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ORIGINAL PAPER

Formative Research on Knowledge and Preferences for Stool-based Tests compared to Colonoscopy: What Patients and Providers Think

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Abstract

The rates of colorectal cancer (CRC) screening in the U.S. remain below national targets, so many people at risk are not being screened. The objective of this qualitative research project was to assess patient and provider knowledge and preferences about CRC screening modalities and specifically the use of the fecal immunochemical test (FIT) as a first line screening choice. Nine focus groups were conducted with a medically underserved patient population and qualitative interviews were administered to their medical providers. Thematic analysis was used to synthesize key findings. Both providers and patients thought that the FIT would be a good option for CRC screening both as an individual choice and for an overall program approach. The test is less expensive and therefore more readily available for patients compared to colonoscopy. Overall, there was consensus that the FIT offers a reasonably priced, simple approach to CRC screening which has broad appeal to both providers and patients. Concerns identified by patients and providers included the possibility of false positives with the FIT which could be caused by test contamination or failing to perform the test properly. Patients also described feelings of disgust toward performing the FIT and difficulties in following the instructions. Study findings indicate provider and patient support for using the FIT for CRC screening at both the individual and system-wide levels of implementation. While barriers to the use of the FIT were listed, benefits of using the FIT were perceived as positive motivators to engage previously unscreened and uninsured or under-insured individuals in CRC screening.

Keywords Colorectal cancer · Early detection of cancer · Fecal immunochemical test · Colonoscopy · Medically underserved

Introduction

Colorectal cancer (CRC) is the second leading cause of cancer death in the United States with over 50,000 deaths estimated in 2018 [1]. In South Carolina, the disease is estimated to be diagnosed in 2410 people in 2018, with approximately 860 deaths

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from the disease [1]. CRC deaths can be reduced through effective screening programs which help to identify cancers at an earlier, more treatable stage. The U.S. Preventive Services Task Force has recently updated their screening recommendations to include screening for average risk, asymptomatic patients using a multitude of different screening strategies, including: direct visualization (e.g., colonoscopy); or stool-based fecal immunochemical test, known as FIT or FIT-DNA (U.S. Preventive Services Task Force et al. [2]). A recent article updating CRC screening recommendations from the U.S. Multi-Society Task Force of Colorectal Cancer identifies both colonoscopy every 10 years and annual FIT as first-tier tests [3].

Although colonoscopy has the highest sensitivity and specificity of CRC screening modalities, the cost per procedure is high, preparation is sometimes difficult, and health services capacity is insufficient to screen all at-risk patients [3]. A recent large pragmatic clinical trial demonstrated that outreach for scheduling a colonoscopy or returning a mailed FIT increased the proportion of screening completion for those patients who had not participated in screening in over 3 years [4]. Some patients will forego CRC screening if colonoscopy is the only choice available to them. If patients were more informed about the known benefits of other modalities of evidence-based CRC screening, which includes stool-based tests such as the FIT and the fecal occult blood test (FOBT), they might be more likely to receive screening [5]. A clinical trial conducted in a safety net system in Texas reported higher screening participation for FIT compared to colonoscopy outreach in a medically underserved population [6]. Therefore, FIT outreach is one potentially effective strategy to reach a larger number of medically underserved individuals in states such as South Carolina, which has a higher proportion of uninsured residents (9%) and higher cancer death rates (174 per 100,000) than many other U.S. states [7]. However, patient perceptions are not the only barrier to CRC screening.

While patients are apprehensive about undergoing a colonoscopy and may prefer a less invasive screening modality, some providers hold negative attitudes toward the FIT and have a misconception that colonoscopy should always be recommended over the FIT, despite a lack of data or evidence to support these beliefs [8]. Therefore, in some patient-provider interactions, a tension may exist between provider and patient beliefs, preferences, and perceptions about screening for this preventable cancer.

CRC screening has lower screening adherence rates among the general population than other evidence-based cancer screening tests (e.g., breast and cervical). Further, uncertainty exists about patient preferences for stool-based tests and ways to enhance screening uptake in underserved populations in which barriers to care, such as health literacy, are more prevalent. However, there are strong evidence-based methods to increase colorectal cancer screening with stool-based tests including client reminders (e.g., postcards or telephone messages), small media (e.g., videos and brochures), and reducing structural barriers (e.g., offering translation services and increasing convenient hours of operation) [9].

The objective of this qualitative research project was to assess patient and provider knowledge and preferences about CRC screening modalities and, specifically, the use of the FIT as a first line screening choice. Results can inform our understanding of what type of education and other materials might be needed to support both patient preferences and satisfy provider needs when choosing a CRC screening modality.

Methods

This project was conducted in coastal South Carolina among a medically underserved patient population seen in safety net health care clinics and medical providers who served them. Data collection included key informant interviews with seven individual medical providers and one administrator, collectively referred to as providers, and nine focus group discussions with 36 male and female patients of the free clinics. All providers interviewed either worked in or volunteered at the free medical clinics. Focus groups were drawn from a racially diverse, medically underserved patient population attending the free clinics. The study protocol was submitted to and approved by the Institutional Review Board (IRB) at the Medical University of South Carolina in 2014. Participants agreed to participate in the research via verbal informed consent prior to the interviews or focus groups. Interview participants were read an introductory script prior to the interview, and focus group participants received a participant informational letter describing the study. Participant characteristics from the interviews and focus groups are described in Tables 1 and 2.

Recruitment and Interview Procedures

Providers were recruited over the phone, in person, or through email, and were interviewed either over the phone or in person. Interviews lasted approximately 15 min regardless of modality. Questions asked about familiarity with, and usage of, the FIT or other FOBT products, opinions regarding potential use of the FIT with average risk patients,

Table 1 Details of providers participating in qualitative interviews

Sex	Position/role	Type of practice	Number
Female	Family practice physician	Free medical clinic	2
Female	Administrator	Free medical clinic	1
Female	Nurse or nurse practitioner	Free medical clinic	3
Male	Retired Surgeon	Free medical clinic	1
Male	Gastroenterologist	Private practice	1

Provider $N = 8$; Sites = 4

Table 2 Focus group participant demographics

Variable	n (%)
Gender	
Male	8 (22)
Female	28 (88)
Race/ethnicity	
White	6 (17)
African American	28 (78)
Hispanic	2 (5)
History of colonoscopy	
Yes	6 (17)
No	30 (83)

N = 36. African American participants were between the ages of 45 and 64, and White and Hispanic participants were between the ages of 50 and 64 to align with the age for initiating screening according to the American Gastroenterological Association [10]

perceptions of patient advantages and disadvantages of FIT usage, perceived willingness of patients to be tested using FIT and adherence expectations regarding annual testing, and suggestions of how FIT testing could best be implemented statewide for average risk populations.

Focus group participants were recruited through convenience sampling from two free medical clinics. All focus groups were facilitated at one of the free clinics. Six (17%) participants reported a history of colonoscopy screening. Focus group participants of mixed genders and race/ethnicity categories were moderated by an experienced facilitator for between 30 and 90 min. Questions were posed to participants to understand whether the FIT was an effective screening modality, if there was a preference for a specific FIT, and whether they thought any specific educational instructions were needed to participate in a FIT program. Participants examined the FIT kit from Polymedco, Inc. (OC-Light® S FIT), and the clinics used this brand of FIT kit in the project. The focus group script included questions concerning patient awareness of, and experience with, CRC testing methods and barriers to getting screened, likes/dislikes/suggested changes to the FIT kit as presented to them, identification of populations that might respond well or negatively to the FIT, effective processes for distributing the FIT kit and returning the sample for analysis, and best ways to receive test results. Notes were taken at each focus group to supplement recorded data and assist the transcriptionist with identifying speaker order. All individual interviews and focus group discussions were audio-recorded and transcribed.

Data Analysis

The project team developed a codebook to capture the primary codes emerging from the data using content analysis techniques. Data from focus group notes and transcriptions of digital recordings of provider interviews and patient focus groups were analyzed using content analysis methods for systematic theme identification [11, 12]. Codebooks were developed by reading and rereading all transcripts and outlining and organizing the key themes addressed by participants as they related to the project purpose and script question topics. In addition to the transcripts, notes from the focus groups were matched to the focus group transcripts as a data check to ensure that the most salient information was captured in the transcripts. Data were also analyzed from different perspectives depending on whether comments came from the provider or patient perspectives, for example, expecting more medically accurate information about screening recommendations in the provider responses. The codebook and comparison tables of themes became templates for the more formal analysis of the transcripts to examine patient and provider data. A template style of analysis was used [13]. Two detailed findings comparison tables were constructed—one for health care providers and one for patients [14].

Results

Overlap in the repeating patterns (i.e., subthemes) between the results of the providers and patients was found as well as unique responses in different categories of participants. Therefore, the "Results" section is structured to first present the results of the provider interviews and next to report the results of the focus group discussions with patients by thematic category. Representative statement summaries to illustrate themes are reported in Table 3. Similarities and differences between the two groups of participants are noted in both the "Results" and "Discussion" sections.

Providers

Demographics

The medical providers from the free clinics included three physicians (one male, two female), three nurses (all female), and a medical assistant (female). One local gastroenterologist (male) from a small private practice was also interviewed who had participated in CRC screening programs directed at medically underserved populations.

Familiarity With and Usage of the FIT

While providers were familiar with the FIT, only two of them used a stool-based test (FIT or FOBT) as a routine part of their practice, which they opted for when the patient refused colonoscopy or when placing the patient under anesthesia would be risky. A reason for not using the stool-based test mentioned by one provider was, "at a free clinic, you can't do much if there is a positive finding from this kind of test."

Table 3 Key themes and summary statements

Themes	Statement summaries (patient or provider)
Knowledge of CRC screening	
Screening guidelines	• Colonoscopy every 10 years unless they find polyps, then every 5 years (patient) • Once a year or every 4–5 years (patient) • Not familiar with difference between FIT and FOBT (patient)
Barriers to CRC screening	
Insurance	• Having insurance or knowing I could get it without insurance (patient)
Fear	• Fear of invasive test and what other people tell you about it (patient) • Fear of what they will find (patient) • Not knowing how it is done (patient)
Access	• Don't know how to get it, lack of transportation (patient)
Technical aspects of FIT administration	
Sampling process	• More opportunity for contamination (patient) • Disgusted by the process and putting it in the mail (patient) • Should provide globes with the kit (patient) • May be a problem to sample it before it touches water (patient)
Instructions	• Instructions don't say "wrap tube in tissue and put in bio-hazard bag for mailing" (patient) • Add instructions in Spanish (patient) • Hard to read label with bad eyesight or write on it with tremors (patient) • Include a phone number or website for people who have questions or did not receive the results as expected (patient)
Barriers to FIT administration and receiving test results	
Mail procedures	• Worrying about whether the mail was tampered with or that the results might get mixed up (patient)
Wait time	• Having to wait for the results is stressful (patient)
Test administration preferences	• Some would prefer that the doctor do the testing for them (patient)
Communication	• Get the results in a doctor's office where I am not alone and can get an explanation of what to expect next (patient) • Both mail and phone to make sure I get the results (patient) • Meaning of word "negative" screening outcome should be explained (patient)
Advantages and disadvantages of FIT	
Expense	• Would make less expensive testing available to more people (provider) • Potential cost and insurance coverage could be a drawback (provider) • It has a low cost (patient)
Referral	• Helps as a referral mechanism if we need to refer for sigmoid- or colonoscopy (provider)
Privacy	• Patient does not have to go to a gastroenterologist (provider) • Can do it in the privacy of your home and not intrusive (patient) • Some would prefer to take it to the doctor's office (patient)
Convenience	• No preparation involved like colonoscopy (provider) • Good, simple, and easy (patient)
Safety	• Avoids possibility of tears in the colon (patient)
Reliability	• Chance of a false positive, anxiety if blood is found in the stool that may be hemorrhoidal bleeding (provider)
CRC screening education preferences	
Provider preferences	• Provider or nurse explains the kit and steps needed, stresses ease of use and the need to return the kit quickly (patient) • Provide patient information on importance of CRC screening, and have visual aids such as DVD (patient)
Other influencers	• Well-known media figures pushing FIT (patient) • Family members urging you to do it (patient)
Population-based CRC screening and FIT for average risk patients	
Cost-effectiveness	• The concept sounds good (regarding offering FIT statewide) (provider)
Special populations	• A lot of people may need help to do it—disabled, sick, dementia, elderly (patient)
Mail considerations	• Transient populations change addresses too frequently (provider) • Mail might work for more rural populations (provider) • You may just put the mail aside and not do it (patient)
Screening access using FIT	• Usage of FIT would make CRC screening less expensive and increase access (provider)

Usage of FIT for Average Risk Patients

In response to the question about the potential usage of the FIT for average risk patients, providers' responses were positive. Some providers believed it would make CRC screening less expensive and increase access. Another provider said that using FIT could help as a referral mechanism for a colonoscopy. There were some different opinions of the value of FIT: one provider suggested that a colonoscopy was preferable; another provider suggested the FIT was a better test than other stool-based tests like FOBT; and a third provider explained that patients who refused a colonoscopy would be more likely to use FIT. One provider answered, "They would prefer FIT, but a baseline colonoscopy should be done before that and then every 10 years." As far as offering the FIT across South Carolina as a low-cost alternative, most agreed that the approach would be cost-effective, but one provider emphasized that patient education was needed before this alternative was offered. Only one provider believed that potentially offering FIT statewide could be sending the wrong message since colonoscopy was a superior screening test. Another provider believed that cost and insurance coverage for the FIT could be a potential drawback.

Advantages and Disadvantages of FIT

Providers agreed that there were many advantages of the FIT including: patients could complete the test at home and not have to make a separate appointment; there is no preparation involved like a colonoscopy; the test is faster; and the test does not involve any risk of complications. The only negative potential consequence perceived by providers was in the case of a false positive or if someone noticed blood in the stool, which could be the result of a common condition like hemorrhoids and could cause unnecessary anxiety. Providers were also in agreement that most patients would complete a FIT if recommended by their doctor. They mentioned patients would also be motivated to complete a FIT if they were interested in prevention, received education about the importance of screening, trusted in their physician's recommendation, and received a screening prompt or reminder. However, providers also noted that some patients would not want to complete the FIT, and some patients would only complete a screening if they presented with symptoms. It was also mentioned that providers had to remember to order the FIT, send confirmation calls the day the test should be done, and be aware that the FIT might be a more convenient and affordable option for their uninsured or low socioeconomic status patients.

Population-Based CRC Screening

Providers were also asked what they considered to be the best method for administering the FIT to large numbers of people. They mentioned that some of their patients changed addresses frequently, so mail might not be the most efficient approach and that even after mailing the FIT, someone in their office would need to follow through with the patient. The mail delivery method was viewed as potentially effective for their more rural patients. Providers also discussed that in-person recruitment and explanation of the FIT would be important to increase adherence to this screening modality.

To summarize, the providers were generally open to the use of FIT based screening within the free medical clinic setting but several possible barriers to implementation were noted including health service delivery issues (e.g., burden on clinical staff, tracking patients, lack of insurance for follow-up) and other patient related barriers (e.g., need for education, patient's internal motivation).

Patients

Demographics

Nine focus groups were held with 36 participants ages 45–64; twenty-eight of whom were women and eight were men. Participants self-identified as African American ($n=28$), non-Hispanic White ($n=6$), and Hispanic ($n=2$). Four of nine focus groups had at least five participants. Six of the 36 participants had undergone a previous colonoscopy.

Knowledge of CRC Screening

Patients in all discussion groups acknowledged that early detection was important for cancer prevention, but also said they were not very knowledgeable about CRC or CRC screening. At least 17 individuals across eight focus groups had heard of colonoscopy, but only one person had ever heard of sigmoidoscopy. About half of all focus group participants had heard of the stool-based test, but many participants were not familiar with the terminology to refer to these tests—FIT or FOBT. Participants in five focus groups had heard that there was a 10-year interval for screening with a colonoscopy which was shortened to every 5 years in the case of polyp detection.

Barriers to CRC Screening

Participants listed several common barriers to receiving CRC screening including: lack of health insurance and cost; fear of an invasive test; fear of a positive diagnosis; and lack of knowledge about the procedure. Other barriers not listed as frequently included complications from the screening

procedure, not needing to be screened due to lack of family history or positive view of one's health status, and not knowing where to receive screening. One participant mentioned that there was the belief in the Hispanic community that the screening was unnecessary.

Technical Aspects of FIT Administration

In terms of the technical considerations of reading the instructions and being able to complete the FIT, participants commented that the pictorial instructions were self-explanatory and simple, and they liked the packaging and method for stool sample collection. Participants disliked some of the written instructions, which were viewed as too complicated, especially regarding specific instructions for distinguishing collection papers and packing and labeling instructions. One participant noted, "you don't have to touch the smear." In addition, participants across three focus groups recommended that instructions include a phone number or website for patients who had questions or did not receive their results as expected. One participant noted that instructions were not provided in Spanish.

Barriers to FIT Administration and Receiving Test Results

In eight focus groups, participant perceptions of general, though not necessarily their own reasons for not doing the FIT at home, included procrastination, laziness, forgetfulness, and lack of interest in health care. Other common barriers listed in six focus groups included having physical or mental disabilities and being elderly. In four focus groups it was mentioned that doing the FIT in the doctor's office would be preferable. Reasons for not returning the test included forgetfulness, procrastination, or laziness, as well as embarrassment about the package contents.

Participants had varied opinions about receiving their test results from the FIT. Many participants explained that a letter was sufficient but the meaning of the word "negative" as the screening outcome should be explained. Other participants indicated a preference for a phone call, while others wanted both a letter and a call. Many participants said they would prefer to be notified of a positive result in a doctor's office so they could receive some explanation about what would happen next. In one focus group, a participant said patients should have the option to bring a family member to the follow-up appointment and be offered an opportunity to be retested. If the patient received a negative result, participants wanted information about when their next test would be, some information about CRC prevention, a phone number for whom to call for more information, and a referral card to recommend a friend or family member get screened.

Advantages and Disadvantages of FIT

Focus group participants discussed some topics that were not directly asked about in the focus group guide. Some of these discussions paralleled responses from the provider interviews. For example, the advantages of the FIT were similar, such as being able to complete the FIT in one's home, the ease of completing it compared to a colonoscopy, and the low cost of the test. Some perceived disadvantages included quality control issues for completing the test such as preventing contamination of the specimen, the feeling of disgust from having to put feces in an envelope, the need to use gloves—which were not provided with the kit—and worry associated with the mailing procedure and with waiting for results to be returned. For example, one participant commented, "It may be a problem to sample it before it touches water." Across most groups, there was a positive attitude toward using the FIT, and the ease of completing the procedure. In about half the focus groups, participants expressed that doing the test once a year—which only took 5 min—was an easy way to "keep up with your health." It was acknowledged however that there were groups of people—the homeless, disabled, sick, and elderly—who would need help to complete the FIT. Among a smaller number of groups, participants said that they would prefer a doctor performing the stool-based test rather than having to do it at home.

CRC Screening Education Preferences

When asked about the delivery of CRC screening education, participants in eight focus groups preferred a provider or a nurse explain the kit and the steps needed to perform the test, as well as best practices for returning the sample. Some participants believed that a video would help patients understand the process better, using spokespersons such as a celebrity or a prominent person in the community. Participants also wanted clear information about how accurate the FIT was compared to a colonoscopy. Importantly, participants wanted to know how long it would take to receive their results. Participants also wanted to know and understand why screening was important and hear from fellow community members about their experiences. In a few focus groups, participants expressed that a lighter approach using humor could help to overcome embarrassment about the FIT. In terms of availability, participants wanted assurance that they could have access to the FIT without insurance, or possibly have it available in a pharmacy as an affordable self-test kit.

Population-Based CRC Screening

In response to the question about the optimum method for reaching a wider population, participants agreed that the

best outreach method was to first receive a phone call and then receive the FIT in the mail. In contrast to the provider interviews, in one focus group, it was mentioned that living in a rural area could actually be a barrier for the mail delivery method. However, there was not a strong preference for receiving the FIT in the mail compared to receiving the FIT in the doctor's office.

Overall, the FIT screening option was viewed positively by most patients. Many potential barriers mentioned by patients were similar to those mentioned by providers. Most commonly, patients stressed the need for patient education (e.g., descriptions of how to use the test, why the screening test was needed, how it compared to other screening tests) and how to navigate the health care system, especially if the test was positive.

Discussion

Providers and patients thought that the FIT would be a good option for CRC screening for an overall program approach. The test is less expensive and therefore more readily available for patients compared to colonoscopy. There was consensus that having the FIT as an option was appropriate, especially for those who showed no interest in colonoscopy. Many providers and patients agreed that the convenience of the FIT was a great advantage; it is completed at home, simple to complete (e.g., requires no dietary restrictions, no preparation, no immediate medical risk, no sedation, no perforation from scoping) and is low cost. Overall, there was consensus that the FIT offered a reasonably priced, simple approach to CRC screening which has broad appeal to both providers and patients. Concerns identified by patients and providers included the possibility of false positives with the FIT (caused by bleeding from menstruation or hemorrhoids, test contamination, or failing to perform the test properly).

Addressing Barriers to Implementation

Several issues emerged that could be helpful in promoting and guiding successful implementation of FIT as an option for patients. First, both medical providers and patients agreed that a system needed to be in place to provide education and patient support services throughout the screening process, for both stool-based tests and colonoscopies. Some uncertainty on behalf of the medical providers existed about how to meet increased demands for both education and health services, especially within the context of a busy, free medical clinic practice with an often transient and impoverished patient population with low literacy.

Patient and provider education as part of a FIT screening program should focus on informing patients about the importance of CRC screening in general, the different types of screening modalities, and the specifics associated with completing each recommended screening test [15]. In a clinical trial using an educational intervention, FIT completion rates over 80% were reported in the intervention group, suggesting that the inclusion of targeted materials with the FIT can be an effective strategy to increase CRC screening [16]. However, one concern about the FIT is that patients with an abnormal test will not complete a follow-up colonoscopy. In one study in an urban safety net setting, researchers examined factors to explain a lack of follow-up colonoscopy following an abnormal FIT test result; they reported that while patient-level factors were the most common predictors, provider- and system-level factors also contributed to lack of follow-up [17], suggesting providers and programs can engage in practices to ensure proper comprehension of CRC screening methods and follow-up procedures.

For example, in our previous work within a colonoscopy-based screening program [18], patients were educated about CRC, the benefits of getting screening, how to prepare for a colonoscopy, and how they would receive their test results. Information was provided to patients within the free medical clinics through pamphlets, publicly available videos, and in-person discussions with prevention navigators. There is also evidence from clinical trials that mailing invitations for FIT or colonoscopy are effective methods for increasing screening completion rates in diverse urban populations [4].

Limitations

The applicability and generalizability of these findings are limited by several factors. The sample was small for both patients and providers, not representative of the specific geographic area or the practice sites in the area, and the focus groups included only individuals receiving care in free clinics. The resulting sample is not representative of the general population of either all health care patients in the regions served by these clinics, the broader community of individuals in need of CRC screening, or any other group experiencing a disparity in either CRC screening or CRC mortality or morbidity. Focus group participation was not constructed so that analyses could include findings specific to participants' gender, race or health care home.

Findings from the small number of provider interviews were based on responses to the same set of scripted general interview questions, but additional information was also included in our findings that followed unscripted prompts to elicit clarification or elaboration of responses to the scripted questions. The inclusion of this information, while informative, could have also introduced bias associated with the more open-ended nature of the interview process. Provider interview responses also could have varied by the provider's work role (e.g., nurse, physician, administrator),

but the sample was too small to confirm any differences in findings by provider role.

Conclusion

Study findings indicate both provider and patient support for using the FIT for CRC screening at both the individual and system-wide levels of implementation. While barriers to the use of the FIT were cited, benefits of using the FIT were perceived as positive motivators to engage previously unscreened and uninsured or under-insured individuals in CRC screening. Additional resources identified to support CRC screening participation included both patient and provider education and provision of support services such as calls, reminders, and navigation to assure timely and accurate participation in CRC screening via the FIT. Additional research is needed to understand specific access barriers, educational and support needs, technological advances in FIT screening including new products (e.g., Cologuard®), and patient preferences and accommodation for them in practices.

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Compliance with Ethical Standards

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

Ethical Approval This study was reviewed, approved, and continuously overseen by the Institutional Review Board at the Medical University of South Carolina. 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.

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