A QUALITATIVE EXPLORATION OF HEALTHCARE WORKERS' PERSPECTIVES ON AND EXPERIENCES WITH COLORECTAL CANCER SCREENING IN THE WESTERN AND EASTERN CAPE

by

ALEXANDRA PAYNE
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UCT plagiarism declaration

DECLARATION

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A qualitative exploration of healthcare workers' perspectives on and experiences with colorectal cancer screening in the Western and Eastern Cape

Abstract

Background

In South Africa (SA), colorectal cancer (CRC) incidence and mortality is growing at an alarming rate. CRC is often diagnosed at an advanced stage in SA with a noted increase in younger diagnoses and poor outcomes. However, CRC screening and specifically faecal immunochemical testing (FIT) is not currently offered in the public healthcare sector in SA. Before implementing any sort of screening test, it is important to address health system related factors that are specific to the South African context to better understand the potential feasibility and acceptability of a screening test. To establish a foundation for the potential implementation of a FIT screening program, this qualitative study aimed to explore primary and secondary healthcare workers' perceptions of CRC screening.

Materials and Methods

The PRECEDE portion of the PRECEDE-PROCEED model, which identifies predisposing (intrapersonal), reinforcing (interpersonal) and enabling (structural) constructs within the context of health behaviours, served as the theoretical framework for this study. Eight healthcare providers (*n=6* physicians and *n=2* nurses) practicing in both the Western and Eastern Cape were convenience sampled to participate in semi-structured qualitative interviews. Interviews were analysed using thematic analysis guided by the model.

Results

Perceived barriers to CRC screening were identified as socioeconomic status, work status and personal discomfort with tests (predisposing); geographical challenges and healthcare worker related factors (reinforcing); and pathology lab services, high test costs, lack of proper ablutions, and lack of clinical continuity and communication (enabling). Perceived facilitators were identified as health education (predisposing); primary care physicians' training in CRC risk and testing location (reinforcing); and test affordability, communication across different health systems, and test availability at primary care level (enabling).

Conclusion

This study identifies context specific perceived barriers and facilitators among primary and secondary healthcare workers to CRC screening in South Africa. If CRC FIT screening were to be implemented in SA, relevant policy makers and stakeholders would need to address these perceived barriers across multiple levels.

Key words: qualitative research; colorectal cancer; colorectal cancer screening; Faecal immunochemical test (FIT); primary health care; barriers and facilitators; South Africa; Low- and middle- income countries (LMIC)

Introduction

Colorectal cancer (CRC) is the third most commonly diagnosed cancer (9.6%) and second highest cause of cancer death (9.3%) globally.[1] According to GLOBOCAN 2024 data, South Africa (SA) has an age-standardised incidence rate (ASIR) of 13.5 and an age-standardised mortality rate (ASMR) of 8.9 for CRC.[2] Additionally, the number of new CRC cases in SA is projected to rise from 7,340 in 2022 to 13,300 by 2045.[2] An epidemiological study in SA using National Cancer Registry (NCR) data found that between 2002 and 2014, the overall ASIR and ASMR of CRC in South Africa increased by 2.5% and 1.3%, respectively.[3] Additionally, CRC incidence rates have been steadily rising in countries undergoing major transitions, including those in Sub-Saharan Africa, with South Africa being a notable example.[1] Epidemiological data demonstrates the increasing CRC incidence and mortality rates in South Africa, with projections indicating a significant increase in new cases by 2045, reflecting broader trends seen in transitioning countries across Sub-Saharan Africa. While CRC burden is higher in high income countries compared to low- and middle- income countries (LMIC), it is important to note the gap between incidence and mortality being much smaller in LMIC, indicating a lack of cancer prevention and control interventions, yielding higher mortality rates and poorer outcomes due to a lower rate of early diagnosis.[4] The smaller gap seen between age-standardised incidence rates and age-standardised mortality rates in LMIC indicates later diagnosis and poorer health outcomes, with a smaller age-standardised incidence rate highlighting a lack of adequate population-based screening and therefore lower rates of early detection.[4]

Screening has been shown to have great effect in minimising incidence and mortality for CRC in HIC and is one of the most common preventative measures for CRC in HIC.[4] Polyps form on the colon, which due to a long latency period, can be detected via colonoscopy and removed before becoming cancerous, serving as an ideal candidate for early detection and screening interventions.[5] Colorectal cancer screening tests are broken up into two main categories, stool testing [faecal occult blood tests (FOBT) and faecal immunochemical test (FIT)] and endoscopy-based tests [e.g. flexible sigmoidoscopy and total colonoscopy].[6] While the expense of mounting a mass screening effort in most LMIC is not currently justified given the significant costs of colonoscopy and inadequate implementation of diagnostic and treatment services, there are other potentially more affordable options in terms of screening for CRC in

LMIC.[4] Some evidence suggests that guaiac testing (FOBT) and faecal immunochemical tests (FIT), may be a cost-effective alternative to colonoscopy, and may offer a viable option for controlling the growing burden of CRC.[4] FIT testing has replaced FOBT as a major screening test due to higher sensitivity, specificity and similarly low cost.[7]

With no national or provincial screening policy for CRC in place in the public healthcare system in South Africa, there is a need to better understand the feasibility, availability and acceptability of implementing a potential screening program. An opinion journal article published in South Africa in 2022 addressed the need to assess factors related to the implementation of a potential screening program in SA, most notably to better understand provider related factors such as provider knowledge, education, competency, and recommendation, as well as availability and functionality of equipment.[8] A novel community based cross-sectional study conducted in Nigeria assessed the feasibility of FIT tests as a screening tool in the public health care sector. The study found that FIT within the Nigerian context is feasible and acceptable to average-risk asymptomatic patients; however, with a low positive predictive value and high endoscopy burden investigating false positives suggests that it may not be the most appropriate screening tool in their setting.[9] These findings illuminated the need for country-level and context specific data on the acceptability of FIT screening, and highlights a need for more locally relevant data to address the feasibility of FIT as a screening modality in resource limited settings.[9] A recent qualitative study in Egypt addressed barriers and facilitators to implementing a CRC screening program in the Egyptian cultural context, laying a significant foundation of understanding in a similar LMIC context.[10] Barriers to CRC screening identified in this study included: SES status, limited focus on prevention, fear, financial constraints, the perception that screening is only necessary for high-risk individuals, lack of trust in healthcare providers' ability to conduct and interpret screening tests accurately, high costs, limited test availability and insufficient training for both laboratory technicians and healthcare providers.[10] Facilitators to CRC screening identified in this study included: strategies to improve screening rates (such as media campaigns highlighting early detection, treatability and prevention, education and active involvement, reduction of costs, widespread test availability and enhancing provider training.[10] Researchers in Egypt identified these perceived barriers and facilitators to FIT test implementation, developing foundational knowledge for context specific factors that would facilitate or hinder FIT screening in the Egyptian context.[10]

The overall objective of cancer screening is to apply a relatively simple, affordable test to a specific population group to catch asymptomatic patients early before the disease has progressed.[11] For a screening program to be ethically and successfully implemented, it must be acceptable, equitable, accessible, sustainable in terms of follow-up and continuity of the program over time, and economically efficient for the target population.[12] In the South African context, CRC screening meets many of the Wilson and Jungner classic screening criteria.[13, 14] CRC is a significant public health concern, with increasing incidence rates, particularly in urban populations, making it an important disease for early detection.[2] The natural history of CRC is well understood, with precursor lesions (adenomatous polyps) developing over time, allowing for effective early intervention.[15] FIT testing is a relatively simple, non-invasive, and cost-effective method that has been widely endorsed in high-income countries due to its high sensitivity and specificity compared to guaiac-based FOBT.[7] Additionally, effective treatment options exist for early-stage CRC, improving survival rates when detected early.[16] However, despite these strengths, one of the key gaps in meeting the Wilson and Jungner criteria is the lack of evidence on the acceptability of CRC screening, particularly the use of FIT testing, among the South African population. Previous studies on breast and cervical cancer screening in South Africa have highlighted significant personal and systemic barriers, including low awareness, fear of diagnosis, stigma, and structural healthcare limitations.[17, 18] Similar barriers may affect CRC screening uptake, making research on provider knowledge, patient acceptability and behavioural factors crucial before large-scale implementation.

To establish an empirical basis of understanding about the development of a CRC FIT test screening program in South Africa, this study aimed to explore South African primary and secondary healthcare workers' perspectives on and opinions of FIT testing in the Western and Eastern Cape. In South Africa's public healthcare system, primary care is the first point of care for most patients, provided at local clinics and community health centers; secondary care takes place at district and regional hospitals which manage referrals and have limited specialized services such as internal medicine, general surgery and diagnostic radiology; and tertiary care is delivered at academic and central hospitals, which offers specialized services such as specialized cancer diagnosis and treatment.[19] Understanding public primary healthcare workers' knowledge and attitudes surrounding health education and patient care is essential because most patients in South Africa first enter the public healthcare system via primary care clinics. Secondary

healthcare workers were included due to their knowledge of colonoscopy services and referrals, and their opinions and perspectives about how FIT tests would influence colonoscopy services.

Materials and Methods

Theoretical Framework

The Predisposing, Reinforcing, and Enabling Constructs in Educational/environmental Diagnosis and Evaluation (PRECEDE) – Policy, Regulatory, and Organisational Constructs in Educational and Environmental Development (PROCEED) model served as the theoretical framework for this study, specifically the PRECEDE portion of the model.[10, 20, 21] A similar study run in Egypt used the PRECEED/PROCEED model successfully to evaluate CRC screening implementation and suggests it is a good framework for use in this study.[10] The PRECEDE-PROCEED model consists of two main components: PRECEDE, which focuses on planning, and PROCEED, which addresses implementation and evaluation.[20, 21] The PRECEDE component includes four main phases, (1) social assessment, (2) epidemiological, behavioural, and environmental assessment, (3) education and ecological assessment, and (4) administrative and policy assessment and intervention alignment.[21, 22] The PROCEED component includes another four main phases, (5) implementation, (6) process evaluation, (7) impact evaluation, and (8) outcome evaluation.[21, 22] For the purposes of this study, only the PRECEDE component of the model will be utilized, due to the exploratory planning nature of the aims and objectives of this study, building off previous research done by Brand Bateman et al. in Egypt and adapted for the purposes of this study.[10]

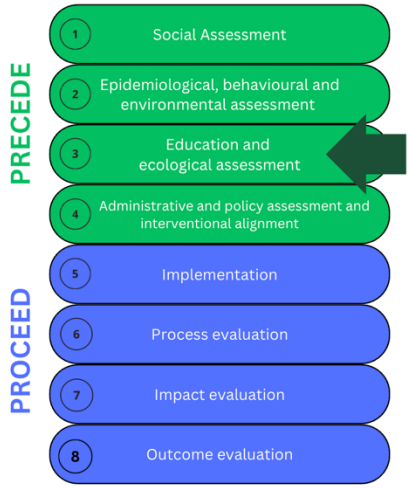


Figure 1: PRECEDE-PROCEED framework phases

This study specifically utilised Phase 3 of the PRECEDE model, the educational and ecological assessment, which urges examination of the broader causal factors behind the social and health issues prioritised in the earlier stages.[10, 20, 21] The phase of the model is organised with predisposing factors including intrapersonal knowledge, such as beliefs that would influence individual behaviours.[10, 21] Reinforcing factors including interpersonal factors such as community or social influences on healthcare decision making.[10, 21] Enabling factors which include structural and organisation factors involved in the individual's engagement in target behaviours.[10, 21] The analysis addressed potential perceived barriers and facilitators for FIT testing organised by predisposing, reinforcing, or enabling factors. This portion of the theoretical framework was utilised for the analysis of the data, where perceived facilitators and barriers to CRC screening were then organised into the three PRECEEDE framework categories: predisposing, reinforcing, and enabling barriers and facilitators.

Study design

This study was an exploratory, descriptive qualitative study that utilised the PRECEED theoretical framework, semi-structured interviews and thematic analysis to explore participants' opinions on and perceptions of FIT testing in the Western and Eastern Cape provinces. This qualitative design was chosen to capture the depth and complexity of participants' theoretical opinions on a screening method that is not yet utilised in the public healthcare sector.

Study setting

The study was conducted among eight healthcare professionals, including physicians and nurses, with six based in the Western Cape and two in the Eastern Cape. Participants worked in diverse geographical settings, ranging from urban areas like Cape Town to peri-urban and semi-rural locations such as Vredenburg, as well as rural regions such as Lusikisiki. Both primary and secondary healthcare workers were included; primary healthcare workers served as the initial point of contact for patients, while secondary healthcare workers managed referred cases at higher levels of care. While the small sample size limits the generalizability of findings to the broader populations of the Western and Eastern Cape, the inclusion of providers from varied

geographical contexts offers important insights into the differing challenges and needs of both healthcare workers and patients across these varied settings.

Sample and Recruitment

The target population was primary and secondary healthcare workers in the Western and Eastern Cape provinces that have some experience with potentially symptomatic CRC patients. A geographical stratified purposive sampling approach was used, with elements of snowball sampling. This sampling approach was chosen to ensure data was obtained from urban, peri-urban, semi-rural and rural catchment areas across both provinces in order to ensure representation across different healthcare contexts in South Africa. This was done with the idea that a diverse geographical sample of practitioners would lend valuable varied insights on their perceptions of screening tests, particularly within the context of their specific areas. Given the specificity of participants to be included in this study, and the nature of recruitment, a homogeneous group sample was the most effective and feasible type of convenience sample to draw for the study. Initial participants were identified with assistance from research collaborators at the Cancer Research Initiative at the University of Cape Town, and a snowball sampling approach was used to identify further participants by asking participants to refer additional participants who met the inclusion criteria and were willing to be interviewed. A smaller sample size was justified as this qualitative study aimed to explore complex, context-dependent experiences around CRC screening; however, given the small sample size, it still contributed to potential study limitations. A smaller sample allowed for an in-depth analysis of individual viewpoints and rich, detailed descriptions, which can reveal nuanced insights that larger samples may overlook, while still reaching sufficient data saturation.[23]

Eight physicians and/or nurses consented to participate in the study. There were no refusals, and no participants removed themselves from the study during the interview. See Table 1 in results section for a breakdown of the participants' demographics.

FIT test

A faecal occult blood test (FOBT) is a test that checks for occult, or hidden, blood in the stool. A small sample of stool is placed in a special collection tube or on a special card and sent to a doctor or laboratory for testing.[24] Blood in the stool may be a sign of colorectal cancer or other problems, such as polyps, ulcers, or hemorrhoids.[24] Guaiac FOBT and faecal immune-chemical test (FIT) are two types of FOBTs. Guaiac FOBT uses a chemical substance called guaiac to check for presence of blood in the stool.[24] Faecal immuno-chemical test (FIT), uses an antibody to check for blood in the stool.[24] For FIT tests, the summary estimated specificity is 94% and sensitivity is 75-85%.[25] For guaiac FOB tests, the specificity is 78% and the sensitivity is 50%.[26] The sensitivity of FIT tests has been proven to be significantly higher for stages 3 and 4 colorectal cancer than for stages 1 and 2 ($p = 0.01$), and is insignificant for the guaiac FOB test ($p = 0.07$).[27] Extensive research recommends FIT over Guaiac FOB because it offers significantly higher sensitivity and specificity while maintaining a similar cost.[25]

Data Collection

Semi-structured interviews were conducted in English by the main investigator, with a focus on both clarification and elaboration of the data during the interview process. As English is the language of work for most healthcare professionals in South Africa, all eligible participants in this study were comfortable with interviews in English. An interview guide was used to frame questions; however, it was concise and used mainly for guiding purposes, which allowed for an evolution of the qualitative data collection as interviews were performed. The semi-structured interview guide was collaboratively developed by the primary researcher with input from their supervisor to ensure a comprehensive exploration of healthcare workers' perceptions and experiences with colorectal cancer screening. The guide was designed to align with the study's qualitative approach, incorporating open-ended questions that allowed participants to share their insights while ensuring key topics were consistently addressed while allowing the researcher to probe further when appropriate. Iterative revisions were made based on discussions between the researcher and supervisor to refine question clarity, relevance, and alignment with the study objectives. Data collection utilised active listening, rapport building, note-taking and audio recording. Most interviews (n=6) were conducted via Microsoft Teams, as participants explicitly requested a preference for virtual interviews due to schedule constraints and an increased

comfort with the virtual method. Other interviews were conducted in-person. Interviews ranged from 20 to 45 minutes long.

Data Analysis

Thematic analysis was used, utilising NVivo 14 qualitative data analysis software for organising themes and codes. Thematic analysis allowed for identification and analysis of patterns of meaning within the data.[28] In employing a thematic content analysis, a five step approach was used in data analysis, (1) immersion in raw data by re-reading post-interview, (2) identification of a thematic framework, (3) indexing and coding, (4) charting, and (5) mapping and interpretation.[28, 29]

All data was transcribed by Way with Words and was read back by the investigator with the recording to ensure accurate transcription. The main investigator read through the transcribed data twice to refamiliarize herself with the data. Overarching themes were then identified, and the data was coded for main themes and sub-themes using NVivo 14 qualitative software. The PRECEDE framework was utilised in the final coding of data, to deductively categorize the codes that arose more inductively from the data.

Researcher reflexivity and rigour

Researcher reflexivity was considered from conceptualisation of the research question continuously through data analysis and write up. For context, I am a public health researcher and student with over six years of experience in both quantitative and qualitative research. I hold a Master's in Psychological Science, with qualitative research experience in psychology and public health. My training in qualitative data methods and analysis spans both fields, gained through master's coursework, training workshops, and practical research experience. My supervisor, A/Prof Knight, an expert in qualitative research, provided guidance on study design, rigor, and reflexivity to ensure the trustworthiness of the methodology. I kept un-focused notes on Microsoft word that I would write in before and after each interview and re-familiarized myself with these notes during the data collection and analysis process. I was consistently aware of my personal opinions surrounding FIT as a CRC screening tool, working as a public health researcher in cancer prevention and control, and made sure to position myself and my questions

to allow respondents to articulate their opinions without my influence in the interviews or data analysis. My perception is that participants seemed more comfortable expressing their opinions and speaking in a detailed free manner when interviews were conducted via Microsoft teams rather than in-person in this study. It seemed to me that the "anonymity" of Microsoft teams allowed interviews to take place at a comfortable time and location and could have played a role. While I am not a clinician, I do work in the public health field, which could have potentially played a role in social desirability bias. Rapport building was essential considering this potential bias, where I assured participants that all interviews were private and confidential. I also reiterated to each participant that the nature of this interview was exploratory in nature, and that I was asking about their opinions in theory, rather than their personal experiences. This rapport building and reiteration minimized the likelihood of participants being hesitant to be honest with their opinions. This was evident by participants' comfort with bringing up "negative" opinions. My positionality as a non-clinician public health researcher allowed me to connect with the participants while still maintaining my position as an observer instead of a peer. Certain questions did seem to prompt more guarded or short answers. Keeping reflexivity in mind, I attempted to probe such questions in a way that was not leading or influencing, keeping questions open-ended and un-opinionated. The scope and resources of this study didn't allow for a second researcher to code the data; however, as the lead researcher, I made sure to constantly reflect in my reflexive notes during each iteration of reading through the data and coding to mitigate as much bias as possible. Reflexivity in this research enhances rigour by fostering transparency about the researcher's positionality and influence on the study, thereby strengthening the credibility and depth of data interpretation.[30, 31]

Ethical considerations

An application for ethical approval was made to the Human Research Ethics Committee (HREC) at the University of Cape Town (UCT) and ethics consent was received on 4 July 2023 [HREC REF 349/2023]. All research performed in this study involving human participants was in accordance with the ethical standards of UCT institutional HREC, Western and Eastern Cape Provincial ethics committees and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Written informed consent was obtained from all individual participants involved in the study.

Results

The results present healthcare providers' perceptions on and experiences with colorectal cancer screening, specifically FIT testing, in the Western and Eastern Cape. Participant characteristics are summarized in Table 1, detailing their professional roles, healthcare settings, and geographical locations.

Table 1: Participant characteristics

ID	**Professional role**	**Location**	**Geographic area (Catchment area distribution)**	**Level of care**	**Years experience (at current place of employment)**
01	Family physician & Senior Lecturer	Vredenberg, Western Cape	Peri-urban, semi-rural, rural	Primary & secondary (hybrid)	10+ years
02	Head of surgery	Mitchell's Plein, Western Cape	Urban	Secondary	8+ years
03	Sigmoidoscope nurses (small-group interview)	Cape Town, Western Cape	Urban	Secondary	Collectively, 5-11+ years
04	General Practitioner, Family Physician	Observatory, Western Cape	Urban	Primary	10+ years
05	GI surgeon	Cape Town, Western Cape	Urban	Secondary	9+ years
06	Family physician, Primary Care physician (expert)	Cape Town, Western Cape	Urban	Primary	16+ years
07	Surgical and oncology clinic nurse	Lusikisiki, Eastern Cape	Semi-rural, rural	Secondary	8+ years

08	Family physician, Head of Family Medicine discipline in the EC	Mthatha, Eastern Cape	Peri-urban, semi-rural, rural	Primary & secondary (hybrid)	10

Data analysis revealed sub-themes, which were divided into three pre-determined categories (predisposing, reinforcing and enabling) across two overarching groups (barriers and facilitators) based on the PRECEED model. See figure 1 for this visual breakdown.

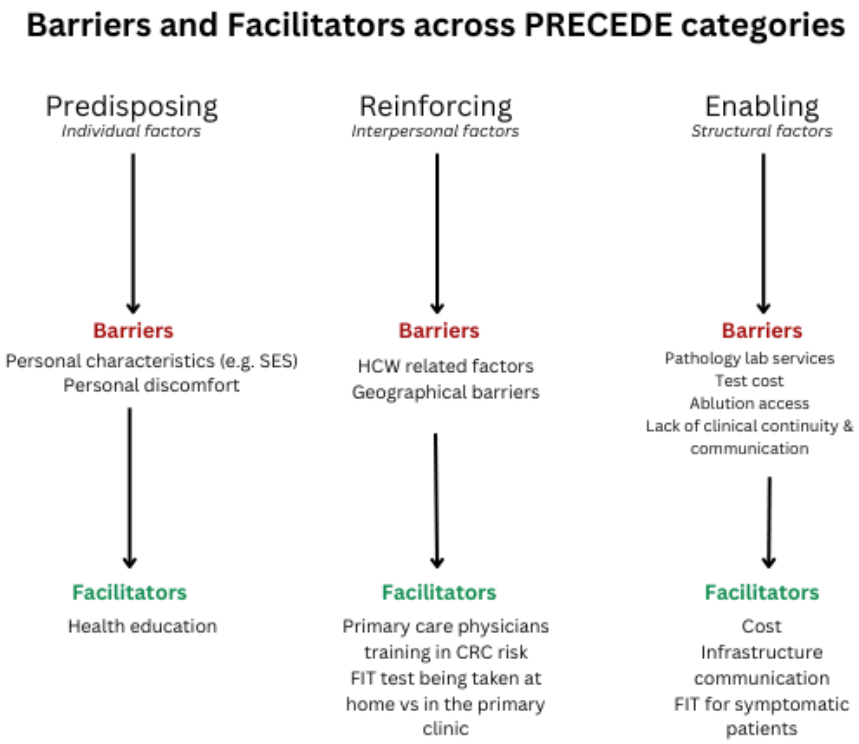


Figure 2: Sub-themes across the PRECEDE categories and barriers/facilitators groups

Predisposing (intrapersonal) barriers

Predisposing barriers are categorised by the theoretical framework as perceived barriers at the intrapersonal or individual level, for example: beliefs that would influence individual behaviours. Results are organised by sub-theme for each category and group.

Personal characteristics

Most providers noted different demographic factors as being potential barriers at the intrapersonal level. Socioeconomic status and work status were often perceived as potential barriers for successful FIT test screening. One provider noted:

> *...people have barriers to accessing care, because if they don't have a job, it costs. If they do have a job, there is not only the cost of going to hospital, but there's the cost of loss of income for the day that they're unable to work. And so I anticipate this being a barrier in our area. (ID01, Primary & secondary care physician, Vredenberg, WC)*

Another provider also stated that:

> *It's the same thing we're concerned about with following up all our patients. They struggle to access even the most accessible healthcare systems because of things like getting off work, getting transport. (ID06, Primary care physician, Cape Town, WC)*

High personal cost for follow-up appointments as a barrier was brought up by most participants.

Providers had varied opinions on FIT acceptability for men versus women. While some providers noted that they did not anticipate gender differences in test acceptability others felt that men tend to be more difficult to manage in terms of health seeking behaviours and willingness to participant in uncomfortable tests. Health care workers perceived gender differences in test acceptability and health seeking behaviours:

> *I think women are always more proactive when it comes to their health. Men generally are going to wait until it's too late, and then the FIT test is useless because they need to have some type of more serious intervention. It's unfortunate, but it's been shown in almost all our other diseases that we manage in primary care, that women are way more forthcoming, looking for diagnoses and submitting themselves to screening tests. (ID06, Primary care physician, Cape Town, WC)*

...yes, it's really that the perceptions they differ with the gender. You know that the males they are always difficult to deal with. But it depends on the skills and the expertise of the clinician that is dealing with them (ID07, Secondary care nurse, Lusikisiki, EC)

Socioeconomic status, work status, personal cost for medical services, and gender differences were also reported as potential demographic barriers by providers.

Personal discomfort

A perceived barrier to FIT testing was that it requires a stool sample, which some patients may find personally uncomfortable to collect. Providers reported:

I know that doing the examination in the first place, some people won't do. So, that could be the barriers that people are not wanting to do it anyway. (ID04, Primary care physician, Cape Town, WC)

However, there were varying perceptions among providers on personal discomfort and acceptability of the test as a barrier, with some providers anticipating patients lack of personal discomfort:

Look, in primary care, we get patients to give us samples all the time. So, it's gunky phlegm and all sorts of things. So, I think if they understood the importance of the test, it would not be a major issue. We generally don't have a queasy patient population in our underserved areas. Generally, not. I don't want to stereotype, but that's been my experience. When we've asked for stool samples, they're forthcoming. We've asked for all sorts of samples. They're forthcoming. So no, I don't think procuring the specimen would be a major problem. (ID06, Primary physician, Cape Town, WC)

Given the nature of FIT tests requiring a stool sample from the patient, personal discomfort with providing the sample or being given the test was reported by a few providers as a perceived barrier. However, providers generally had mixed perceptions on personal discomfort as a barrier,

with some providers arguing that the stool sample would not act as a barrier for FIT testing among their patient populations.

Reinforcing (interpersonal) barriers

Reinforcing, or interpersonal, barriers to CRC screening are factors related to community or social structures, such as family, friends, healthcare workers, or community members.

Healthcare worker related factors

Common perceived reinforcing barriers in terms of CRC cancer at the healthcare worker level in this study were healthcare workers' clinical decision making and healthcare workers' reluctance to use the test. Providers reported that:

> *Most of our younger personnel might not do it [FIT testing], because we have a lot of young community service doctors without so much experience. Because the tests, what you order for the patient, depend on your clinical suspicion, and clinical judgement. And that depends on your year of experience, and what you think is wrong with the patient. (ID08, Primary & secondary care physician, Mthatha, EC)*

Individual providers' clinical experience and their index of suspicion or ability to assess risk or symptoms as serious, were reported among providers as a potential barrier to FIT test implementation:

> *The challenge would be the clinician having a good index of suspicion that this could be a colorectal thing, and requesting the test. (ID08, Primary & secondary care physician, Mthatha, EC)*

Another perceived barrier was anticipation of other providers' reluctance to use the test in their settings:

So, it's like, if I potentially see this patient for 15 minutes, three or four times a year, what are the things I need to engage with this person about? And a very real thing, you literally have one hour per year per patient, and then you need to ask, how do I prioritize that my work within that one hour? (ID05, Secondary care physician, Cape Town, WC)

Some providers expressed competing health priorities as a perceived barrier. That in their opinion, CRC does not take precedence over more common chronic diseases such as diabetes and hypertension at the primary care level in resource limited settings:

Yes, but also, yes, cancer's part of non-communicable diseases, but what's the overwhelming majority of non-communicable diseases that are killing people? It's hypertension and diabetes. And those are so common and so overwhelming that, yes, cancer, it's important, but it's such a small percentage of the population, that if we could just get stuff right with hypertension, HIV, and TB and diabetes, trauma, we would be happy (ID01, Primary care physician, Vredenberg, WC)

Others did note that it is still important to identify symptomatic patients as potentially cancerous.

Geographical barriers

Geographical factors and transportation were also identified by providers as perceived barriers for FIT testing and screening, especially for those who provide health services for patients in rural and semi-rural areas. One participant in a semi-rural area of the Western Cape noted that:

it seems like it is not an uncommon complaint from patients to say, the transport didn't pick me up, or there was some issue with transport. And so accessing care has geographical implications as well (ID01, Primary care physician, Vredenberg, WC)

Similar geographical barriers were acknowledged in the rural Eastern Cape (EC) as well, with one EC provider stating:

…in the rural areas, just to go on with that, in the rural setting, most people come from… Transportation is not easy. The roads are a big challenge. So, to go home and come back the next day might not be a good option for some patients. (ID08, Primary care physician, Mthatha, EC)

Transportation costs also play into this observed geographical barrier, with high transportation costs for rural and semi-rural patients:

And they are often followed up at secondary and tertiary level just because that's how it's always been done, although that obviously places a massive cost burden on the patient in terms of getting from here to there just for the screening tests (ID01, Primary care physician, Vredenberg, WC)

Given that the FIT testing requires a stool sample being taken, it may require multiple healthcare visits, each of which involve transportation. Geographical location is seen as a barrier due to limited accessibility to healthcare facilities, especially for patients in rural or semi-rural areas where distance and transportation infrastructure are challenging.

Enabling barriers

Enabling barriers are barriers perceived by providers at the structural or organisational level.

Pathology lab services

Most participants noted pathology and laboratory services as being an observed structural barrier for FIT test implementation. One provider brought up a question about the existing laboratory services in South Africa, stating:

It depends on what's the level of laboratory processing? What's the backlog going to be like? Is there potential for fast tracking of potential cancer tests through the system? (ID06, Primary care physician, Cape Town, WC)

Providers expressed that slow laboratory processing times and communication between primary care and laboratory services act as a strong perceived barrier to successful implementation of FIT testing. If FIT tests were to be implemented in South Africa, this potential barrier would need to be addressed for testing to be successful.

High test costs

Cost was one of the biggest structural barriers for FIT test implementation, specifically the cost of implementing FIT tests in the healthcare system:

> *I think cost is the biggest problem at the moment, given our climate of budget cuts and very, very limited healthcare resources, more so than ever at the current time. So, that would be the most prohibitive factor (ID06, Primary care physician, Cape Town, WC)*

While the individual cost of the actual FIT test is quite low, the cost of broad implementation in the healthcare system could be quite high and would require financial investment and allocation from the national and provincial levels.

Ablution access

Many participants brought up access to proper ablution facilities within the community and for many public health facility patients as a major perceived structural barrier to FIT testing or screening, particularly in rural and semi-rural catchment areas. This was due to the structural aspect of ablution services being provided by and maintained by organisational entities. One provider who works in a semi-rural setting observed:

> *My thought would be that the patient would be more comfortable collecting stool sample in their own home rather than in the facility. But that has its challenges also, yes, in lots of different aspects. Not everyone lives in a brick house with their own toilet inside. And that's not going to be a barrier only in our area, that's across the metro, it's across the country, it's across Africa where you have informal settlements where there are shared toilets, those porta potty type shared toilets. (ID01, Primary & secondary care physician, Vredenberg, WC)*

Another participant working in the Eastern Cape noted that:

> *My work is not only limited to Mthatha. I work in the rural areas around here, nearby district hospitals, and all of that, so I have quite a good view of what happens in these facilities. To be honest, most of the issue is because of lack of proper ablution facility in these places. (ID08, Primary care physician, Mthatha, EC)*

Lack of proper ablution services both at home and in the healthcare facilities could act as a strong barrier to FIT testing, particularly for patients in rural and semi-rural areas.

Lack of clinical continuity & communication

Lack of clinical continuity and communication between the primary care, secondary and tertiary care levels was a common perceived barrier. FIT tests could require multiple healthcare follow-ups, and providers had varying opinions on the possibility of successful follow-ups. A provider who works in an urban setting in Cape Town noted that patients are already used to multiple clinic visits, especially symptomatic or high-risk patients. He stated that:

> *So, at the end of the day, it might lead to an additional visit to your primary healthcare centre. Which happens all the time. Patients are told to follow up results two, three, four times sometimes, and it requires additional visits, because we often don't have another route of communication with some of our patients. Fortunately, today, most people have a phone, or they know someone with a phone. So, there's that route of communication. (ID06, Primary care physician, Cape Town, WC)*

However, for rural and semi-rural areas, loss-to-follow up was a big concern, with one healthcare provider working with rural catchment areas noting:

> *The only challenge will be that sometimes they will have to go home, and bring the sample the next day, and the challenge could be the transport back and forth. Because in some places there may be no toilet, or something like that, but most people, they will need*

to go home, and bring it the next day or something. That could be the challenge. (ID08, Primary care physician, Mthatha, EC)

The feasibility of multiple healthcare visits and adequate follow-up seems to interplay with the geographical area in which the patients live. Providers that work within urban catchment areas perceived that multiple visits and follow ups were feasible within their contexts, but participants that work within rural catchment areas perceived multiple site visits as a barrier.

Another provider indicated that clinical continuity can be a barrier, as FIT testing may require multiple follow-up visits and feedback, complicating consistent engagement with patients throughout the testing process. He stated that:

One of the biggest challenges we face, particularly in our bigger health facilities in primary care, is that there is a serious lack of continuity. So, a patient may come in today, have a test taken and then when they come back for the results, whenever they're told to come back, it's a completely different health care practitioner who now doesn't know what's going on. (ID05, Secondary care physician, Cape Town, WC)

Gaps in communication between primary and secondary levels of care, providers, and patients during multiple site visits could undermine the testing process and act as a potential barrier.

Predisposing facilitators

Predisposing, or intrapersonal, facilitators are categorised by the theoretical framework as perceived facilitators at the individual level, for example: beliefs that would influence individual behaviours.

Health education (acceptability and health seeking behaviours)

Health education was perceived as a potential facilitator for implementing FIT testing. Providers from both the Western and Eastern Cape stated:

Patients most of the time are always cooperative and very keen for their health. If they are educated, if we intensify education, I don't foresee any challenges that we may experience from our patients. They are looking on to whatever care they can get. (ID07, Secondary care nurse, Lusikisiki, EC)

I think if the instructions are clear, if they're made culturally accessible and language instructions are accessible to all our different groups of the population, I can't see why there would be an issue with using them [FIT tests] as the rest of the world use them. (ID05, Secondary care physician, Cape Town, WC)

Health seeking behaviours among symptomatic women, were perceived by participants as high, noting a need to target any health education campaigns to population groups with lower health seeking behaviours. This statement not only highlights the importance of clear, culturally appropriate communication, but also highlights the broader consideration of how FIT testing could be formally recognized and incorporated within future policy and healthcare planning frameworks.

Reinforcing (interpersonal) facilitators

Reinforcing, or interpersonal, facilitators to CRC screening are factors that relate to community or social structures, such as family, friends, healthcare workers, or community members.

Primary care physicians training in CRC risk

A need for adequate training of primary care physicians in CRC risk factors, screening and diagnosis was perceived as a facilitator among participants. Most patients in the public healthcare sector in South Africa enter the health system through primary care clinics and facilities, so there is a need for proper education and training among primary care physicians and nurses to manage patients, especially those at higher risk or with potential CRC symptoms. One participant stated that:

It means the test has to be made accessible as well as the clinicians have to be made to be clearly able to do so and interpret it. (ID07, Secondary care nurse, Lusikisiki, EC)

Another potential facilitator noted by participants was a need for primary healthcare workers to be informed and educated in how to disseminate test information and needs to their patients. With one provider stating:

> *Yes, that's my experience … once it's explained and if you explain to them… One doesn't have to explain that it's necessarily a cancer test. You can say, I'm looking for signs of bleeding which would mean we would need to investigate further. So, it's not a test that you need to put the fear of God into them… You just say, it's a test. If I see the presence of blood, and if I can test it, it just will give me more information, or suggest we need to look further. (ID04, Primary care physician, Cape Town, WC)*

This highlights the critical facilitating role of clear, reassuring communication by primary healthcare workers in promoting patient understanding and acceptance of FIT tests.

Test being taken at home vs in the primary clinic

There were varied responses from participants as to whether FIT tests should be given to patients to take at home versus in the primary clinic. One primary care physician noted the importance of patients being directly involved in their own healthcare, stating that:

> *I do think that when we ask patients to do things at home, that it is a way of more firmly ensuring that they are part of the process of their own diagnoses. Even though there's always the risk that you're going to have some loss to follow-up. (ID06, Primary care physician, Cape Town, WC)*

However, participants who work in rural or semi-rural settings seemed to have different opinions, mostly stating the difficulty for their patients to travel to and from their homes to healthcare facilities for multiple visits. One rural/semi-rural participant noted that:

In fact, for some patients it is not even an option at all. So, they would rather wait there, and do what they can from this visit today, so they don't have to come back tomorrow. (ID08, Primary & secondary care physician, Mthatha, EC)

Given these varied responses, a blanket approach to screening may not be acceptable in the South African context. Providing FIT testing for patients to take home and return may be feasible in urban settings. However, in rural areas, providers recommended that the test be completed at the healthcare facility during the initial visit to minimize transportation and geographical barriers.

Enabling (structural) facilitators

Enabling facilitators are perceived by providers at the structural or organisational level.

Test affordability and infrastructure communication

Participants felt that the most important structural facilitator was cost of FIT testing. If FIT tests are affordable, all participants encouraged their support of a roll out in the primary care setting. Providers also noted a need for smooth communication between primary care facilities and laboratory services as a facilitator in corroboration with lower cost, with one participant stating that:

Yes, it [FIT testing] may be feasible because currently now the rollout of clinicians has improved so much. It may be feasible, but if also the laboratories will be equipped, and then I think in the sense of clinicians, it starts with a matter of training and education, but it may be feasible. (ID07, Secondary care nurse, Lusiksiki, EC)

This highlights a need for smooth communication between the different levels of care, as well as adequate education and training among healthcare workers to properly facilitate FIT testing. In terms of policy and government structural facilitators, one participant noted that:

I think it's like with any new thing, it needs to be driven from the top within our hierarchical health systems. So, there needs to be clear supply chain processes in place.

The problem is that if I go and run a few seminars for doctors in primary care, and I say, listen, this is coming in, and nine months down the line, they still don't have the tests available in their facilities, then chances are we going to fall flat on our faces. So there needs to be a coordinated approach. Policy-driven, supported by managers, and from the ground up. (ID05, Secondary care physician, Cape Town, WC)

All participants stated that they believe FIT testing should be implemented at the primary care level, in clinics, given their increased accessibility to the community and patients.

Utilising FIT to screen symptomatic patients

Most participants disagreed with a population-based screening approach using FIT testing, stating that it is not currently feasible in the South African setting. Instead, most recommended that FIT testing be utilised as an extra testing measure for symptomatic patients or high-risk patients, which would help guide clinical certainty of symptoms at the primary care level and reduce the burden of unnecessary colonoscopies on an already over-saturated healthcare system. One participant noted that:

Screening across the board would not… Then it would be a problem because then you're saying to somebody, I need to get a stool sample, won't you just lie down quickly. Then they'd feel weird. But if they're coming to you with a bum problem, then they would feel less weird about it. (ID04, Primary care physician, Cape Town, WC)

Participants also stated that FIT testing could be utilised to better manage referrals and CRC patients' movement from primary care facilities to secondary and tertiary care facilities:

So, it gives you an additional branch of that triaging system, which can go straight to colonoscopy is indicated. What we're talking about is our more electronic automated referral system. That would make it even easier, because if you've got a FIT test and it's positive, you get a date. It takes even more thinking out of it. (ID05, Secondary care physician, Cape Town, WC)

Acknowledging that screening is aimed toward identifying asymptomatic patients before symptom onset, developing a risk-stratified approach to FIT testing could help reduce the burden of cost on the health system and should be considered before implementation.

Discussion

Utilising phase 3 of the PRECEDE model as our theoretical framework, we identified perceived barriers and facilitators to CRC FIT test screening from primary and secondary healthcare workers' perspectives. These can serve as foundational evidence for potential implementation of a CRC screening program in the public healthcare South Africa. The findings of this study reveal a range of challenges and opportunities influencing the potential implementation of FIT-based colorectal cancer (CRC) screening in South Africa. Personal discomfort with stool collection and socioeconomic barriers emerged as key individual-level obstacles, though health education was identified as a means to improve acceptability. At the interpersonal level, healthcare worker knowledge and geographic disparities posed challenges, yet physician training and the option for patients to complete FIT testing at home or at the clinic depending on distance traveled were seen as facilitators. Structural barriers, including the cost of tests, limited pathology services, and inadequate access to ablution facilities, highlighted broader systemic constraints. However, improved communication, reduced costs, and better infrastructure could help support screening efforts. These findings emphasize the interplay between personal, healthcare, and structural factors in shaping CRC screening feasibility and point to critical areas for policy and programmatic intervention. Keeping this in mind, this research aimed at better understanding factors related to patient acceptability and feasibility from healthcare providers' perspectives, in anticipation of a future potential CRC screening program in South Africa.

Participants felt that the bulk of the predisposing barriers, or barriers at the individual level, to CRC FIT screening were personal characteristics, most notably socioeconomic status and work status, as well as personal discomfort with taking the test. Participants identified patient income and work status as a major perceived barrier to accessing screening. Given the nature of informal daily paid work, which is quite common in SA, participants felt that continued

healthcare visits would be difficult to manage for those patients that may lose out on a day's wage to access care. Similar personal characteristic barriers, such as lack of knowledge and awareness, geographical isolation, inadequate financial resources, and a shortage of adequately trained healthcare professionals and facilities to diagnose and treat cancer, were noted in other breast and cervical cancer screening studies in South Africa.[32] One key lesson from cervical cancer screening in South Africa is the use of task-shifting, where primary care nurses and mid-level providers are trained to directly refer high-risk patients to colposcopy services, streamlining the diagnostic pathway.[33] A similar task-shifting approach for CRC screening—where primary healthcare workers could be trained to interpret FIT results and refer positive cases directly for colonoscopy, bypassing unnecessary delays—could improve efficiency and feasibility within the South African healthcare system. Future revisions will more explicitly connect these parallels to strengthen the discussion on intervention planning. In terms of personal discomfort with obtaining a stool sample, health education and access to proper ablutions were noted as potential facilitators that could help increase test acceptability at the individual level.[12]

Providers recommended that FIT tests be made available in the primary care sector, but many of these did not recommend a population-based screening approach due to limited resources in South Africa at this time. Instead, they recommend that FIT testing could be a viable solution for screening symptomatic patients, helping guide clinical certainty of symptoms at the primary care level, and reduce the burden of unnecessary colonoscopies on an already over-saturated healthcare system. One provider recommended a risk stratified approach to screening, which has been proven to be effective in resource constrained contexts if the risk groups are well identified and established.[34] ASCO guidelines have been published identifying a risk stratified approach to CRC cancer in resource limited settings, that would be advantageous to consider in the SA context.[34] While these ASCO guidelines specifically target asymptomatic people in a screening based approach, it would be well worth exploring a specific risk stratified approach to early detection over population-based screening in South Africa. Because many providers did not recommend a population-based screening approach, future research would be well-suited to identify a more specified target population for a proposed screening program in the South African context. Rather than looking at similar screening programs in HIC that use age to identify a screening target population, one primary healthcare provider recommended to rather implement screening for a specified higher risk population. For instance, those that are exposed

to generally accepted CRC risk factors such as obesity, excessive alcohol consumption, diet (high consumption of red and processed meats and foods), and hereditary risk would be ideal target populations for a CRC screening program.[35] A risk stratified approach to screening could be useful in the South African context with limited resources, but further research would be needed to address its feasibility and context specific targeted risk factors.

The findings highlight concerns about secondary care capacity in managing increased referrals if FIT-based CRC screening were implemented in South Africa. Secondary facilities, already facing resource constraints, bottlenecks in specialist care, and geographic disparities, may struggle to provide timely confirmatory diagnostics and treatment.[36] Without investment in endoscopy services, trained personnel, and referral systems, screening could overload the system, undermining early detection benefits.[37] These capacity challenges were reflected in participant responses, with some healthcare providers expressing skepticism about introducing a population-based screening program, emphasizing instead that FIT tests could be more effectively used to prioritize and manage symptomatic patients or higher risk patients rather than traditional asymptomatic screening. This could help mitigate overuse of colonoscopy services for patients without CRC, which are highly resource heavy. While this study lightly touched on primary-to-secondary care referrals, future research should explore how secondary care can be strengthened to prevent delays in diagnosis and treatment, ensuring that any CRC screening initiative—whether targeted or population-wide—can be effectively implemented without overwhelming existing services.[37]

Another barrier tied to this is the quadruple burden of disease in South Africa, and physicians' assessment of cancer as not a priority compared to other diseases managed in the primary care sector such as diabetes, TB, and HIV.[38] Reinforcing facilitators that could help combat this perceived barrier would be effective training of primary healthcare workers on CRC risk factors and screening, as well as development of a validated risk assessment tool allowing for easier identification of the potential screening target population.[39, 40]

Providers that work in urban settings highlighted the accessibility of taking the FIT test home and returning to the clinic. While providers that work in rural or semi-rural settings highlighted the difficulty of multiple healthcare visits due to geographical and travel constraints, and recommended patients may prefer to obtain the stool sample while at their first clinic visit. This would require adequate ablution services in clinics, which was a noted barrier, particularly

among rural Eastern Cape providers. Previous studies in Sub-Saharan Africa and South Africa with breast cancer patients have shown that community health workers, mobile follow-ups, or family involvement, as well as single-site visits whenever and wherever possible, may lower these obstacles and encourage CRC screening, particularly in rural regions.[41] Similar geographical barriers to cancer screening, particularly in rural and semi-rural areas, were also noted in other studies in South Africa and Sub-Saharan Africa.[42, 43] In high-income countries, FIT-based colorectal cancer screening is commonly implemented through centralized, home-based systems where kits are mailed to individuals and returned via post, significantly reducing the need for in-person healthcare visits and mitigating logistical barriers such as transportation.[44, 45] However, in the South African context, especially in rural or low-resource areas, challenges such as postal unreliability, informal housing, and limited infrastructure may hinder the feasibility of this model. These contextual constraints were reflected in healthcare providers' assumptions that multiple facility visits would be required, revealing important insights into current provider knowledge and perceived feasibility of FIT testing. Therefore, while home-based screening models have been successful in high-income countries, adapting these approaches to the South African setting requires careful consideration of the existing infrastructural limitations.

Enabling factors such as clinical continuity, pathology or laboratory services and cost were commonly mentioned by providers as potential barriers to CRC screening. In order to mount a successful screening program in South Africa, there would need to be adequate stewardship from the National Department of Health all the way down to primary care facilities, with adequate policies, health system communication, provider training and test funding in place.[46] Providers noted enabling facilitators such as affordable test cost and smooth communication between the different levels of care in the health system would help offset some of the noted barriers to CRC screening if effectively implemented. To achieve this, the South African National Department of Health would need to invest not only in FIT test costs, but also in provider training and laboratory services.

Cost of FIT tests and implementation costs were commonly addressed as potential barriers and facilitators. A more detailed economic analysis would be essential to assess the cost-effectiveness of implementing FIT-based CRC screening or early detection in South Africa. Studies from similar resource-limited settings on cervical cancer screening found that while

upfront costs of a screening or early detection program can be significant, they are often offset by long-term savings due to earlier detection and reduced treatment costs for late-stage disease.[47] Additionally, incorporating disability-adjusted life years (DALYs) into the analysis would provide a more comprehensive understanding of the broader economic and public health benefits, as screening and early detection programs have been shown to significantly reduce CRC-related morbidity and mortality when effectively implemented.[48] Future research could model different screening scenarios to determine the most cost-effective approach given South Africa's healthcare system constraints.

Limitations

The sample used for this study was a convenience sample of physicians and nurses who agreed to participate, rather than a purposive sample. Most participants preferred virtual interviews via Microsoft Teams rather than in-person interviews due to their work schedules and time constraints. However, it is important to note, that participants seemed to be more comfortable and forthcoming with conversation virtually compared to those that were interviewed in person. Some participants held both academic and clinical positions, but all respondents actively worked in a clinical setting at the time of interview. While a few had academic roles, they were asked to provide responses based on their clinical experience, with theoretical insights grounded in their day-to-day practice. The overlap between academic and clinical roles may blur the distinction between theoretical and practical perspectives, but the researcher did all she could to attempt to limit this through questioning and probing during the interviews, and this has been acknowledged as a potential limitation of the study.

A small sample size posed as a limitation for this study; however, data saturation was reached within the small sample, as the exploratory nature of the study led to consistent themes emerging across interviews. Given the absence of a formal colorectal cancer screening program or FIT testing in the country, discussions were largely theoretical rather than lending from practical experience, focusing on healthcare providers' perceptions of FIT testing and its potential implementation. As interviews progressed, no new significant insights or perspectives emerged, indicating that key themes had been thoroughly explored. The relatively homogenous professional backgrounds of the participants, combined with the focused research objectives, further contributed to achieving saturation within this sample size.

While incorporating patient perspectives and/or public health professionals' perspectives would have been valuable, it was not feasible within the scope and timeline of a Master's dissertation due to the lengthy ethics clearance process for a patient sample versus a provider sample. During the initial development of the research proposal, the student and supervisor agreed that including patients in the sample would be too challenging given these constraints, and would be better suited for a larger project such as a PhD or independent grant project. However, building on the insights from these healthcare provider interviews, future research could explore patient perspectives and/or public health professionals' perspectives to gain a more comprehensive understanding of barriers and facilitators to CRC screening in SA.

The transferability of findings in the study is influenced by the specific healthcare contexts of the Western and Eastern Cape, where participants were recruited. While the insights from primary and secondary healthcare providers offer valuable perspectives on colorectal cancer screening with FIT testing, they may not fully reflect the experiences of providers in other provinces or healthcare settings. However, the study's focus on diverse geographical areas- including urban, peri-urban, and rural contexts- enhances its relevance for understanding broader challenges and considerations in potentially implementing FIT tests in resource-limited settings in South Africa.

Despite limitations, we contend that this exploratory study establishes a vital groundwork for future research focused on the potential development of a culturally specific, multilevel CRC screening program in South Africa.

Implications

The findings of this study have important implications CRC screening efforts in South Africa, particularly regarding the potential integration of FIT testing into routine clinical practice. Healthcare providers highlighted key challenges, including resource constraints, test availability, and the need for culturally and linguistically appropriate patient education. These insights emphasize the necessity for clear policy direction, training for healthcare workers, and structured referral pathways to ensure effective implementation if a national screening program is introduced. While referrals from primary to secondary care were addressed in part during this study, future research would be well suited to further examine this area. If a screening test or early detection program were to be implemented at any stage, it would be essential to further

examine the capacity of secondary care facilities and healthcare workers to manage an increase in referrals. Additionally, provider perspectives on FIT testing suggest that while the test is seen as feasible in principle, addressing logistical and systemic barriers will be crucial for its success.

Future research should also explore patient perspectives on CRC screening, as understanding patient awareness, acceptability, and potential barriers to screening uptake is essential for designing effective public health interventions. Additionally, implementation-focused studies assessing the real-world feasibility of FIT testing in South African primary care settings would provide valuable evidence for policymakers. Research into cost-effectiveness, workforce training needs, and integration strategies within existing healthcare infrastructure would further inform the development of a sustainable screening program. Lastly, comparative studies evaluating CRC screening models in other resource-limited settings could provide insights applicable to the South African context.

Acronym list

South Africa (SA)
Colorectal cancer (CRC)
Age-standardised incidence rate (ASIR)
Age-standardised mortality rate (ASMR)
Faecal immunochemical test (FIT)
Low- and middle-income countries (LMIC)
Faecal occult blood test or guaiac testing (FOBT)
Predisposing, Reinforcing, and Enabling Constructs in Educational/environmental Diagnosis and Evaluation model (PRECEDE)
Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development model (PROCEED)
University of Cape Town (UCT)
Human Research Ethics Committee (HREC)
Western Cape (WC)
Eastern Cape (EC)
Healthcare workers (HCW)

References:

1. Bray F, Laversanne M, Sung H, Ferlay J, Siegel RL, Soerjomataram I, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA: A Cancer Journal for Clinicians. 2024;74(3):229-63.
2. Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, et al. Global cancer observatory: cancer today (version 1.1). Lyon, France: International Agency for Research on Cancer. 2024.
3. Motsuku L, Chen WC, Muchengeti MM, Naidoo M, Quene TM, Kellett P, et al. Colorectal cancer incidence and mortality trends by sex and population group in South Africa: 2002–2014. BMC cancer. 2021;21:1-11.
4. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA: A Cancer Journal for Clinicians. 2021;71(3):209-49.
5. Welch HG, Robertson DJ. Colorectal cancer on the decline—why screening can't explain it all. New England Journal of Medicine. 2016;374(17):1605-7.
6. Stracci F, Zorzi M, Grazzini G. Colorectal cancer screening: tests, strategies, and perspectives. Frontiers in public health. 2014;2:210.
7. Song L-L, Li Y-M. Current noninvasive tests for colorectal cancer screening: An overview of colorectal cancer screening tests. World journal of gastrointestinal oncology. 2016;8(11):793.
8. Magwaza S. "Colorectal Cancer Screening in South Africa: Consideration for National Risk Differentiated Colorectal Cancer Screening Programme". Open Access Journal of Biomedical Science. 2022;4(1).
9. Alatise OI, Dare AJ, Akinyemi PA, Abdulkareem FB, Olatoke SA, Knapp GC, et al. Colorectal cancer screening with fecal immunochemical testing: a community-based, cross-sectional study in average-risk individuals in Nigeria. The Lancet Global Health. 2022;10(7):e1012-e22.
10. Brand Bateman L, Khamess S, Abdelmoneim S-E, Arafat W, Fouad MN, Khamis Y, et al. Designing an Effective Colorectal Cancer Screening Program in Egypt: A Qualitative Study of Perceptions of Egyptian Primary Care Physicians and Specialists. The Oncologist. 2020;25(10):e1525-e31.
11. Hulka BS. Cancer screening degrees of proof and practical application. Cancer. 1988;62(S1):1776-80.
12. Shah SC, Kayamba V, Peek RM, Heimburger D. Cancer Control in Low- and Middle-Income Countries: Is It Time to Consider Screening? Journal of Global Oncology. 2019(5):1-8.
13. Andermann A. Revisting wilson and Jungner in the genomic age: a review of screening criteria over the past 40 years. Bulletin of the World Health Organization. 2008;86(4):317-9.
14. Wilson JMG, Jungner G, Organization WH. Principles and practice of screening for disease. 1968.
15. Lala V, Mohamed A, Tate D, Seabi N, Mokgoko D. Colorectal cancer screening: An update and South African perspective. Wits Journal of Clinical Medicine. 2024;6(2):95-102.

16. Brand M, Gaylard P, Ramos J. Colorectal cancer in South Africa: An assessment of disease presentation, treatment pathways and 5-year survival. South African Medical Journal. 2018;108(2):118-22.
17. Srinath A, van Merode F, Rao SV, Pavlova M. Barriers to cervical cancer and breast cancer screening uptake in low-and middle-income countries: a systematic review. Health policy and planning. 2023;38(4):509-27.
18. Bukirwa A, Mutyoba JN, N. Mukasa B, Karamagi Y, Odiit M, Kawuma E, et al. Motivations and barriers to cervical cancer screening among HIV infected women in HIV care: a qualitative study. BMC women's health. 2015;15:1-11.
19. Health Do. National Health Act, 2003: Regulations relating to categories of hospitals. 2012.
20. Porter CM. Revisiting Precede–Proceed: A leading model for ecological and ethical health promotion. Health Education Journal. 2016;75(6):753-64.
21. Kreuter MW, Green MC, Cappella JN, Slater MD, Wise ME, Storey D, et al. Narrative communication in cancer prevention and control: A framework to guide research and application. Annals of behavioral medicine. 2007;33:221-35.
22. Kim J, Jang J, Kim B, Lee KH. Effect of the PRECEDE-PROCEED model on health programs: a systematic review and meta-analysis. Systematic Reviews. 2022;11(1):213.
23. Vasileiou K, Barnett J, Thorpe S, Young T. Characterising and justifying sample size sufficiency in interview-based studies: systematic analysis of qualitative health research over a 15-year period. BMC medical research methodology. 2018;18:1-18.
24. Institute NNC. NCI Dictionary of Cancer Terms: fecal occult blood test United States of America: National Institute of Health; [Available from: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/fecal-occult-blood-test.
25. Robertson DJ, Lee JK, Boland CR, Dominitz JA, Giardiello FM, Johnson DA, et al. Recommendations on fecal immunochemical testing to screen for colorectal neoplasia: a consensus statement by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2017;152(5):1217-37. e3.
26. Elsafi SH, Alqahtani NI, Zakary NY, Al Zahrani EM. The sensitivity, specificity, predictive values, and likelihood ratios of fecal occult blood test for the detection of colorectal cancer in hospital settings. Clinical and experimental gastroenterology. 2015:279-84.
27. Niedermaier T, Tikk K, Gies A, Bieck S, Brenner H. Sensitivity of fecal immunochemical test for colorectal cancer detection differs according to stage and location. Clinical Gastroenterology and Hepatology. 2020;18(13):2920-8. e6.
28. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006;3(2):77-101.
29. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC medical research methodology. 2013;13:1-8.
30. Jootun D, McGhee G, Marland GR. Reflexivity: promoting rigour in qualitative research. Nursing standard. 2009;23(23):42-7.
31. Thomas L. The Researcher's Gaze. Doing Good Qualitative Research. 2024:23.

32. Joffe M, Ayeni O, Norris SA, McCormack VA, Ruff P, Das I, et al. Barriers to early presentation of breast cancer among women in Soweto, South Africa. PloS one. 2018;13(2):e0192071.
33. Finocchario-Kessler S, Wexler C, Maloba M, Mabachi N, Ndikum-Moffor F, Bukusi E. Cervical cancer prevention and treatment research in Africa: a systematic review from a public health perspective. BMC women's health. 2016;16:1-25.
34. Lopes G, Stern MC, Temin S, Sharara AI, Cervantes A, Costas-Chavarri A, et al. Early detection for colorectal cancer: ASCO resource-stratified guideline. Journal of global oncology. 2019;5:1-22.
35. Wong MCS, Wong SH, Ng SC, Wu JCY, Chan FKL, Sung JJY. Targeted screening for colorectal cancer in high-risk individuals. Best Practice & Research Clinical Gastroenterology. 2015;29(6):941-51.
36. Stefan DC. Cancer care in Africa: an overview of resources. Journal of global oncology. 2015;1(1):30-6.
37. Lee R, Holmes D. Barriers and recommendations for colorectal cancer screening in Africa. Global Health Action. 2023;16(1):2181920.
38. Meyer S, Harries J, Torode J, Baldwin-Ragaven L. Harnessing the law to advance equitable cancer care in South Africa: exploring the feasibility, desirability and added value of a dedicated national cancer act. ecancermedicalscience. 2024;18.
39. Omran S, Barakat H, Muliira JK, Aljadaa N. Knowledge, Experiences, and Barriers to Colorectal Cancer Screening: A Survey of Health Care Providers Working in Primary Care Settings. Journal of Cancer Education. 2014;30(1):53-61.
40. Magaña-Valladares L, González-Robledo MC, Rosas-Magallanes C, Mejía-Arias MÁ, Arreola-Ornelas H, Knaul FM. Training Primary Health Professionals in Breast Cancer Prevention: Evidence and Experience from Mexico. Journal of Cancer Education. 2016;33(1):160-6.
41. Foerster M, Anele A, Adisa C, Galukande M, Parham G, Zietsman A, et al. Few Losses to Follow-up in a Sub-Saharan African Cancer Cohort via Active Mobile Health Follow-up. American Journal of Epidemiology. 2020;189(10):1185-96.
42. Sarmah N, Sibiya MN, Khoza TE. Barriers and enablers to breast cancer screening in rural South Africa. Curationis. 2024;47(1).
43. McFarland DM, Gueldner SM, Mogobe KD. Integrated Review of Barriers to Cervical Cancer Screening in Sub-Saharan Africa. Journal of Nursing Scholarship. 2016;48(5):490-8.
44. Tinmouth J, Lansdorp-Vogelaar I, Allison JE. Faecal immunochemical tests versus guaiac faecal occult blood tests: what clinicians and colorectal cancer screening programme organisers need to know. Gut. 2015;64(8):1327-37.
45. Group ECCSGW. European guidelines for quality assurance in colorectal cancer screening and diagnosis: overview and introduction to the full supplement publication. Endoscopy. 2013;45(01):51-9.
46. Coovadia H, Jewkes R, Barron P, Sanders D, McIntyre D. The health and health system of South Africa: historical roots of current public health challenges. The Lancet. 2009;374(9692):817-34.

47. Campos NG, Castle PE, Wright Jr TC, Kim JJ. Cervical cancer screening in low-resource settings: A cost-effectiveness framework for valuing tradeoffs between test performance and program coverage. International journal of cancer. 2015;137(9):2208-19.
48. Arnold M, Sierra MS, Laversanne M, Soerjomataram I, Jemal A, Bray F. Global patterns and trends in colorectal cancer incidence and mortality. Gut. 2017;66(4):683-91.

Word count excluding title, abstract, tables, figures, references and appendices:
7042 words

Appendices

Appendix A: HREC approved research proposal (with minor amendment made and accepted in November 2023)

A qualitative exploration of healthcare workers' perspectives and experiences with colorectal cancer screening in the Western and Eastern Cape

MPH Thesis Proposal, Final Draft

Alexandra Payne, PYNALE002

Minor amendment: 2 NOVEMBER 2023

Introduction

Colorectal cancer is the third most commonly diagnosed cancer (10.0%) and second highest cause of cancer death (9.4%) globally (Sung, et al., 2021). With an age standardized rate (ASR) of 19.5 per 100,000 people, colorectal cancer has the fourth highest cancer incidence rate globally (IARC, 2020). While colorectal cancer has a higher burden in higher income countries (HICs), it is important to note that increased incidence is portrayed as a factor of socio-economic development, where incidence rates tend to increase uniformly with increasing HDI (Sung et al., 2021). This should be considered when addressing the growing burden of colorectal cancer in low- and middle-income countries (LMICs) and South Africa specifically, as rates of cancer are increasing due to both an ageing population and adoption of associated risk factors such as physical inactivity, smoking, alcohol consumption, and poor nutrition (Graham, et al., 2012).

While colorectal cancer burden is higher in HICs compared to LMICs, it is important to note the gap between incidence and mortality being much smaller in LMICs, indicating a lack of a cancer prevention and control policies, yielding higher mortality rates and poorer outcomes due to a lower rate of early diagnosis (see appendix figure 1). For instance, for ASR of males with colorectal cancer, incidence versus mortality rates in HICs are 29.0 versus 13.1 per 100,000

people, compared to ASRs for incidence versus mortality rates in LMICs being 7.4 versus 4.7 per 100,000 people (Sung et al., 2021). The smaller gap seen between ASIR and ASMR rates in LMIC indicate later diagnosis and poorer outcomes, with a smaller ASIR highlighting a lack of adequate population based screening and therefore lower rates of early detection. This marks a significant justification for the consideration of screening recommendations in addressing the future rising burden of colorectal cancer in South Africa specifically.

Statement of the problem

Screening has been shown to have great effect in minimizing incidence and mortality for colorectal cancer in higher income countries, and is one of the most utilized preventative measures for colorectal cancer in HICs. Polyps form on the colon, which due to a long latency period, can be detected via colonoscopy and removed before becoming cancerous. The expense of mounting a mass screening effort in most LMICs is not currently justified given the significant costs of colonoscopy and inadequate implementation of diagnostic and treatment services (Sung, et al., 2021). However, there are other potentially more affordable options in terms of screening for LMIC. Some evidence suggests that guaiac testing and fecal immunochemical tests, may be a cost-effective alternative to colonoscopy, and may offer a viable option for controlling the growing burden of colorectal cancer (Sung, et al., 2021). While this is a viable population based option, it is still important to note the need for access to colonoscopy screening for those with genetic hereditary risk, such as individuals with lynch syndrome or a history of adenoma polyps. With no national or provincial screening policy in place in the public healthcare system in South Africa, there is a need to better understand the feasibility, availability and acceptability of implementing a potential screening program, with FIT tests being the most

recognized option in resource limited settings. An opinion journal article published in South Africa in 2022 addressed the need to assess factors related to the implementation of a potential screening program, most notably to better understand provider related factors such as provider knowledge, education, competency, recommendation, and availability and functionality of equipment (Magwaza, 2022).

A novel community based cross-sectional study was published in July of 2022 in Nigeria that assessed the feasibility of FIT tests as a screening tool in the public health care sector. The study found that FIT within the Nigerian context is feasible and acceptable to average-risk asymptomatic patients; however, with a low positive predictive value and high endoscopy burden investigating false positives suggests that it may not be the most appropriate screening tool in their setting (Alatise et al., 2022). These findings illuminated the need for country-level and context specific data on FIT screening, and highlights a need for more culturally specific data to address the feasibility of FIT as a screening modality in resource limited settings (Alatise et al., 2022). As such, this highlights the need for a further knowledge and understanding across various levels of the healthcare system to address whether this would be a viable screening option (Alatise et al., 2022). This supports the need for qualitative work to path the road for further implementation studies in South Africa.

Rationale of the study

A systematic review that assessed 29 clinical practice guidelines and consensus statements found that the majority of guidances and recommendations were not well-described, the methodology was not clarified, the target population was not well-defined, values and preferences of the target population were not considered during the recommendation of such guidelines, and there was no registration of gaps in evidence, future research suggestions, or

assessment of barriers to screening in target populations (Maes-Carballo, 2023). As South Africa currently does not have a colorectal cancer screening program, and there is no published research on the potential implementation of one, it is essential to address these limitations highlighted in this systematic review preemptively in order to develop strong evidence based studies here in South Africa that demonstrate the applicability, feasibility, and acceptability of a potential screening program while attending to all of these situational factors. A qualitative study addressing facilitators and barriers to screening from the perspective of healthcare workers is an essential step toward building a strong foundation of research with the aim toward identifying a screening program in South Africa.

To date, there is no colorectal cancer screening program implemented in the public primary care setting in South Africa, and there is little to no published research produced in South Africa that is relevant to the implementation of a colorectal cancer screening program. The proposed research for this study is therefore novel in its aims and objectives, and would greatly contribute to the field, taking a step toward identifying factors that would contribute to or act as barriers toward implementing a colorectal cancer screening program in South Africa. Starting to address this gap by running a qualitative study would give valuable insight into healthcare workers' opinions and perceptions on potential screening techniques, as well as guide research toward potential facilitators and barriers to implementation, and identifying areas that require further research.

Research Aim: To understand healthcare workers' perspectives on and experience with colorectal cancer screening in the Western and Eastern Cape

Objectives

- To understand healthcare workers' awareness and opinions on screening [for example, fecal immunohistochemical tests (FIT), Fecal occult blood testing (FOBT), or flexible sigmoidoscopy] for colorectal cancer at the primary health care level
- To understand facilitators to colorectal cancer screening at the primary health care level
- To understand barriers to colorectal cancer screening at the primary health care level

Methods

Study design

The general study design for this study will be a descriptive qualitative study design, allowing for a more descriptive, less-specified design.

Study site

This study will be conducted both in the Western Cape and Eastern Cape provinces, at local primary care clinics and secondary district hospitals. Both the Western and Eastern Cape provinces are chosen as study sites due to their drastic cultural and geographical differences within the South African context, lending valuable data toward potential differences in feasibility and acceptability of a population based screening program across different provinces.

Population and Sampling

The overall population of interest for this study is primary and secondary health care physicians and nurses in the Eastern and Western Cape that work with potentially symptomatic colorectal cancer patients. Primary and secondary care physicians and nurses are thought to have the most knowledge around potential CRC symptoms and referral systems within the primary care setting, and therefore they are most likely candidates to lend information rich data addressing a potential implementation of a population based screening tool. Therefore, primary and secondary care physicians and nurses will make up the target population. A geographical

stratified convenience sampling approach will be used in this study, with elements of snowball sampling when necessary. This sampling technique will be used to identify and include primary and secondary care physicians and nurses that are knowledgeable about cancer presentation within the primary healthcare system and the appropriate referral systems. A geographical stratified approach is necessary in order to obtain data from either rural, urban, or peri-urban clinics. Prof. Tasleem Ras and Prof. Jennifer Moodley have agreed to assist with identifying participants that would be knowledgeable in the field and able to contribute rich data. Once potential participants have been identified, I will reach out to them via Whatsapp inquiring about their agreeableness to be included in the study, and further set up a time and place for the interview to take place. This process will be repeated until the sample size or data saturation has been reached. Given the specificity of participants to be included in this study, a homogeneous group sample would be the most effective and feasible type of purposive sampling to be utilized in this study.

The proposed sample size is 16 total participants [eight in Western Cape, eight in Eastern Cape]. This number was determined to be an ideal number of respondents in order to reach optimal data saturation with high quality rich data upon discussion with A/Prof. Lucia Knight. This study will utilize in-person qualitative interviews

Framework

The Predisposing, Reinforcing, and Enabling Constructs in Educational/environmental Diagnosis and Evaluation (PRECEDE)- Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development (PROCEED) model will act as the theoretical framework for this study. For the scope of this study, the PRECEDE aspect of the model will be utilized, as it focuses on predisposing, enabling and reinforcing factors in intervention

implementation, evaluation and development (. Due to the novel nature of this proposed study, as well as the lack of any CRC screening program in South Africa, implementation frameworks are too far ahead for the purposes of this study. Instead, a modified approach to the PRECEDE model will be taken, looking at facilitators and barriers toward a potential CRC screening program in South Africa. This framework was identified with the assistance of a similar study run within the last year in Egypt, which aimed to identify facilitators and barriers toward a colorectal cancer screening program by qualitatively interviewing primary care physicians as a first step. The aims and objectives of this study aim to understand primary healthcare physicians' opinions on potential screening feasibility and implementation, which are outlined well in this conceptual framework.

Data collection

Due to the nature of the details surrounding the aims and objectives, a semi-structured interview technique will be used, with a focus on both clarification and elaboration of the data during the interview process. An interview guide will be used to frame questions, although it will be short and used mainly for guiding purposes, rather than a rigid structured interview that would limit the evolution of the qualitative data in this study design.

Data collection will be systematic in approach, with the utilization of active listening, rapport building before the interview, note-taking, and interview recording. The interview guide will be pilot tested outside of the sampled population in order to clarify questions, better prepare the interviewer, and identify key areas and codes that will benefit from further elaboration during interviews. Data collection will be audio-recorded and each interview will be transcribed prior to analysis. Data analysis and collection will occur concurrently when possible, in order to allow both to inform one another and allowing for flexibility in data collection. It is most likely to be

concurrent in the Western Cape; however, due to travel and time constraints, concurrent collection and analysis may be difficult to achieve in the Eastern Cape.

English is the language of work for most health care professionals in South Africa, so it is generally accepted that all eligible participants in this study will be comfortable with interviews being held in English. I will conduct the interviews myself, and they will most likely be held at the place of work for all eligible physicians. Due to foreseeable time constraints and because of the potential high workload of each physician, I will actively be flexible to the needs and constrains of each participants' schedule.

Data analysis plan

Data analysis will comprise of thematic analysis, comprising of codes that are gathered both from the interview guide as well as from the transcribed interviews. Thematic analysis will be employed via a color coordinated word document. This type of analysis would be most appropriate for this study, as gathered from other similarly conducted qualitative studies in a similar context.[4] Data analysis will be conducted at the same time as data collection where possible, and thematic content analysis will be utilized. Due to the proposed nature of traveling to the Eastern Cape for half of the data collection, it may not be possible to run analysis concurrent with collection for the Eastern Cape sample; however concurrent analysis and collection should be feasible for the Western Cape sample. In employing a thematic content analysis, a five step approach will be utilized in data analysis, (1) an immersion in raw data, (2) identification of a thematic framework, (3) indexing and coding, (4) charting, and (5) mapping and interpretation (Brand et al., 2020). Codes will be roughly pre-determined a priori, and will most likely evolve as the interview process progresses, in order to account for new themes that may arise during further data collection.

Rigour

In order to maintain rigour throughout the study, multiple techniques will be employed during the research process in order to ensure credibility, dependability and confirmability of the data. One of the most important ways of ensuring rigour will be to document researcher reflexivity and this I will be do this by keeping a journal throughout the study period. Reflexivity enhances the quality of the research by allowing for the researchers to reflect in how their own ideals and bias could influence the process of constructing meaningful qualitative research.[10] It also gives researchers the ability to handle and present the data more effectively while considering how their own ideals and positioning can influence the understanding of a social phenomenon and addressing it appropriately.[11] If the financial and time constraints allow it, member-checking would be a valuable tool in maintaining rigour, by taking raw data after analysis back to the respondents and asking about reflection. However, this may not be possible due to the time constraints of the primary practitioners. While co-coding would be ideal, given the nature of this MPH thesis project, I will debrief and discuss codes with my supervisors in order to maintain rigour. A declaration of theoretical position will be written up and attached with the study write up, as well in order to insure rigour in the data analysis. An audit trail is also essential in recording the research procedure, making data collection and analysis transparent and justified when the direction is changed.

Ethical considerations

While the aim and objectives of this study are not sensitive in nature, steps will be taken in order to ensure confidentiality and comfort among the respondents of this study. Informed consent will be explained and given before each interview, as well as an emphasis on the confidentiality of the respondent's data and permission to audio-record the interview. The

researcher's bias and its potential effect on the relationship between the researcher and the participants will be addressed via reflexive journals being recorded consistently throughout the research process, in order to ensure participant comfort.

There are no health risks posed to the participants given the interview based nature of this study. The researcher will utilize an interview guide that poses no risk to the participants. The interviewer will ensure to pose questions in a sensitive manner. There is little to no stigma associated with questions surrounding colorectal cancer screening for healthcare workers; however, the participants will be informed during the consent process before enrollment that they are able to withdraw from the study at any point in time should they feel any level of concerning discomfort or no longer wish to participate. The results of this study do not directly benefit the participants; however, the implications of such a study could serve to inform colorectal cancer screening pathways that could be utilized in the primary healthcare system.

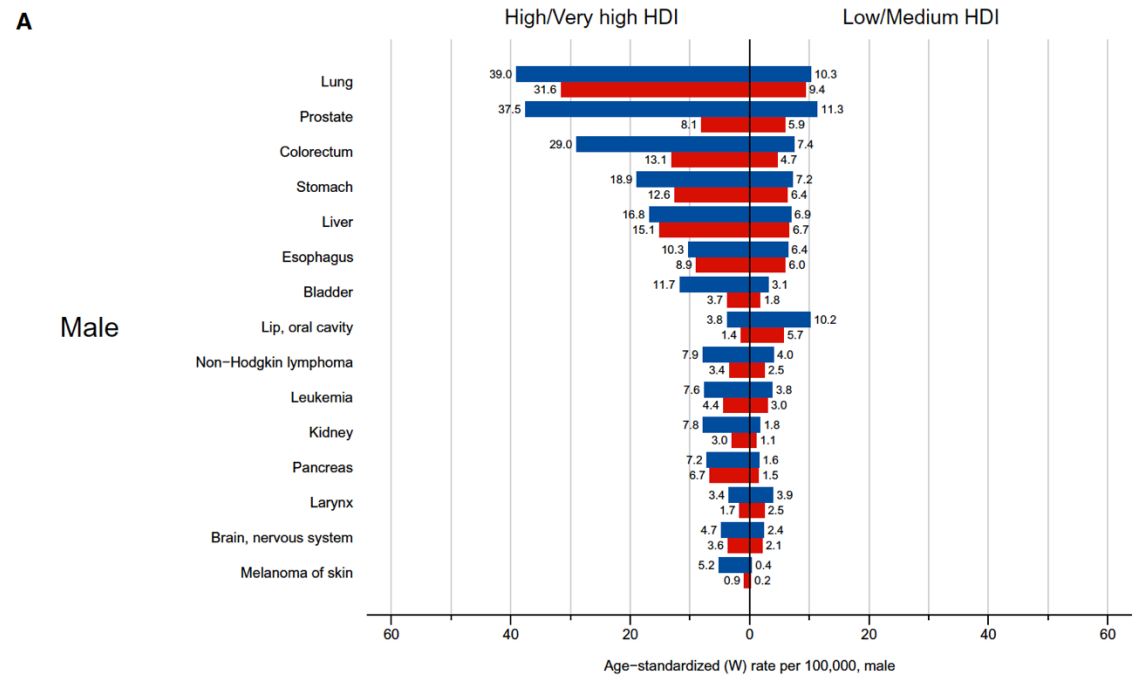
During the informed consent process, all participants will be told of the emphasis of anonymity during the entire research study. All data will be stored in a password protected, encrypted file that only the researcher can access. In order to protect individual participant anonymity, no data will be traceable to the individual participant's identity, and at the moment of introduction into the study, each individual will be coded with a specific participant ID code that will be used in all data collection and analysis. Only necessary personal information relevant to the objectives of this study will be collected, and no data will be traceable to the individual's identity in any way. The only stage where the respondents' identity will be used is in the informed consent process, with all hard copies kept in a locked and secured desk during analysis and write up. All data recorded during the interview on a recording device and in reflexive journals will be kept in a secure locked-door when not being used, and no personal identification

information will be included in either domain. In terms of data disposal, all data will be kept in the secured encrypted data storage after publication for up to two years after completion of the study in case there is a need for secondary data follow-up. After this time, data will be disposed of properly in order to protect the privacy of the participants.

Participants will be identified with assistance from Dr. Tasleem Ras, Prof. Jennifer Moodley and the AWACAN-ED research team. Once a participant has been identified, the researcher will ask if they can approach the participant about a study of interest, where if the participant agrees, a location for the interview will be negotiated. Each participant will be given both verbal and written assurances that their participation in the study will be anonymous and poses no serious risk to themselves. An informed consent letter drafted with information provided by the UCT ethics team will be given to each participant in English, and the interviewer/researcher will further explain the consent form verbally in order to minimize confusion. In order to avoid undue pressure, all consent and interview processes will be performed in privacy when possible, which will be pre-negotiated beforehand. If the participant agrees to the study immediately and time allows it, then the interview and recruitment will be done at the same time. However, there will be an allowance for the participant to be given informed consent upon initial meeting, return at a later scheduled date to sign the consent form and continue with the interview process.

This research will be performed in both the Western Cape, city of Cape Town and in the Eastern Cape, city of Mthatha and Lusikisiki. As such, the following ethics clearances will be required and applied for prior to the start of this research: UCT Ethics, Western Cape Provincial Ethics, Eastern Cape Provincial Ethics, City of Cape Town Ethics, and City of Mthatha Ethics.

Figure 1:
International Agency for Research on Cancer 2021, *Cancer today, Globocan 2020,* viewed 8 March 2021, < https://gco.iarc.fr/today/online-analysis-multi-bars>



References:

1. Sung, H., Ferlay, J., Siegel, R.L., Laversanne, M., Soerjomataram, I., Jemal, A. and Bray, F., 2021. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA: a cancer journal for clinicians*.
2. International Agency for Research on Cancer 2021, *Cancer today, Globocan 2020,* viewed 8 March 2021, < https://gco.iarc.fr/today/online-analysis-multi-bars>
3. Graham, A., Davies Adeloye, L.G., Theodoratou, E. and Campbell, H., 2012. Estimating the incidence of colorectal cancer in Sub–Saharan Africa: A systematic analysis. *Journal of global health*, *2*(2).
4. Florea, A., Sangaré, L. and Lowe, K., 2020. A multinational assessment of gastric, esophageal, and colorectal cancer burden: a report of disease incidence, prevalence, and fatality. *Journal of gastrointestinal cancer*, *51*(3), pp.965-971.
5. Motsuku, L., Chen, W.C., Muchengeti, M.M., Naidoo, M., Mac Quene, T., Kellett, P., Mohlala, M.I., Chu, K.M. and Singh, E., 2021. Colorectal cancer incidence and mortality trends by sex and population group in South Africa: 2002–2014. *BMC cancer*, *21*(1), pp.1-11.
6. CANSA - The Cancer Association of South Africa. 2022. *Colorectal Cancer - CANSA - The Cancer Association of South Africa*. [online] Available at: <https://cansa.org.za/colorectal-cancer/#:~:text=Colorectal%20or%20colon%20cancer%20is,being%20diagnosed%20with%20colorectal%20cancer.> [Accessed 12 August 2022].
7. Koo, M.M., Unger-Saldaña, K., Mwaka, A.D., Corbex, M., Ginsburg, O., Walter, F.M., Calanzani, N., Moodley, J., Rubin, G.P. and Lyratzopoulos, G., 2021. Conceptual

framework to guide early diagnosis programs for symptomatic cancer as part of global cancer control. *JCO global oncology*, *7*, pp.35-45.
8. Magwaza, S., 2022. Colorectal Cancer Screening in South Africa: Consideration for National Risk Differentiated Colorectal Cancer Screening Programme.
9. Brand Bateman, L., Khamess, S., Abdelmoneim, S.E., Arafat, W., Fouad, M.N., Khamis, Y., Omar, A., Abdelmoneim, R.S. and Scarinci, I., 2020. Designing an effective colorectal cancer screening program in Egypt: a qualitative study of perceptions of Egyptian primary care physicians and specialists. *The oncologist*, *25*(10), pp.e1525-e1531.
10. Alatise, O.I., Dare, A.J., Akinyemi, P.A., Abdulkareem, F.B., Olatoke, S.A., Knapp, G.C., Kingham, T.P., Alatise, O.I., Kingham, T.P., Olatoke, S.A. and Dare, A.J., 2022. Colorectal cancer screening with fecal immunochemical testing: a community-based, cross-sectional study in average-risk individuals in Nigeria. *The Lancet Global Health*, *10*(7), pp.e1012-e1022.
11. Unger-Saldaña, K., Saldaña-Tellez, M., Potter, M.B., Van Loon, K., Allen-Leigh, B. and Lajous, M., 2020. Barriers and facilitators for colorectal cancer screening in a low-income urban community in Mexico City. *Implementation Science Communications*, *1*(1), pp.1-15.
12. Elsafi, S.H., Alqahtani, N.I., Zakary, N.Y. and Al Zahrani, E.M., 2015. The sensitivity, specificity, predictive values, and likelihood ratios of fecal occult blood test for the detection of colorectal cancer in hospital settings. *Clinical and experimental gastroenterology*, pp.279-284.

Appendix B (included as Appendix A in research proposal): Semi-structured Interview Guide

From the National Cancer Institute in the United States of America: A fecal occult blood test is a test that checks for occult (hidden) blood in the stool. A small sample of stool is placed in a special collection tube or on a special card and sent to a doctor or laboratory for testing. Blood in the stool may be a sign of colorectal cancer or other problems, such as polyps, ulcers, or hemorrhoids. Guaiac FOBT and immunochemical FOBT are two types of FOBTs. Guaiac FOBT uses a chemical substance called guaiac to check for blood in the stool. Immunochemical FOBT uses an antibody to check for blood in the stool. Also called fecal occult blood test. For FIT tests, the specificity is 80-90% and sensitivity is 75%. For guaiac FOB tests, the specificity is 75% and the sensitivity is 50%. The sensitivity of FIT tests has been proven to be significantly higher for stages 3 and 4 colorectal cancer than for stages 1 and 2 ($p = 0.01$), and is insignificant for the guaiac FOB test ($p = 0.07$).

Research Aim: To understand primary health care providers' perspectives on and experience with colorectal cancer screening in the Western and Eastern Cape
Objective 1: To understand primary health care providers' opinions on screening techniques [for example, fecal immunohistochemical tests (FIT)] for colorectal cancer at the primary health care level
Objective 2: To understand facilitators to population based colorectal cancer screening in South Africa
Objective 3: To understand barriers to population based colorectal cancer screening in South Africa

1. Can you tell me a bit about what you would do if a patient presents to this facility with potential colorectal symptoms (such as bleeding in the stool, a persistent change in bowel habits, persistent abdominal discomfort (such as cramps, gas or pain), or a feeling that your bowel doesn't feel empty)?
    a. Probe: Are there any difficulties you experience with managing such patients? Please expand
    b. Probe: Referral for colonoscopy?
    c. Probe: Waiting times?
    d. Probe: Feedback?
2. Are you aware of screening tests for patients with possible colorectal cancer symptoms that can be done at primary health care facilities?
    a. If the participant **is unaware of any tests**, then give them a brief description as follows:
        i. ***From the National Cancer Institute in the United States of America:*** A fecal occult blood test is a test that checks for occult (hidden) blood in the stool. A small sample of stool is placed in a special collection tube or on a special card and sent to a doctor or laboratory for testing. Blood in the stool may be a sign of colorectal cancer or other problems, such as polyps, ulcers, or hemorrhoids. Guaiac FOBT and immunochemical FOBT are two types of FOBTs. Guaiac FOBT uses a chemical substance called guaiac to check for blood in the stool. Immunochemical FOBT uses an

antibody to check for blood in the stool. Also called fecal occult blood test. For FIT tests, the specificity is 80-90% and sensitivity is 75%. For guaiac FOB tests, the specificity is 75% and the sensitivity is 50%. The sensitivity of FIT tests has been proven to be significantly higher for stages 3 and 4 colorectal cancer than for stages 1 and 2 ($p = 0.01$), and is insignificant for the guaiac FOB test ($p = 0.07$).

   b. If the participant **says yes,** ask them to elaborate. But before, read the snippet from above (NCI) to ensure all participants have the same base knowledge
      i. Which tests do you know of?
      ii. How do they work?
      iii. Have you ever used the test?
      iv. Anything else that you know of the test?
3. State: "The tests I have described above (FIT and FOBT) are currently not in use in the South African public sector as a screening test. How would you feel about having these tests available to screen patients presenting with colorectal symptoms?
   a. Probe: What would be some of the facilitators to this?
   b. What would be some of the challenges for you in using these tests?
   c. Do you have a preference for one of these tests? Probe why
   d. Have you used either of these tests in any setting (public, private setting or working in another country)
      i. If yes, probe which test? What was your experience using the test?
4. In your opinion, would the tests (FOBT and FIT) be acceptable to patients?
   a. If yes or no, why?
5. In your opinion, would there be a difference in challenges for men versus women in obtaining the stool sample?
   a. Probe: What would those be? And why?
6. In your opinion, should patients collect the stool sample for the test in the clinic or at home?
   a. Probe why?
7. Would you anticipate any other challenges to introducing either of these as screening tests for patients with colorectal symptoms?
   a. Probe at the individual level? From doctors? From nurses? From community members?
8. Is there anything else you'd like to say or ask?

Appendix C: Informed consent form

Information and informed consent

A qualitative exploration of healthcare workers' perspectives onand experiences with colorectal cancer screening in the Western and Eastern Cape

In-depth semi-structured interviews with healthcare workers (nurses and physicians)at the primary and secondary healthcare level

Supervisor: A/Prof Lucia Knight

Department of Social Behavioural Sciences
School of Public Health, Faculty of Health Sciences
University of Cape Town, Cape Town, South Africa

Student: Alexandra Payne, M.Sc.

MPH student
Cancer Research Initiative
Department of Social Behavioural Sciences
School of Public Health, Faculty of Health Sciences
University of Cape Town, Cape Town, South Africa

Introduction

Please let me introduce myself, my name is …Alexandra Payne……
and I work at the University of Cape Town. I am a student completing her mini-thesis for a masters of public health. For this mini-thesis, I will be conducting a qualitative study, aiming to understand primary and secondary healthcare workers' perspectives on and experiences with colorectal cancer screening in both the Western and Eastern Cape.

The main objective of this study is to understand healthcare workers' awareness and opinions on screening [for example, fecal immunohistochemical tests (FIT), fecal occult blood testing (FOBT), or flexible sigmoidoscopy] for colorectal cancer at the primary and/or secondary

health care level. We also aim to understand facilitators and barriers to colorectal cancer screening atthe primary health care level.

I would like to invite you to take part in the study. If there is anything that you do not understand at any time, I will be happy to explain. Please note, your participation in this study is entirely voluntary and you are free to stop participating at any time.

If you decide to take part in this study:

- I will ask you to sign a consent form
- With your permission I will record our discussion and also make some notes
- The information collected will be stored in a secure database
- The interview will last about an hour
- Your name will not be recorded for this study, you will be given a pseudonym
- You can choose to skip any questions you do not want to answer

If you decide not to take part in this research project:

- You do not have to take part in this study if you do not wish to do so. You may stop taking part in the interview at any time that you wish. Not taking part or not answering any questions will in no way affect your employment now or in the future

Let me explain the benefits of participating in this study

Your participation in this study will help us understand awareness, opinions, barriers, and facilitators for colorectal cancer screening at the primary and secondary care level. Your participation will not directly benefit you now, however it will assist future research in identifying and implementing a colorectal cancer screening program in the public healthcare sector in South Africa.

Let me explain possible risks of participating in this study

There are no direct risks involved in participating in this study. There is a slight risk that you mayshare some personal or private information by chance or that you may feel uncomfortable about talking about certain things. However, we do not wish this to happen, and you may decide to not answer any question or not take part in a part of the interview if you feel the question(s) are personal or if talking about them makes you uncomfortable. The questions are not aimed to be personal, and hold little to no stigma.

Confidentiality

The information that we collect from this research project will be kept confidential. We will notrecord your name for this study, instead we will assign you a psuedonym. Your name will not be used in any of the results from this study.

Right to refuse or withdraw

You do not have to take part in this study if you do not wish to do so, and not taking part will notaffect your treatment at the health facility in any way.

Additional information

If you have any questions or if anything we discussed is unclear, please let me know and I will behappy to explain now or at any time during the study.

If you need more information about this study, you may contact:

Alexandra Payne, M.Sc.
Cancer Research Initiative and Department of Social Behavioural
SciencesUniversity of Cape Town
Tel: +27 78 373 5393
Email: pynale002@myuct.ac.za

If you have any questions regarding your rights as a study participant, please contact:

Professor M Blockman
Chairperson, Human Research Ethics
CommitteeUniversity of Cape Town
Tel: +27 21 406 6338

Consent

I have read and I understand the information provided for participation in the study entitled: A qualitative exploration of healthcare workers' perspectives on and experiences with colorectal cancer screening in the Western and Eastern Cape.

I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I have had time to consider whether I will take part.

I understand that taking part in this study is confidential and that no material which couldidentify me will be used in any reports on this study.

Declaration by participant

I,_____(full name and surname) hereby consent to participating in this study entitled: A qualitative exploration of healthcare workers'

perspectives on and experiences with colorectal cancer screening in the Western and Eastern Cape.

Signature_____Date _____

Declaration by investigator

Project explained by_____Alexandra Payne_____(full name and surname)
Signature _____Signed by candidate_____Date____

Appendix D: Suggested academic journal submission guidelines

Suggested journal for publication: African Journal of Primary Health Care & Family Medicine
Word count: 3000 – 7500 words (7500 words for original qualitative research)
Referencing style: Vancouver with superscript in-text citations, 60 or less references
Abstract: 250 words max, must include headings
Main text: requires structural headings, 'ethical considerations' is a required sub-section and must include

- Name of ethical review committee
- Study approval number
- Manner of consent (written, oral) for human participants
- Description of measures taken to maintain the confidentiality of data

Tables, figures and graphs: 7 or less
File format: DOC, DOCX, or RTF
Font: Standard font size and standard font family
Keywords: Identify 8 keywords that represent the content of your manuscript and are specific to your field or sub-field.
Layout and spacing: Manuscript text should have 1.5 line spacing
Page and line numbers: Include page and line numbers in manuscript file. Use continuous line numbers
Language: Manuscripts must be written in British English, according to the Oxford English Dictionary
Abbreviations: Define abbreviations upon first appearance in the text. Do not use non-standard abbreviations unless they appear at least three times in the text.

Appendix E: Ethics approval packet (UCT HREC approval letter, UCT HREC amendment approval letter, UCT HREC renewal letter, Western Cape Provincial ethics approval letters, and Eastern Cape Provincial ethics approval letter)

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room 45 E-52-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/home/human-research-ethics

04 July 2023

HREC REF: 349/2023

A/Prof L Knight
Public Health & Family Medicine
Division of Social & Behavioural Sciences
Email: Lucia.knight@uct.ac.za
Student: pynale002@myuct.ac.za

Dear A/Prof Knight

PROJECT TITLE: A QUALITATIVE EXPLORATION OF PRIMARY CARE PHYSICIANS' PERSPECTIVES AND EXPERIENCES WITH COLORECTAL CANCER SCREENING IN THE WESTERN AND EASTERN CAPE-
(MASTERS CANDIDATE-MS ALEXANDRA PAYNE)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 July 2024.

You are required to submit a progress report form, using the standardised Annual Report Form (FHS016) if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledges that the student: Ms Alexandra Payne will also be involved in this study.

Please quote HREC REF 349/2023 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637. Institutional Review Board (IRB) number: IRB00001938 NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Form FHS006: Protocol Amendment

HREC office use only (FWA00001637; IRB00001938)		
☑ Approved	☑ Type of review: Expedited	☐ Full committee
This serves as notification that all changes and documentation described below are approved.		
Signature HREC Chairperson / Designee		Date: 8/11/2023

Note: All **Major** amendments must include a **Cover Letter** and a local **PI Synopsis** justifying the changes for the amendment. Please note that incomplete amendment submissions will not be reviewed.

Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za with subject line: FHS006 + (HREC Reference number).

The latest forms are found on our website.

http://www.health.uct.ac.za/fhs/research/humanethics/forms

Please also clarify your plan for research-related activities during COVID-19 lockdown.

HUMAN RESEARCH ETHICS COMMITTEE
- 8 NOV 2023
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

Comments from the HREC to the Principal Investigator:
Note: The approval of this protocol amendment does not grant annual approval. Please complete the FHS016 / FHS017 form for annual approval at least one month before study expiration.

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	6/11/23		
HREC REF Number	349/2023		
Protocol Title	A qualitative exploration of primary care physicians' perspectives and experiences with colorectal cancer screening in the Western and Eastern Cape - (Masters Candidate- Ms. Alexandra Payne)		
Protocol Number (if applicable)			
Principal Investigator	A/Prof Lucia Knight		
Department / Office Internal Mail Address	Division of Social and Behavioural Sciences Falmouth Building, Office 3.47		
1.1 Is this a major or a minor amendment? (see FHS006hlp) Major (tick box) Minor (tick box)		☐ Major	☑ Minor
1.2 Does this protocol receive US Federal funding?		☐ Yes	☑ No

1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval? **Note:** Any protocol amendments for **Full Committee Review** MUST be submitted on the monthly HREC submission dates. (Please email an electronic copy to hrec-enquiries@uct.ac.za)	☐ Yes	☑ No
1.4 Did the initial study require UCT No-Fault Insurance	☐ Yes	☑ No

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval. This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.
The only ammendment to the proposal, is change the sample from primary care physicians to include both nurses and physicians at the primary and secondary care levels.

3. Protocol status (tick ✓)

☐	Open to enrolment
☑	No participants have been enrolled
	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only

4. Proposed changes will affect: (tick ✓ all the categories that apply)

Protocol	
☑	Study objectives, design (including investigator's brochure, clinical activities, study length)
☐	Study instruments, questionnaires, interview schedules
☐	Sample size
☐	Recruitment methods
☐	Eligibility criteria (inclusion and exclusion criteria)
☐	Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information)
☐	Data collection/ analysis

☐	Principal Investigator. (Please attach revised conflict of interest and PI declaration statements. Refer: sections 7 and 8.4 in the New Protocol Application Form FHS013)
☐	Consent form and information sheet
☐	Recruitment materials (e.g. advertisements)
☐	Administrative (e.g. change in sponsor's name, change in contact information)
☐	Other. Please specify:

**Note: Amendment changes involving study length, sample size, additional sites and eligibility criteria (i.e. inclusion of minors and /or pregnant woman) need to be declared to the Insurance office. Please liaise via fhs.sponsorship@uct.ac.za regarding the required documentation and information to be submitted to obtain an updated UCT No-fault Insurance Certificate- it should be included herewith*

4.1 In your opinion, will there be any **increase** in risk, discomfort or inconvenience to participants?	☐ Yes	☑ No
If yes, please provide a detailed justification/explanation:		

4.2 What follow-up action do you propose for participants who are already enrolled in the study?	
☐	Inform current participants as soon as possible
☐	Re-consent current participants with revised consent/assent forms (append)
☑	No action required
☐	Other. Please describe:

5. Detailed description of the change(s)

Please attach, for each amendment, a summary of all changes which clearly indicates:

i. Old wording (e.g. ~~strikethrough~~ text, CHANGED FROM and CHANGED TO)

ii. New wording (e.g. *italicized*, **bold**, tracked)

iii. Detailed rationale/ justification/ explanation for each change

6. Ethics Review for Amendment Levy – cost including vat

Amendment Review Costs including VAT

Please tick amount to be billed:

Submission Type	*Description*	*New fee (Vat Incl.)*	*tick* ✓
Research funded solely from UCT departmental/ divisional/group budget	Major/ Minor Amendments	**R0,00**	☐
Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges	Major/ Minor Amendments	**R0,00**	✓
Protocol amendment - Major (FHS006 Form)	Clinical Trial & International Grant Funded Research - Any changes to the protocol that requires Full Committee review	**R8 000.00**	☐
Protocol amendment - Major (FHS006 Form)	Clinical Trial & International Grant Funded Research - Any change to the protocol that requires Expedited review that does not require Full Committee Review	**R5 000,00**	☐
Protocol amendment - Minor (FHS006 Form)	Clinical Trial & International Grant Funded Research - Minor amendments, administrative changes that do not affect study design e.g. changes to informed consent form, changes in study staff, etc.	**R2 250,00**	☐
Protocol amendment - Major (FHS006 Form)	National grant funded research - Any change to the protocol that requires Full Committee review	**R7 000,00**	☐
Protocol amendment - Major (FHS006 Form)	National grant funded research - Any change to the protocol that requires Expedited review that does not require Full Committee review	**R2 500,00**	☐
Protocol amendment - Minor (FHS006 Form)	National grant funded research - Minor amendments, administrative changes that do not affect study design e.g. changes to informed consent form, changes in study staff, etc.	**R1 000,00**	☐

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for Invoicing, either complete section 1 or 2 :

1. Invoice billing – Directly to Sponsor

Sponsor's name	
Billing Address of Sponsor:	
Vat Number:	
Contact person:	
Telephone number:	
Email Address:	

2. Internal Journal Billing:

Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

7. Amendment Submission checklist (tick ✓)

7.1 Please tick that all the documents are attached before submitting to the HREC. NB: Incomplete submissions will not be processed	
☑	Latest FHS006 form completed with all sections completed as per our website
☑	Cover Letter
☐	PI Justification/ Summary for the reasons for the amendment
☑	Protocol - Track changes & Clean Copy (where necessary)
☐	Informed Consent Forms (ICF), if applicable (Any changes made to ICF tracked & clean copy)
☐	Any other additional documentation in support of amendment
☐	Updated no fault insurance certificate (if applicable)

Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za with subject line: FHS006 + (HREC Reference number). The latest forms are found on our website.

8. Signature

My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval, I will seek further approval from the HREC.			
Signature of PI	Knight	Date	02 Nov 2023

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) **This serves as notification of annual approval, including any documentation described below.**			
☑ Approved	Annual progress report	Approved until/next renewal date	30.11.2025
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	19/11/2024

Note: Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.

Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Comments to PI from the HREC
Thank you for the deviation document

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	12 Nov 2024		
HREC REF Number	349/2023	Current Ethics Approval was granted until	08 Nov 2023
Protocol title	A qualitative exploration of primary health care physicians' perspectives and experiences with colorectal cancer screening in the Western and Eastern Cape		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes	X No	
If yes, could you please provide the HREC Reference number for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	A/Prof Lucia Knight		

Department and email address	Division of Social and Behavioral Sciences School of Public Health

1.1 Does this protocol receive US Federal funding?	☐ Yes	xNo
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic combined copy if for full committee review to hrec-submission@uct.ac.za)	☐ Yes	☐ No

If yes in 1.2 please complete section 1.3 below for invoicing purposes

1.3 Ethics Renewal Fee

Please **(tick ✓)**appropriate box for billing purposes:

Submission Type	***Description***	***New fee (Vat Incl.)***	***tick ✓***
Research funded solely from UCT departmental/ divisional/group budget/self-initiated research	Annual evaluation of research progress report for re-certification	**R0,00**	☐
Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges	Annual evaluation of research progress report for re-certification	**R0,00**	X
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R7700,00**	☐
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review	**R3800.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R5000.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review	**R1650,00**	☐

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for Invoicing, either complete section 1 or 2 :

1. Invoice billing – Directly to Sponsor

Sponsor's name	
Billing Address of Sponsor:	

Vat Number:	
Contact person	
Telephone number	
Email Address	
2. **Internal Journal Billing:**	
Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

2. List of documentation included to support this approval where applicable

3. Protocol status (tick ✓)

☐	Open Enrolment
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☑	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Publication or thesis submitted and final completion?
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	8
Number of participants enrolled, since last HREC Progress report (continuing review)	8
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	**0**

6. Cumulative summary of participants

Total number of participants who provided consent	**8**
Number of participants determined to be ineligible (i.e. after screening)	0
Number of participants currently active on the study	0
Number of participants completed study (without events leading to withdrawal)	8
Number of participants withdrawn at participants' request (i.e. changed their mind)	0
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	0
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	0

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
Data collection and analysis for the study is completed. The draft of the paper is written up and still being revised with my supervisor A/Prof. Lucia Knight, with the intention to submit by beginning of December 2024.

8. Protocol violations and exceptions (tick ✓ all that apply)

☑	No prior violations or exceptions have occurred since the original approval
☐	Prior violations or exceptions have been reported since the original approval and have already been acknowledged or approved If so, did these occur in the last review period

☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

☐	No Prior amendments have been made since the original approval
☑	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
No adverse events

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☐ Yes	☐ No	☑ Not applicable
If yes, please describe:		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
☐ Yes	☐ No	☑ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	☐ No	☑ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name		Report attached	☐ Yes	☐ No	☐ Not applicable
		DSMB report attached	☐ Yes	☐ No	☐ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	☑ No
If yes, please explain:	

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
☑	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

13. Insurance

Please confirm that valid no fault insurance is still in place? **(tick ✓)**			
☐ Yes		☐ No	
If yes, please complete the following:			
Insurer's name:			
Policy no.		*Coverage Period:	
For UCT sponsored studies please liaise the Insurance office via fhs.sponsorship@uct.ac.za regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate.			

14. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	☑ No

If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):

15. Signature

My required signature certifies that the above is complete and correct.			
Signature of PI	Knight	Date	18 Nov 2024

Form FHS011: Study deviation

HREC office use only (FWA00001637; IRB00001938)			
This serves as acknowledgement of a protocol deviation as described below.			
Chairperson of the HREC signature/ Designee		Date	19/11/2024

Note: Please note that incomplete submissions will not be reviewed.
Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za. Our website address: https://health.uct.ac.za/home/human-research-ethics

HUMAN RESEARCH ETHICS COMMITTEE
19 NOV 2024
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	18 Nov 2024
HREC REF Number	349/2023
Project Title	A qualitative exploration of primary health care physicians' perspectives and experiences with colorectal cancer screening in the Western and Eastern Cape
Protocol number (if applicable)	
Principal Investigator	A/Prof Lucia Knight
Department and Email address	Division of Social and Behavioral Sciences School of Public Health Lucia.knight@uct.ac.za

2. Protocol deviation description

Please describe the deviation below, including the reason why the deviation has occurred.
Failure to submitting renewals on time.

3. Follow-up actions

3.1 Please describe any follow-up action(s) taken or planned as a result of this deviation e.g. DSMB reporting, report to sponsor, informing participants.

Follow-up action is diarising renewals and future submission on time.
3.2 Please describe what action(s) have or will be taken to prevent similar deviations in future.
To prevent similar issues, the research team will implement new monitoring strategies.

4. Principal Investigator's acknowledgement of responsibility

The required signature indicates the PI has reviewed the deviation, taken appropriate follow-up action and implemented or plans to implement preventative steps where possible.			
Signature of PI	Signed by candidate	Date	18 Nov 2024

Western Cape Government

DIRECTORATE: HEALTH INTELLIGENCE
Health.Research@westerncape.gov.za
tel: +27 21 483 0866: fax: +27 21 483 6058
24th Floor, 4 Dorp Street, Cape Town, 8001

REFERENCE: WC_202312_006
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
Observatory
Cape Town
7925

For attention: Ms Alexandra Payne, Prof Lucia Knight

Re: A qualitative exploration of healthcare workers' perspectives and experiences with colorectal cancer screening in the Western and Eastern Cape

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research. Please contact the following people to assist you with any further enquiries in accessing the following sites:

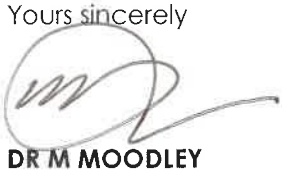
District 6 CHC	**Reuben A Christoffels/ Adelein M Engelbrecht**	**021-833 5444**
Mamre CDC	**Amanda Marcus**	**021 576 1175**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, provided that normal activities at requested facilities are not interrupted and staff are not put under pressure to comply with the research activities.
2. Researchers must provide the department with an electronic copy of a Final Report using the Annexure 9 template within six months of completion of research. This can be submitted to Health.Research@westerncape.gov.za. Future research will not be allowed on the health platform if a Final Report is not submitted.
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, or the final date of the ethics clearance letter, researchers are expected to complete and submit a progress report (**Annexure 8**) and an updated ethics clearance letter to Health.Research@westerncape.gov.za. Failure to do so will render this approval letter void.
4. Please note that if you are conducting a folder audit, and you do not have consent from individual study participants/subjects, you may not capture **identifiable patient information** in your database, as per the Protection of Personal Information Act 4 of 2013 (POPIA).
5. If you do have consent from individual participants in this study, and you are collecting identifiable patient data through your chosen research methodology, you should not keep the data for any longer than is required to complete this research, as per POPIA.
6. The reference number above should be quoted in all future correspondence

7. You are required to notify the substructure office when you commence with your study at the above-mentioned facility(ies) and inform them when you have completed the study at the facility. **Southern- Western Substructure**: Raymond Nell - 021 202 0929 or Raymond.Nell@westerncape.gov.za

Yours sincerely



DR M MOODLEY
PROVINCIAL HEALTH RESEARCH AND EVALUATION
DATE: 26-02-2024

Western Cape Government

DIRECTORATE: HEALTH INTELLIGENCE
Health.Research@westerncape.gov.za
tel: +27 21 483 0866: fax: +27 21 483 6058
24th Floor, 4 Dorp Street, Cape Town, 8001

REFERENCE: WC_202312_006
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
Observatory
Cape Town
7925

For attention: Ms Alexandra Payne, Prof Lucia Knight

Re: A qualitative exploration of healthcare workers' perspectives and experiences with colorectal cancer screening in the Western and Eastern Cape

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research. Please contact the following people to assist you with any further enquiries in accessing the following sites:

Mitchells Plain Hospital	**Dr Jacek Marszalek**	**021 377 4782**
	Jonathan Naude	**021 377 4760**
New Somerset Hospital	**Dr Donna Stokes**	**021 402 6408**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, provided that normal activities at requested facilities are not interrupted and staff are not put under pressure to comply with the research activities.
2. Researchers must provide the department with an electronic copy of a Final Report using the Annexure 9 template within six months of completion of research. This can be submitted to Health.Research@westerncape.gov.za. Future research will not be allowed on the health platform if a Final Report is not submitted.
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, or the final date of the ethics clearance letter, researchers are expected to complete and submit a progress report (**Annexure 8**) and an updated ethics clearance letter to Health.Research@westerncape.gov.za. Failure to do so will render this approval letter void.
4. Please note that if you are conducting a folder audit, and you do not have consent from individual study participants/subjects, you may not capture **identifiable patient information** in your database, as per the Protection of Personal Information Act 4 of 2013 (POPIA).
5. If you do have consent from individual participants in this study, and you are collecting identifiable patient data through your chosen research methodology, you should not keep the data for any longer than is required to complete this research, as per POPIA.

6. The reference number above should be quoted in all future correspondence

Yours sincerely

DR M MOODLEY
PROVINCIAL HEALTH RESEARCH AND EVALUATION
DATE: 06.02.2014

Province of the
EASTERN CAPE
HEALTH

Room 31 • 1st Floor • Grosvenor Lodge • 31 Taylor Street • King Williams Town• Eastern Cape
Private Bag X0038 • Bhisho • 5605 • REPUBLIC OF SOUTH AFRICA
Tel.: +27 (0)43 605 4540• 043 6054535 •Email: ncebagixela22@gmail.com

Date: 05 December 2023

A qualitative exploration of healthcare workers' perspectives and experiences with colorectal cancer screening in the Western and Eastern Cape. (EC_202312_002)

Dear Ms. Alexandra Payne

The department would like to inform you that your application for the research mentioned above topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having written approval from the Research Ethics Committee.

2. You are advised to ensure, observe, and respect the rights and culture of your research participants maintain confidentiality of their identities, and shall remove or not collect any information which can be used to link the participants.

3. The Department of Health expects you to provide a progress update on your study every 3 months (from the date you received this letter) in writing.

4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Eastern Cape Health Research Committee secretariat. You may also be invited to the department to come and present your research findings with your implementable recommendations.

5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE