrals to and appointments with specialists.

There are limitations to our study. Data from focus groups may be less generalizable due to possible selection bias in participation, small number of participants, and differences in individual group dynamics. While there were differences in content discussed at each site, our broad themes were consistent across sites and thus likely represent real concerns of parents of AI children in the Upper Midwest. Another possible limitation is that selection of themes and representative quotes is based on judgment and may be inherently biased by those coding the data and selecting quotes. In our study, we had two coders who had reasonably good agreement with each other in coding quotes into themes, suggesting possible mitigation of this bias. We also tried to represent both positive and negative opinions by focusing on barriers, facilitators, and recommendations to ensure that positive experiences were well represented.

Overall, we found common concerns among AI parents, which included the healthcare environment, access to care, and interaction with healthcare providers. Parents wanted a better healthcare environment with easy access to care without incurring financial burdens. Parents also wanted to have a positive interaction with the healthcare providers which included good communication. Communicating these results with healthcare providers may help them better understand their patients and families, as well as any struggle parents face in providing quality care for AI children. Acting on some of the recommendations or discussing solutions for noted barriers would improve relationships between hospitals and AI communities they serve as well as providing better care for AI children.



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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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