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A mixed methods study exploring requests for unproven COVID therapies such as ivermectin and healthcare distrust in the rural South

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ABSTRACT

The COVID-19 pandemic has led to contentious discourse regarding unproven COVID-19 therapies (UCTs),(e.g. ivermectin). Despite recommendations against it, ivermectin remains, in some areas, highly demanded. The goal of this study is to understand patient and provider perspectives about UCTs (e.g., ivermectin) and how responses to requests for UCTs impact healthcare distrust. This mixed methods observational study was conducted in a rural healthcare system in the Southern United States. Adults (n = 26) with a history of COVID-19 or clinicians (n = 8) from the same system were interviewed using questionnaires assessing healthcare distrust and qualitatively interviewed exploring perceptions about UCTs. Patient themes were: 1) Importance of anecdotal stories for decision-making; 2) Use of haphazard approaches to 'research'; 3) Strong distrust of government and healthcare organizations; 4) Inherent trust in local healthcare; 5) Decision-making as weighing pros/cons; and 6) Feeling a right to try medications. High survey medians indicated high distrust with differences of 8.5 points for those who requested/used ivermectin versus those who did not (p = 0.027). Clinician themes were: 1) Frustration when patients trust social media over clinicians; 2) Acceptance of community beliefs about UCTs; 3) Distrust originating outside of the healthcare system; 4) Feeling torn about prescribing UCTs to build trust; and 5) Variable educational strategies. When clinicians are perceived as aligned with government, this may void patients' trust of clinicians, Clinicians should leverage trust in local healthcare and distance themselves from distrusted information sources. Ethical questions arise regarding appropriateness of acquiescing to patient requests for ivermectin for building trust.

1. Introduction

The COVID-19 pandemic has led to contentious discourse in mainstream and scientific communities about vaccines and therapies for COVID-19 (Aloweidi et al., 2021; Chavda et al., 2022; Sattui et al., 2020). This discourse has resulted in politicization of science and medicine, causing unparalleled tension between the public, healthcare workers, and government (Van Scoy et al., 2022; Van Scoy et al., 2021; El-Mohandes et al., 2021; Abbas, 2022; Schmidt, 2022).

From this dialogue has emerged scientific discussion about the role of unconventional therapies for COVID-19. Early in the pandemic, there was enthusiasm for using repurposed but unproven medications, including hydrochloroquine, ivermectin and others (Schellack et al., 2022; Beltran Gonzalez et al., 2022; Taccone et al., 2022). Medical misinformation was widely circulating throughout the COVID-19 pandemic, causing an "infodemic" (Zarocostas, 2020; World Health Organization, 2021), particularly regarding the drug ivermectin (Fittler et al., 2021).

Originally developed as an antiparasitic drug, ivermectin was found to have antiviral properties in vitro (Wagstaff et al., 2012; Lehrer and Rheinstein, 2020; Martin and Jans, 2021). Early in the pandemic, ivermectin was shown to be a potent in-vitro inhibitor of the COVID-19 virus (Caly et al., 2020) leading to a flurry of clinical studies testing its efficacy as treatment and prophylaxis for COVID-19 (Rajter et al., 2021; Bryant

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et al., 2021). However, early studies had methodologic flaws or unreliable data leading to withdraw (Reardon, 2021). A 2021 *meta*-analysis of 14 randomized studies did not support using ivermectin due to low quality, potentially biased evidence (Popp et al., 2021). Subsequent randomized trials found no impact of ivermectin for COVID-19-related outcomes (López-Medina et al., 2021; Vallejos et al., 2021; Reis et al., 2022; Lim et al., 2022). Even so, and despite National Institutes of Health and World Health Organziation recommendations against clinical use (Agarwal et al., 2020), ivermectin remains heavily used, and in some geographic areas, highly demanded (Chua et al., 2022).

The appropriateness of using such unproven COVID-19 therapies (UCT) has been widely debated (Schellack et al., 2022; Lim et al., 2022; Zuckerman et al., 2021; Al-Heeti et al., 2022; Mastroleo and Daly, n.d.). Distrust of clinicians is amplified when patients requests are denied, yet clinicians have an ethical obligation not to prescribe ineffective medications that have risk of side effects. That said, clinicians face backlash from patients for not complying with requests which perpetuates healthcare distrust (Love et al., 2020; Khubchandani et al., 2021).

Clinicians practicing in rural areas in the South, which have among the lowest COVID-19 vaccination rates (30–42%) (Vaccine et al., 2022), have been inundated with requests for UCTs (Cuadros et al., 2021; COVID-19-Vaccinations-in-the-United-States., 2021; Murthy et al., 2021). When denied these requests, community members have taken to social media to express outrage, often accusing the healthcare system of nefarious intent. To better understand this phenomenon and consider solutions to address this social unrest, this study explores perceptions within a community particularly affected by healthcare distrust, low vaccination rates, and surging cases. The objective of this mixed methods study was to understand the perspectives of patients and providers regarding requests for UCTs and if and how responses to these requests relate to healthcare distrust.

2. Materials and methods

2.1. Study design and setting

This convergent, mixed methods observational study (Creswell and Creswell, 2017) explored skepticism towards healthcare and attitudes about UCTs from November 2021-May 2022 in a rural Southern town in the United States and in collaboration with the local health system, which includes a 99-bed hospital.

2.2. Recruitment

Institutional Review Boards at the involved institutions approved all procedures. Eligible patients were English-speaking adults diagnosed with COVID-19 within the last 6 months and received care within the study's health system. Eligible clinicians provided care for a COVID-19 patient in the past 6 months within the local health system. Exclusion criteria included those unable/unwilling to provide informed consent or participate in an audio-recorded phone interview. Study clinicians identified eligible patients during inpatient, outpatient pulmonary, or family medicine care. With permission, recruiting clinicians passed contact information to researchers who then elicited verbal informed consent, and conducted the phone interview. Purposive sampling was used to recruit diverse participants regarding two strata (vaccination status and UCT request/usage, which were confirmed by reviewing interview transcripts) with a goal of 16 per group and 8 clinicians expected for data saturation (eMethod 1).

2.3. Interviews

Interviewers followed semi-structured interview guides that explored healthcare system trust (perceived quality of care, perceptions of pandemic response) and behaviors related to UCTs and vaccination. Some examples of patient questions and prompts are: 1) What are your

thoughts about your physician who treated you for COVID-19? 2) On your survey, you responded to some items suggests that you don't entirely trust your healthcare system. Can you say more about why you answered those items in that way? 3) To what extent, if at all, did the hospital/doctor's stance on ivermectin make you feel towards healthcare in general? Did you trust what they were saying? Why or why not? 4) How do you decide if your clinician is trustworthy or not? 5) What type of data or information would you need from your doctor to make a decision [about ivermectin]? 6) In what way would you want your doctor to help you decide whether or not to take these kinds of medications? 7) When you're considering whether to take a new medical treatment related to COVID, can you talk me through the thought process you go through to make a decision about whether or not to take that new therapy? 8) What are the features of an information source [eg. a website, news company] that make you comfortable or not comfortable trusting their information? The full interview guide is available in eMethods 2.

The clinician interview guide (eMethod 3) explored clinicians' perceptions about pandemic response federally and locally and their experiences with UCT requests. Some example questions and prompts are: 1) To what extent do you feel that patients trust you regarding COVID-19 issues? Why do you feel that way? 2) To what extent do you feel that patients trust CRMC regarding COVID-19 issues? Why do you feel that way? 3) What have been your experiences related to requests for UCTs during the pandemic? How common is it that you receive these kinds of request? <u>4)</u> How do these requests impact you personally? What is your typical response?

All interviews were audio-recorded and transcribed verbatim.

2.4. Questionnaires

Quantitative questionnaires included demographics, the validated health system distrust scale (Rose et al., 2004), and validated general COVID-19 mistrust scale (Bogart and Thorburn, 2005; Bogart et al., 2010). Validation and scoring details are found in eMethods 4.

2.5. Qualitative analysis

We used a phenomenological approach to analyzing the qualitative data given our goal of understanding individuals' common, lived experiences (Creswell and Creswell, 2017). Details addressing COREQ guidelines for qualitative data appear in eMethod 5.

We used an inductive approach to thematic analysis (Hsieh and Shannon, 2005) to analyze transcripts using MAXQDA qualitative analysis software (MAXQDA Qualitative Data Analysis Software). Patient and clinician groups were analyzed separately. After independent review of 8 patient and 3 clinician transcripts, two analysts created a codebook, which contained categories, codes and their definitions, and exemplar quotations. Next, two trained coding analysts used the codebook to assign codes to the full dataset using the constant comparison method (Glaser, 1965). Coding reports were reviewed and discrepancies resolved through discussion. The final intraclass coefficient, which assessed inter-coder reliability (Thomas and Magilvy, 2011), was K >0.8. One analyst reviewed and adjudicated all final coding with attention to the dependability and confirmability of codes (Thomas and Magilvy, 2011). Results were reviewed by two qualitative interviewers who were not involved in analysis to assess trustworthiness of findings. Finally, both analysts reviewed the coding patterns to construct themes and subthemes and identify example quotations for each theme.

2.6. Quantitative and mixed methods analysis

Quantitative data was summarized in SPSS Version 26.0 (IBM SPSS Statistics for Windows, 2019). There was no missing data. Groups were compared using independent sample Mann-Whitney U tests. Medians, quartiles, and 95 % confidence intervals are reported. Mixed methods

integration was achieved by constructing a joint display (Myrick and Willoughby, 2022).

3. Results

Table 1 displays demographics for the 8 clinicians and 26 patients

Table 1

Participant Characteristics.

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(100 % and 47 % consent rates, respectively). eFigure 1 shows the consort diagram.

3.1. Patient interview Themes

Supportive quotes are numbered in Table 2.

3.1.1. Theme 1. Anecdotal stories and personal experiences strongly influence participants' decision-making about COVID-19 treatments or vaccines

To assess information and make decisions about COVID-19, patient participants relied heavily on stories and experiences of others, often regarding them as evidence supporting their beliefs about ivermectin (Quote 1) and vaccination (Quotes 2 and 3). Some participants based decisions about COVID-19 medications on whether they personally knew others who had good (or bad) experiences taking the medications (Quote 4). Some noted that personal opinions weighed more heavily than data or medical recommendations (Quote 5).

3.1.2. Theme 2. Participants use a haphazard approach to 'research,' primarily involving 'reading up' online

Both vaccinated and unvaccinated participants described their medical research process as non-systematic internet searches across multiple sites (Quote 6), often prompted by social media links and popups (Quote 7). Most reported using multiple sites for information (Quote 8), perceiving that the volume of websites putting out consistent information was an indicator of trustworthiness (Quote 9). Some coupled online advice with opinions from trusted providers (Quote 10). Last, individuals tended to seek out information consistent with their beliefs, and 'tune out' inconsistent information (Quote 11).

3.1.3. There 3. There was significant distrust of the national government and pharmaceutical agencies

Many viewed government as overt 'liars' that disregard best interests of individual patients (Quote 12). The distrust extended to pharmaceutical companies, whom they perceived as being concerned with financial gains over public health (Quote 13). Although participants demonstrated inherent trust in local clinicians (Theme 4), many felt these clinicians were doing what the government tells them to do (Quote 14). Many participants expressed strong, controversial (often inaccurate) beliefs (Quote 15) or endorsed conspiracy theories derived from beliefs in a dishonest government with corrupt and malicious intent who were 'shutting down' clinicians from prescribing 'helpful' medications (Quote 16). Perceived censorship of a local high-profile doctor who also voiced these concerns amplified these impressions.

3.1.4. Theme 4. Nearly all participants demonstrated an inherent trust in local doctors and the local healthcare system, in part due to the personal nature of the relationships

Participants expressed a strong inherent (and nearly unanimous) trust in their individual healthcare providers (Quote 17). For those who decided not to take ivermectin, this trust played a role in that decision (Quote 18). Many commented about the altruistic nature of local providers caring for the community (Quotes 19) and believed providers in the local health system are trying their best and doing a good job addressing the pandemic. Some felt they had 'no choice' but to trust the system if they were to need medical care (Quote 20).

3.1.5. Theme 5. Decision-making is viewed primarily as weighing perceived pros and cons

'Cons' were commonly framed as side effects (Quote 21) and 'pros' often pertained to how many people the treatment seemed to help (Quote 22). Participants commonly pointed to time on market (for any reason) as key evidence for their safety determination of ivermectin and vaccines (Quote 23). Regardless of the type of data used to appraise treatments, the common thread was that participants valued the role of

Table 2	(continued)
I ADIC 2	(continueu)

					Quotations
Themes	Subtheme (if applicable)	Quotations		applicable)	1.1
Theme 1. Anecdotal stories, personal experiences, and beliefs strongly influence participants' decision-making about whether to take	Stories related to ivermectin	Quote 1: Ivermectin, hydroxychloroquine? I know a person that's been on it for years for a different reason. And in their family, several of them has had COVID. And this certain person here			you had any trouble? Be truthfulage 48; white, unvaccinated female; no UC use, less than high school, Healthcare Distrust Survey 3 COVID Mistrust Survey 61; political affiliation (Patient 25)
COVID-19 medications or vaccines		never had a symptom. She's been on the hydroxychloroquine probably 15, 20 yearsage 66; white, unvaccinated male; UCT use, High school graduate, Healthcare Distrust Survey 31.0; COVID Mistrust Survey 58.0; Independent (Patient 21)	Theme 2. Participants use a haphazard approach to 'research' which primarily involves 'reading up' on the internet.	Non-systematic approaches that follow 'pop-up' websites	Quote 6: I do go on the internet to read a lot, you know, but I try to look at scienceI look at YouTub lot, you know, and comp different things. And I kn they'll say, you know, do go to the internet, but I w to check to see if they're right. And, um, yes, I belie
	Stories related to COVID vaccines	Quote 2: I know one woman who got brain tumors, and the direct cause– direct link, both her doctor and her neurosurgeon, was from the vaccine. I mean, but my point is, no, I didn't like how they were trying to cram it down your throat and threatening you at the same time. And they just found out about it, and all of a sudden [the tumors] just magically appearthat was why I didn't trust itage 66; white, unvaccinated female; UCT use, High school graduate, HealthCare Distrust Survey 27; COVID Mistrust Survey 49 Republican (Patient 23) Quote 3: To be honest, I was not going to get the vaccine, and then several people I knew got very, very sick from COVID. And they did not have the vaccine, and one person even passed away from itage 58; white, vaccinated female; no UCT use, some college, HealthCare Distrust Survey 23; declined political affiliation (Patient			there were people out the sounding the call about th vaccine and all on YouTu on Twitter, and that's wh they were taken off, you know, of those sites becat it was against what the government wanted them say. Interviewer: [Are there] a specific places on the internet that you tend to look at? Patient:on the internet will go to a lot of the like Mayo Clinic just put in what I want to look up, a then I'll look at the sites a see, you know, what they say. <i>-age 51; white, vaccina</i> <i>female; no UCT use,</i> <i>Bachelor's degree, Healthct</i> <i>Distrust Survey 39; decline</i> <i>political affiliation (Patient</i> Quote 7: Well, I read, you know, if I see anything, I mean, I- or from - I did as lot of questions when I w in the hospital and talked the doctors. Um, but all c them basically had the sa answer. They don't have
	Stories relate to decisions about COVID-19 treatments	political afjuiation (Patient 14) Quote 4: I don't know anybody that died taking remdesivir or the antibodies, so that does play into [my decisions] a little bitage 37; white, unvaccinated male; no UCT use, High school graduate, HealthCare Distrust Survey 23; COVID Mistrust Survey 42; no political affiliation (Patient 17) Quote 5: That would be it, your personal opinion. I don't care about what they're saying that they have data on. Because, one thing, I don't trust the data. Tell me- tell me what you- tell me what it felt like. Did you		Multiple sources of information and	answer, rally. There's ju not enough. Interviewer: Yeah. And when you say the interne are there specific um websites, or are there specific news sources or individuals that you migl seek out information fror Patient: No Just some t may pop upso-yeah, nothing in particularag 66; white, unvaccinated female; used UCT, High sch graduate, Healthcare Distri- Survey 27; COVID Mistrus Survey 49; Republican (Patient 23) Quote 8: I don't trust, particularly, just one sour
		get it? And what did it feel like? You know, and have		consistency of information is valued	Like I said, I'll– I'll literal check several different sources and see what they (continued on next pa

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Table 2 (continued)		Table 2 (continued)			
Themes	Subtheme (if applicable)	Quotations	Themes	Subtheme (if applicable)	Quotations
		saying. Like how much are the differences if literally every source I check coming from a different website that is not affiliated says the same thing, to me that says you know, this is pretty accurate informationage 29; white, unvaccinated female; no UCT use, High school graduate, Healthcare Distrust Survey 17; COVID Mistrust Survey 28; no political affiliation (Patient 18)	Theme 3. There was significant distrust of the national government and national healthcare	Government is not trustworthy	won't just give you the new It's got their opinion on it, mixed in with it, and so when I see that, I don't- yo know, I turn it offage 64; white, unvaccinated male; nu UCT use, Bachelor's degree, Healthcare Distrust Survey 22, COVID Mistrust Survey 52; Independent (Patient 13) Quote 12: The United State government have lied to us as a people on so many occasions, not just us, the Indians and everybody
		Quote 9: Interviewer: So are there any specific websites or places online that you typically get information? Patient: Probably-two or three hundred I mean, it's not just one or two It's just like a computer. You go in one door. And then things pop up. And then you can go to that website. And that website will lead you to another website. And there's thousands of themAnd if it work just one or metho even	organizations, and pharmaceutical agencies		elseit's a well-known fac that lying is what politician do. So, do I trust the government? [SCOFFS] I trust them to tell me a lie. trust them to tell me a lie. trust them to tell me whatever they feel like the need to tell me to get me t do whatever they need me do. That's what they doag 66; black, unvaccinated mal UCT use, some college, Healthcare Distrust Survey 4. COVID Mistrust Survey 51; bdamedaet (Dating 2)
		were just one or maybe even 50- but when you get 90 % of off-mainstream news media and you're seeing 90 % of the same thing, there's got to be something to it -age 66; white, unvaccinated male; UCT use, High school graduate, Healthcare Distrust Survey 31; COVID Mistrust Survey 58; Independent (Devinet 21)		Pharmaceutical agencies are in it for financial gain only	Independent (Patient 3) Quote 13: Because big pharma is the problem. It' all about the money. Now, believe that we have good health providers. I'm not- there are some of them the are great, and they do all that they know to do. But b pharma is lying to the American people. There are
	Coupled online with the advice and opinions from trusted providers	(Patient 21) Quote 10: Number one, I would talk to my doctor, see how he felt about it. Then I would kind of research. Me going online, Googling it, to read about itMaybe read about others that had gone through the process before I would make my decision. -age 58; white, vaccinated female; no UCT use, some college, Healthcare Distrust Survey 19; COVID Mistrust			cures. I believe there are cures for things that they give us medicine for just t be able to keep making money. So I think by that you can see, yes, the healt providers, I'm not against them. But it's big pharma. -age 62; white, unvaccinate female; UCT use, high schoo graduate, Healthcare Distru Survey 38; COVID Mistrust Survey 60; Republican(Patie 22)
	individuals tend to seek out information consistent with their own beliefs and 'tune out' information that is not consistent with those beliefs	Survey 23; declined political affiliation (Patient 14) Quote 11: Interviewer: And what makes you trust the information that they, um, they put out there? Patient: Um, well, it's just- basically it's people that are aligned with my way of thinking. I mean, more conservativeso, you know, I feel a part of that group. Interviewer:and what would some features be of an information source that would make you not trustful of the information? Patient: Well, most of the news today is it's not really news. It's opinion. With the		Local doctors just abide by whatever government tells them to do	Quote 14: The local healthcare system is doing exactly what the upper echelon is telling them to d which is the government. These doctors are worried about losing their license. They can't do this. They can't do that. They can't speak the truth on anythingI think that the government has, you know the hook in every doctor whether it be a rural area, New York City, or, you know, California, whereve they're at. I think it's all t same cookie cutter– I thinl the same memo goes out t everybody. <i>-age 50; white,</i>

(continued on next page)

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Table 2 (continued)

Themes	Subtheme (if	Quotations	Table 2 (continued) Themes	Subthem
	applicable)			applicab
	Patients hold fixed beliefs and conspiracy	UCT, High school graduate, Healthcare Distrust Survey 40; COVID Mistrust Survey 61; Republican (Patient 24) Quote 15: Have you heard that the COVID vaccine		
	theories	actually creates- causes your body to create the COVID- the COVID disease in you, in the cells I wish I had wrote down that text message- some <i>T</i> -cell or something age 66; white, unvaccinated		Belief in nature a local pro
		male; UCT use, High school graduate, Healthcare Distrust Survey 31; COVID Mistrust Survey 58; Independent (Patient 21) Quote 16: Um, just everything that we were		
		readin' [online] with him. Um, I mean, don't get me wrong. He's a little out there, you know? Um, but you know, he had been a doctor in- in Moultrie for over 25 yearsand he's very vocal about the health care		No choid local hea
		system. And I think a lot of the reason he got out of it was because of all the restrictions that the government was putting on him. You know, because		
		when I went and got my prescription [for ivermectin] from him He said, they're fixin' to stop me from doing this, because he was writing a lot of those prescriptions.	Theme 5. Decision- making is viewed primarily as a weighing of perceived pros and cons.	Cons fra effects an as how r the medi help
		-age 41; white, unvaccinated female; used UCT, some college, Healthcare Distrust Survey 28; COVID Mistrust Survey 57; Republican (Patient 26)		
Theme 4. Nearly all participants demonstrated an inherent trust in local doctors and the local healthcare system, in	Strong, inherent local healthcare	Quote 17: I trust my health care provider because I feel like they've always been upfront with me. When I got COVID-19, they did everything they could to		
part due to the personal nature of the relationships.		help me rapidly. They'd didn't wait around. Um, so like, my personal physician was- was very knowledgeable about what was going on and awesome age 42 white, vaccinated		
		female; no UCT use, Bachelor's Degree, Healthcare Distrust Survey 10; COVID Mistrust Survey 13; Democrat (Patient 12)		Time on data poi
	Trust in local healthcare extends into their decision-making about UCTs	Quote 18: I trust my physician well enough that if, you know, if I just kind of brought something to them just to see [if my physician] said that they		
		highly doubt that it would work I'm probably not going to pursue it, because I don't want to risk making		

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Themes	Subtheme (if applicable)	Quotations
		myself even worseage 27; white, unvaccinated female; no UCT use, some college, Healthcare Distrust Survey 23 COVID Mistrust Survey 48; Republican (Patient 8)
	Belief in altruistic nature and intent of local providers	Quote 19: Well, I mean, living here in a small town, think the doctors here want what's best for their patient and the community, um, because if they didn't, word would get out and spread quickly. <i>age</i> 66; black, vaccinated male; UCT use, some college, Healthcare Distrust Survey 42; COVID Mistrust Survey 51; Independent (Patient 3)
	No choice but to trust local healthcare system	Quote 20: Well, I would say I- Hmm, I have to trust them, you know? Because if I'm sick I need to go out there then, you know, they do what they have to do. But, yes. I trust themage 78; white, unvaccinated female; no UCT use, some college, Healthcare Distrust Survey 26; COVID Mistrust Survey 54; Republican (Patient 6)
Theme 5. Decision- making is viewed primarily as a weighing of perceived pros and cons.	Cons framed as side effects and pros framed as how many people the medicine seemed to help	Quote 21: Give me a scale [zero] to 100, uh is people getting better or is it low? if it's a lot of side effects, I'n like, no, I ain't gonna try thatage 54; black, vaccinated female; no UCT use, High school graduate, Healthcare Distrust Survey 17; Democrat (Patient 10) Quote 22: What kind of information would you wan your doctor to present to you to help you make a decision about ivermectin, or anothe unproven COVID therapy? SUBJECT: Maybe he'll give me some numbers of people that it helped. You know, the opposite numbers where it didn't help the- this amoun of peopleage 66; black, vaccinated male; UCT use, some college, Healthcare Distrust Survey 51; Ir down dem (Decime 2)
	Time on market is key data point for safety	Independent (Patient 3) Quote 23b: When the polio vaccine was finally administered to us, it had took them 40 years to design it, to get it approved. When you come in and you got something approved in seven or eight months, there's no way that you car safely say that it's not going to affect the ones that's taken it down the road in a year, two years, five years,

don't want to risk making

Table 2 (continued)

Themes	Subtheme (if applicable)	Quotations
Theme 6. Participants valued their right to make autonomous decisions about their own healthcare and feel they have a right to try medications knowing that there are possible risks.	Right to try medications	or 10 years. That's the reason [I didn't get vaccinated]. And with the genetics that's involved in making it, the mRNA- genetics that's in there dissolves in your cells in your system once its put in you, that is something I'm strongly againstage 66; white, unvaccinated male; used UCT, High school graduate, Healthcare Distrust Survey 31; COVID Mistrust Survey 58; Independent (Patient 21) Quote 24: And then the red flag pops up when the medical association [says]- oh no, you can't use [ivermectin for COVID-19]. That's horse medicine. That's what makes my ears perk up. And that's what makes me go to look What's going on here that they don't want you to use it? If a person is willing to
	Role of the clinician was to provide the	It? If a person is writing to take the chance for a treatment, alternative or otherwise, I believe that they should have that right without any prosecution. -age 66; white, unvacinated male; used UCT, High school graduate, Healthcare Distrust Survey 31; COVID Mistrust Survey 58; Independent (Patient 21) Quote 25: I think they should tell them, in their-
	information and risk assessment should be the role of the patient	you know, in their honest opinion, give them all the information. Tell them how they feel about it, what they think. Tell them the pros, the cons, and let the– and if there's nothing– like with ivermectin, what harm is it going it do? Why would you not let that person try that? You tell them what you don't know. You tell them what you do know. Keep your opinion out of the bullshit. And let the patient– it's not like you're doing a– you're not giving them, you
		you re not giving them, you know, what is it? You know, a pain medicine, or something that's going to hurt them. So why would you not do that? -age 50; white, unvaccinated female; used UCT, High school graduate, Healthcare Distrust Survey 40; COVID Mistrust Survey 40; Republican (Patient 24)

science in helping them decide whether to take a medicine.

3.1.6. Theme 6. Participants valued their right to make autonomous decisions about their own healthcare

Many endorsed a right to try medications knowing there are possible risks (Quote 24). Participants felt clinicians' roles were to provide information and professional opinions but that ultimately the decision whether to take ivermectin should rest with the patient based on their own determination of the risks (Quote 25).

3.2. Clinician interview Themes

Eight clinicians participated (see Table 1 for demographics and Table 3 for numbered supportive quotes).

3.2.1. Theme 1. Clinicians do not understand why people trust social media and not their expertise; such distrust is hurtful and frustrating

Clinicians struggled to grasp why patients would dispute their recommendations yet trust the advice of a politician or stranger on social media (Quote 26). Many described a personal toll of this distrust on their mental health, questioning themselves and their role, along with significant frustration and hurt (Quote 27).

3.2.2. Theme 2. Some clinicians expressed feelings of ambivalence or emotional detachment regarding discussions about UCTs; others were generally accepting of community beliefs

Clinicians noted how they kept their personal beliefs and emotions at a distance out of respect for the patient's beliefs (Quotes 28). While they felt frustrated by distrust and UCT requests, in most cases, clinicians were tolerant of patients seeking out or using UCTs but would not prescribe UCTs themselves (Quote 29).

3.2.3. Theme 3. Clinicians perceive that distrust in healthcare originates outside of the healthcare system yet perceive that patients exhibit trust in the local healthcare system

Clinicians perceived that fixed beliefs, often generated within places of worship, contributed to the lack of trust in the healthcare system because of 'word of mouth' being propagated throughout the community that was difficult to penetrate (Quote 30). Clinicians acknowledged that while distrust seemed to manifest from 'outside' the healthcare system, a healthy level of trust was maintained within the hospital and between individual providers and their patients (Quote 31). Clinicians felt that any patient distrust of local healthcare stemmed from patients perceiving alignment of local providers with government (Quote 32) or pharmaceutical companies (Quote 33). Several clinicians noted that distrust dwindled as rapport was established during inpatient stays and patients had "no choice but to trust us" (Quote 34).

3.2.4. Theme 4. Clinicians are torn about whether to use UCTs as a means of building trust and rapport

Many clinicians feared that refusing to prescribe UCTs would undermine their relationships with patients (Quote 35). They expressed openness to prescribing UCTs, feeling it may (at times) be justified to cultivate patient trust and maintain patient rapport (Quote 36) so that patients might heed advice to get vaccinated or to receive evidencebased therapies if they were hospitalized (Quote 37). Others used UCTs to avoid conflict (Quote 38); only two clinicians felt there was no role under any circumstance for ivermectin.

3.2.5. Theme 5. Counseling strategies are variable, yet clinicians spend significant amounts of time on education

Regarding counseling patients about treatment strategies, most clinicians concentrated on sharing recommendations of leading medical societies and evidence-based guidelines (Quotes 39). They perceived that patient education and provision of rational information were key responsibilities of clinicians, particularly when patients hear conflicting

Themes and subthemes from clinician interviews with representative quotations.

N/A	Quote 26: Because some patients somehow they
	will have more trust with
	someone who has never even opened up a science book
	than someone that spent
	years studying to do what
	many physicians doI never
	thought I would see a day where patients would be
	more trusting with a
	Facebook post than they
	were with the family
	medicine doctor that's been taking care of their entire
	family for 30 years. It just
	makes no sense. (Clinician
	004)
	Quote 27: they would get angrier and angrier and
	angrier, and demanding
	ivermectin, and demanding
	hydroxychloroquine and
	demandingyou know, those kinds of things– even
	when this guy was struggling
	to breathe, you know, he was
	still holding to these beliefs.
	He was standing in front of a doctor that had been
	practicing for a decade and a
	half, board certified, had
	been treating COVID from
	the get-go, have actually used some of these medications
	that they were requesting,
	and still would rather believe
	someone on YouTube than the physician in front of him.
	That- that affected me. I was
	like, this is- there's
	something wrong in our
	society today when– when that happens. When you
	come to the hospital and
	you're dying, and you would
	rather believe somebody on
	YouTube, than a medical doctor in front of you. And so
	that affected me
	(Clinician 007)
-	Quote 28: I don't feel like it does [affect me]. I've got
personal impact.	pretty thick skin, and I
	understand where the
	patients are coming from. So
	I don't take it as an affront or as a disrespect or anything
	like that. I think I just, it
	just is what it is. It's just part
	of the conversation I'm
	having with him.(<i>Clinician</i> 003)
Clinicians feel patients	Quote 29: I think that if the
have the right to their	family wants to provide [the
own choices.	UCT] and they bring it in and it could be verified that it's
	appropriate, then if they
	want to administer it, we
	have a right to answer to our
	patients. Because patients
	ultimately have autonomy
	For some clinicians, UCT requests don't have personal impact.

Гhemes	Subtheme	Representative Quotations
		patient was adamant they wanted to try [a UCT],I think that it would be something that they could do of on their own risk, in their own potential benefit. I wouldn't prescribe it for themWe had a patient in the unit that the family was sold [on] getting ivermectin Great, that's fine. Bring it in
Theme 3. Clinicians perceive that the distrust originates <u>outside</u> of the healthcare system although patients do exhibit trust <u>within</u> the local healthcare system	Unreliable 'outside' sources of information or 'bad actors' are to blame	we'll give it. (<i>Clinician 002</i>) Quote 30 I think there are some patients who are lockee in on their beliefs with regard to medicine as opposed to allowing objective input. That seems to be quite prominent in this area It seems to be a more belief- based culture in this region o the country. I'm not from thi area There is a predominance of religious affiliation down here, openly, commercialized as well. And I almost wonder in that type of belief-based- once something is felt to be the solution, it is stuck to not matter what. And no amoun of objective information– I'm overstating this a bit, but- will change one's beliefs. (<i>Clinician 005</i>)
	Patients seem to trust local healthcare	Quote 31: In our community it's pretty deep-rooted in trust for the hospital. So I think that they do, you know the majority of them, do trus the hospital. (<i>Clinician 004</i>)
	Patients align clinicians with government and pharmaceutical companies	Quote 32: A lot of patients is our community it's not that they don't trust CRMC, but that they think that CRMC is part of the bigger scheme and all the hospitals are answering to the government, et cetera, et cetera. And there's people is our community who are ver outspoken against COVID, against the vaccine, against the treatments. So we're having a lot of patients that are coming in saying, well, such and such told me this. And they're people–They're in our community. So we're having–We, as a medical community at CRMC are having–We, as a medical community at CRMC are having to try to fight that fight as well. (<i>Clinician 002</i>) Quote 33: There's still a hesitancy within the genera: population that we are being tricked, not tricked– wouldn't be the right word- but that we're being swayed by pharmaceuticals and hospitals to treat in ways tha aren't actually proven, and/ or aren't beneficial So sometimes it's really clear that their beliefs or their desires are kind of well

Table 3 (continued)

Themes	Subtheme	Representative Quotations
		entrenched and that I'm not
		going to change those.
	** 1. 1. 1	(Clinician 003)
	Hospitalized patients	Quote 34: I feel like, by the
	have no choice but to trust the clinicians	time patients reach me [in the hospital], they don't have
	trust the chincians	much option but to trust me.
		When it comes down to it,
		when they're critically ill,
		can't breathe, and usually
		requiring either non-invasive
		ventilation or invasive
		ventilation, being put on a
		ventilator, they're usually
		are at a critical moment, where it's life or death. And
		they're placing their trust in
		the hands of anyone that can
		reach out to help them. So I
		think that they do trust me at
		that point. (Clinician 004)
heme 4. Clinicians are	Clinicians consider UCTs	Quote 35: I feel torn [about
torn about whether	as a way to build trust	prescribing ivermectin],
to use UCTs as a means of building		honestly, because these patients they just want to get
trust and rapport.		better, and they don't
······································		understand medicine, most
		of them.
		Quote 36: I consider it in
		an effort to establish rapport
		with the patient, um, if I feel like I haven't gotten
		anywhere with educating,
		then I would consider it for
		sure.
		(Clinician 007)
	Using UCTs as a means	Quote 37: I want us to extend
	of building trust may	an arm so that we don't-
	facilitate other desired	we're not cutting these
	health decisions	people off and saying, do it our way or- or no way I
		said, if it's not hurting them,
		why don't I give it to them?
		And then, maybe they will
		also take the infusion. Maybe
		they'll also take some of the
		other therapies that will help.
		As long as we're not hurting
		them, if we're gaining trust and letting them in, then I
		think it was beneficial
		After thorough discussions
		with different providers, we
		said the side effects are not-
		you know, it's relatively a
		harmless drug. And I said I
		don't feel– I guess I did not
		feel that we should not prescribe it. Maybe we
		should prescribe it to gain
		trust. And then, maybe, you
		know, when someone does
		really get into a bind, they
		will come to us versus
		waiting and hopefully not
		dying at home. I didn't
		necessarily see a problem
		with people taking it. I just did not think it worked.
		(Clinician 008)
	Prescribing UCTs to	Quote 38: [A patient] wanted
	avoiding conflict	to be able to take it
	~	prophylactically if he felt like
		he needed prophylactic
		treatment and he showed me
		the data that he was using

Themes	Subtheme	Representative Quotations
Theme 5. Counseling strategies are	Most center around rational information and	And so I finally kinda just defervesced so that I wouldn't get in an argume with him." (<i>Clinician 003</i>) Quote 39: If a patient talks me about [UCTS], then I sa
variable yet clinicians spend significant amounts of time focusing on education	education	the resources that I'm usin the evidence that's coming down through the medical journals, through the medic societies, are not supportin the use of that medicine,
		therefore I don't recommen it. (<i>Clinician 003</i>) Quote 40: I think we have actually, almost a duty to t to educate those as we can (<i>Clinician 005</i>)
	Open discussions around patient beliefs and choice	Quote 41: Just trying to ma sure that I listen to the patient and try to understan why they thought what the did. I guess getting to the source of their information and making sure that it was legitimate source and not necessarily– I guess finding out where they got their information. That's the ma
		thing I wanted to find out. Why did they think that we the best treatment? (<i>Clinici</i> 008)

advice from community sources (Quote 40). Most clinicians prioritized creating an open dialogue with their patients to learn about individual beliefs and choices (Quote 41), but one clinician took a firm approach to denying requests for UCTs, feeling it was more effective to "nip it in the bud very early" without providing extensive explanations that could trigger arguments.

One outlier clinician interview warrants mention as they appraised the literature in favor of ivermectin and other UCTs and felt messaging from government and medical leaders was skewed and misleading (eMethod 6).

3.3. Relationship between Distrust, vaccination and UCT requests

Table 4 shows median healthcare distrust scores were 8.0 points higher for unvaccinated (versus vaccinated) and 8.5 points higher for those whose requested/used a UCT (versus those who did not); p = 0.044 and 0.027, respectively. Similar findings emerged for COVID-19 mistrust scores (Table 4). eTable 1 summarizes itemized responses on the COVID-19 mistrust survey. Table 5 merges qualitative and quantitative findings in a joint display (Guetterman et al., 2015).

4. Discussion

The demand for ivermectin, despite emerging high-quality research refuting its effectiveness, is likely to remain in public dialogue. Our data provide insights into how patients and clinicians living in a southern, rural town with high healthcare distrust struggled with therapeutic alliance while navigating contentious public discourse about ivermectin. These data offer practical insight for public health messaging and bedside clinicians.

Thematic analysis from clinician and patient interviews revealed several areas of overlap. First, patients expressed high levels of government distrust (supported by high distrust scores in the quantitative surveys), and clinicians recognized their concerns. Our quantitative

the data that he was using.

Median and quartiles on the Distrust scales based on vaccination status and use (or request) of ivermectin.

Questionnaire	COVID-19 Vaccination Status			Ivermectin Use or Request		
	Vaccinated (n = 10)	Not Vaccinated (n = 16)	p value	Used or requested ivermectin (n = 10)	Did not use or request ivermectin (n $= 16$)	p value
Healthcare Distrust Survey Summative	e Score					
Median (25th percentile, 75th percentile)	20.0 (17.5, 28.5)	28.0 (23.0, 33.0)	0.044	30.5 (27.25, 36.25)	22.0 (18.5, 29.0)	0.027
COVID-19 Mistrust Summative Score						
Median (25th percentile, 75th percentile)	26.5 (18.5, 37.75)	54.0 (49.75, 60.25)	<0.001	55.5 (49.5, 59.5)	41.5 (26.8, 50.5)	0.081

The Healthcare Distrust Survey score is a of sum 10 items; least amount of distrust = 10, most amount of distrust = 50.

The COVID-19 Mistrust Survey score is a sum of 13 items; least amount of distrust = 13, most amount of distrust = 65.

Non-parametric independent samples Mann-Whitney U test; 95 % CI.

analysis suggests that this distrust is related to behavior, as those with higher distrust were less likely to be vaccinated and more likely to request UCTs. Strong patient distrust, particularly around ivermectin, provided a considerable threat to clinician-patient bedside alliances. For patients, distrust manifested by seeking information from a variety of (at times) questionable online sources. Persuaded by advice of individuals perceived as 'standing up to the government', patients subsequently rejected vital health behaviors (e.g. vaccination) in favor of UCTs. For some clinicians, this distrust was a demoralizing identity threat; they felt undermined by social media and misinformation campaigns in a way that interfered with patient care.

However, both patients and clinicians noted an inherent trust in local providers while noting that patients perceived bedside providers as being 'under the wing of the government'. The consequences of this perception could be significant, suggesting that distrust of government can void trust of clinicians. However, the consensus was that clinicians are more credible and trustworthy than other sources. This suggests that bedside clinicians should construct messages to distance themselves from distrusted sources (e.g., government) without overtly undermining them since dismissing patients' trusted sources (e.g., social media) may further disrupt the therapeutic alliance. Sample messaging is provided in Table 5.

Our analysis demonstrated a key disconnect between patients' and clinicians' approach to reputable health information. Patients reported haphazard, nonsystematic online research strategies and a strong reliance on personal anecdotes and stories as 'data'. Clinicians, by contrast, reported frustration with these approaches and highlighted that their best communication efforts, including considerable time spent on education, open dialogues, and empathic listening, often did not result in well-received shared decision-making or penetration of fixed, false beliefs.

Problems with healthcare trust and high-quality communication between clinicians and patients are by no means a problem exclusive to the COVID-19 pandemic or UCTs. Extensive literature on clinicianpatient communication points to various strategies that may help clinicians improve their ability to communicate effectively with patients, including attending to relational and identity goals in addition to their task goal within the conversation (Scott and Van Scoy, 2020; Scott, 2022). Doing so can be done by demonstrating empathy, acknowledging different perspectives and identities, building relational rapport over time, and demonstrating genuine interest in patients' lives and concerns (Scott and Van Scoy, 2020).

In addition to these techniques, our data highlights commonalities that may provide additional opportunities to restore therapeutic alliances in the context of UCTs. For example, patients and clinicians described their UCT decision-making through the lens of risk/benefit assessment, although patients assessed ivermectin as 'low risk of side effects' versus 'possibly helping despite uncertain data.' In contrast, clinicians assessed ivermectin as 'ineffective or futile' versus 'some risk of side effects'. Even so, clinicians appraised prescribing ivermectin as potentially beneficial for establishing rapport and trust, both of which are known to improve health outcomes (Lee and Lin, 2009; Chandra et al., 2018), leading clinicians to question whether it was ethically appropriate to prescribe ivermectin to leverage this benefit in a community plagued by distrust and skepticism. In some cases, doing so could result in a physician losing their medical license, however, it is a practice that clinicians in our study did consider in order to establish trust and therapeutic alliance. Regardless, the ethics of this are complex and beyond the scope of this manuscript, but our findings open the door for consideration of these emerging, controversial questions. Each clinician must decide what their own latitude of acceptance is in terms of whether they are willing to prescribe UCTs for patients, and, based on that positionality, construct messages accordingly (Table 5). Our data suggest that messages also should invoke patient autonomy and frame options as a clear list of pros/cons (without belaboring the problematic nature of online sources or reciting detailed trials data since patients are likely to align these references with the government or pharmaceutical companies and discount them).

4.1. Limitations

Our findings are not intended to be generalizable (i.e., our sample was small, was predominantly white, and lacked power analysis), as qualitative research is intended to provide deeper understanding of patient and clinician perspectives to generate hypotheses. Since patients were referred to the study by community-based clinicians, it was not feasible to accurately assess decliners, although conservative estimates are that 70 % of participants approached by clinicians agreed to be contacted. Since our consent rate was moderate (47 %) and those with healthcare distrust are less likely to participate in research, selection bias is possible. Nonetheless our sample had high distrust scores and exhibited substantial healthcare distrust in interviews. Our sampling strategy doesn't permit subgroup comparisons nor delineate differences in UCT requests and trust across settings, fields of practice, or intent (treatment versus prophylaxis). Further, our sample included a predominance of female participants which may be significant because female gender is a known predictor of vaccine hesitancy (Aw et al., 2021). Conversely, the clinician sample was predominantly male, which reflects the clinician demographic at the institution. Strengths are that we included both patient and clinician perspectives, had good variability of education level in our patient sample, used mixed methods, and adhered to qualitative rigor guidelines (eMethod 5). Our study offers rare perspectives from a traditionally hard-to-reach and underrepresented group of patients.

Joint Display of Selected Mixed Methods Results.

		Quantitative	Qualitative (summarized)	Interpretation	Sample Messages for Bedside Clinicians
Healthcare Trust	Lack of trust	High levels of distrust on both questionnaires <u>Healthcare distrust</u> 8.0 point difference in healthcare trust for those who were vaccinated ($p = 0.044$)8.5 point difference in healthcare trust for those who requested ivermectin ($p = 0.027$) <u>COVID-19 mistrust</u> 27.5 point difference in COVID-19 mistrust trust for those who were vaccinated ($p < 0.001$)14.0 point difference in healthcare trust for those who requested ivermectin ($p = 0.081$)	Strong patient distrust of government and pharmaceutical companies (<i>Patient Theme 3; Clinician</i> <i>Theme 3</i>) Clinicians find distrust of clinicians and trust of social media frustrating and hurtful (<i>Clinician Theme 1</i>)	Distrust manifests as patients seeking outside information from social media. Government distrust may void clinician trust. Clinicians should distance themselves from government without undermining government or patient-trusted sources. Health messaging strategies for rural areas may be best disseminated by local providers as opposed to government agencies or centralized entities	"It's great that you are considering many options for protecting yourself from COVID-19. I recognize that there is a lot of distrust of the healthcare system, and that's ok, but you can trust that I am not blindly following the government recommendations but rather thinking about this community and your personal health."
	Trust	Only 23.1 % of participants endorsed the item "When it comes to COVID-19, people cannot trust health care providers" compared with 73.1 % who endorsed items related to government hiding information about COVID-19	Patients have inherent trust in local healthcare (Patient Theme 4, Clinician Theme 3)		
Informationa	l Sources	Not measured quantitatively	Patients use a haphazard approach to research (<i>Patient Theme 2</i>) Patients strongly value personal stories and anecdotes as information sources for COVID-19 (<i>Patient Theme 1</i>) Clinicians spend considerable time focused on education about ivermectin and UCTs (<i>Clinican Theme 5</i>)	Patients feel strongly about their autonomy and their right to seek out information from sources they trust (online information, anecdotes, personal stories) Clinicians struggle to understand or appreciate the patient trust in social media sources	There's a lot of places you can get information about COVID-19, and some of them are not as trustworthy as others, so I'm glad that we're talking about this. I've look at a lot of this ifmomation online, and also heard my patients' personal experiences with COVID. I've also done my own independent review of the medical research, so I'm basing my recommendations based on my own judgment from those sources. My recommendation comes from me, and is not necessarily related to government regulations.
Decision-making		Not measured quantitatively	Patients make decisions by weighing pros and cons (<i>Patient Theme 5</i>) Patients value their autonomy and right to try ivermectin (<i>Patient Theme 7</i>) Clinicians are generally accepting of community beliefs about ivermectin (<i>Clinician Theme 2</i>) Clinicians are torn about using ivermectin or UCTs to help build trust and rapport (<i>Clinician Theme 4</i>)	Messages should invoking patient autonomy and framing options as a simple list of pros and cons. It is likely counterproductive to extenstively focus on the problematic nature of online sources for patinets who find them credible Some patients are likely to discount data and trials as aligned with the government or pharmaceutical companies and immediately discount them, so alternative messaging approaches may be beneficial. There is at least some potential benefit of prescribing ivermectin as establishing trust and rapport, although ethically complex and not recommended by guidelines	I completely respect your right to make your own decisions and I think a good approach would be for us to outline the pros and cons of taking ivermeetin; and after reviewing this together, if your choice is to take ivermeetin, we can talk about what next steps might look like. I personally don't feel comfortable prescribing this because it is unproven, but I can understand your reasons and respect your convictions. So, if that is a path you want to take, I'll support you and continue to be your doctor and be here for you in whatever decisions you make going forward. But

5. Conclusion

The COVID-19 pandemic has introduced new challenges to the therapeutic alliance as patients are more distrustful of government healthcare sources and increasingly rely on personal experiences, an ecdotes, and online information. Clinicians are faced with significant communication challenges when counseling patients about UCTs, including ivermectin. Good communication may not always reconcile debates about ivermectin requests, but our data suggest that clinicians should leverage inherent trust in local healthcare, distance their recommendations from government agencies, and attend to patients' autonomy to facilitate trusting relationships with patients for improved shared decision-making. Our study raises interesting questions about the appropriateness of acquiescing to patient beliefs and requests for ivermectin for the benefit of building trust and compliance with higherstakes decisions.

6. Key points

Question. What are the perspectives of patients and providers regarding requests for unproven COVID-19 therapies (e.g. ivermectin)? How do these requests affect healthcare distrust?

Findings. Patients expressed substantial government distrust, trust in local providers, haphazard online research strategies, and reliance on personal anecdotes as 'data'. Both patients and clinicians appraised ivermectin using risk/benefit analyses, yet through different lenses.

Meaning. Bedside clinicians should construct messages to distance themselves from distrusted sources (e.g., government) without overtly undermining them. Dismissing patients' trusted sources (e.g., social media) may further disrupt the therapeutic alliance. Questions remain about the appropriateness of prescribing ivermectin to build trust.

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CRediT authorship contribution statement

Lauren J. Van Scoy: Conceptualization, Methodology, Software, Validation, Formal analysis, Resources, Data curation, Writing - original draft, Writing - review & editing, Visualization, Supervision, Funding acquisition. Sarah H. Duda: Methodology, Software, Validation, Formal analysis, Investigation, Data curation, Writing - review & editing, Visualization. Allison M. Scott: Methodology, Validation, Writing review & editing, Visualization. Arian Baker: Investigation, Resources, Writing - review & editing, Visualization, Project administration. Heather Costigan: Methodology, Software, Validation, Formal analysis, Investigation, Data curation, Writing - review & editing, Visualization, Project administration. Morgan Loeffler: Methodology, Software, Validation, Formal analysis, Investigation, Data curation, Writing - review & editing, Visualization, Project administration. Michael S. Sherman: Conceptualization, Methodology, Writing - review & editing. Michael D. Brown: Conceptualization, Investigation, Resources, Writing - review & editing, Visualization, Supervision, Funding acquisition.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2022.102104.

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