UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

CATASTROPHIC HEALTH EXPENDITURE AND FINANCIAL COPING STRATEGIES AMONG PATIENTS WITH COLORECTAL CANCER (CRC) AND STOMAS: A CROSS-SECTIONAL STUDY AT GROOTE SCHUUR HOSPITAL, WESTERN CAPE, SOUTH AFRICA

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Plagiarism Declaration

DECLARATION

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Dedication

This dissertation is dedicated to my late father, Rekesh Gokool, a colorectal cancer ostomate who was the inspiration for writing this body of work. Incidentally, he had passed on one month prior to me writing the proposal for this study.

Dad, you were my guiding light, my greatest source of strength, and the reason I found purpose in this study. I never got the chance to share this journey with you, to tell you how much of you lives in every word I have written, how every page is a reflection of the love and resilience you carried through your own battle.

I hope, wherever you are, that I have made you proud. I hope that in some way, this work honours you, even if it will never be enough to express the depth of my love and admiration for you. I would give anything to have you here, to see your smile, to hear your voice, to feel your hand on my shoulder telling me that you are proud of me. But though you are not here in body, I carry you with me in every step I take. You are in my thoughts, my heart, and my very being.

This is for you, Dad. It always has been. It always will be.

Thesis Abstract

This dissertation examined catastrophic health expenditure (CHE) and coping strategies of colorectal cancer (CRC) patients with stomas in South Africa. CRC is the second leading cause of cancer mortality globally, with an increasing burden in low- and middle-income countries (LMICs). The high out-of-pocket (OOP) costs associated with CRC and stoma care place a significant financial strain on patients, potentially leading to CHE. Understanding the extent of CHE and the financial coping mechanisms employed by patients is crucial for informing health policy and financial protection strategies.

This exploratory study used a cross-sectional design and was conducted at Groote Schuur Hospital in Cape Town, South Africa. A structured questionnaire was administered to 21 patients with CRC and stomas to collect data on sociodemographic, direct costs, and financial coping strategies. Descriptive statistics were used to analyse sociodemographic information and cost distributions, while a penalised logistic regression model was used to identify the determinants of CHE.

Transportation (48.9%) and medication (27.8%) costs were significant cost drivers of OOP expenditure. CHE, defined as annual health-related OOP expenditure exceeding 10% of household expenditure, affected 38% of CRC patients enrolled in the study. Findings also showed the disproportionate impact that poorer households and patients with late-stage CRC experienced. Among the poorest households, 60% experienced CHE, with 50% of poor households experiencing CHE. Furthermore, stage 3 and stage 4 CRC patients were shown to experience 50% and 33.33% CHE, respectively. To cope with these financial challenges, 81% of households had employed financial coping behaviours such as reducing household expenditure (47.7%) and taking on additional work (19%).

This study highlights the significant financial burden faced by CRC patients with stomas, particularly in low-income households and those with late-stage disease. Expanding financial protection measures, such as essential CRC medicine subsidies and transport assistance programs, may mitigate these financial burdens. Integrating CRC care into proposed universal health coverage (UHC) programs like South Africa's National Health Insurance (NHI) scheme could enhance the affordability and accessibility of care. Additionally, prioritising early screening initiatives could reduce late-stage diagnosis and the associated financial strains. Future research should explore long-term financial impacts on these patients.

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Abbreviations

95% CI	95% Confidence Interval
BMI	Body Mass Index
CRC	Colorectal Cancer
CT	Computed Tomography
DALYs	Disability Adjusted Life Years
FAP	Familial Adenomatous Polyposis
FRP	Financial Risk Protection
GDP	Gross Domestic Product
HICs	High-Income Countries
HREC	Human Research Ethics Committee
IBD	Inflammatory Bowel Disease
LMICs	Low-to-Middle Income Countries
LSMS	The Living Standards and Measurement Study
MRI	Magnetic Resonance Imaging
NHI	National Health Insurance
OOP	Out-of-Pocket
OR	Odds Ratio
PCA	Principal Component Analysis
QOL	Quality of Life
SASS	South African Society of Stomates
SDG3	Sustainable Development Goal 3
SDI	Socio-Demographic Index
SEI	Socioeconomic Impact
SHS	Short Health Scale
SSA	Sub-Saharan Africa
T2DM	Type 2 Diabetes Mellitus
UIF	Unemployment Insurance Fund
UPFS	Uniform Patient Fee Schedule
UHC	Universal Health Coverage
USD	United States Dollar
WHO	World Health Organization
ZAR	South African Rands

1. PART A: Research Proposal

1.1. Background

Globally, colorectal cancer (CRC) is the third most frequently diagnosed and the second most fatal form of cancer in both men and women(1). As per a 2020 report, the incidence of CRC increases by 2-fold every 5 years until 50, whereas after 55 years of age and beyond, there is a 30% increase every 5 years(2). Mortality rates for CRC have suggested 700 000 CRC-related deaths annually(3). CRC incidence is primarily reported in high-income countries (HICs), with 55% of disease detection and 33% of deaths occurring in these HICs(4). It is suggested that an increased incidence and mortality is to be expected, with a minimum of 10% of patients requiring a permanent ostomy to be performed(5). The term "ostomy" originates from the Greek word "stoma" (στόμα), signifying "mouth", and in the medical context, stoma/ostomy denotes the surgical establishment of an opening in a hollow organ on the body's surface to facilitate the discharge of waste products(6).

Ostomies can either be temporary or permanent and allow waste matter to be eliminated effectively(7). There are three main types of ostomies: colostomies, ileostomies and urostomies. A colostomy is the diversion of the large intestine connected to the left or right abdominal wall, depending on the part of the colon being affected(8). Colostomies are used in the case of rectal cancer, obstruction in the large intestine, a birth defect, faecal incontinence, perineal fistulas, or abdominal infections(9). Similarly, an Ileostomy is the diversion of the ilium to the lower right side of the abdominal wall(10). This can be due to irritable bowel disease such as Crohn’s disease or ulcerative colitis(9). Both ileostomies and colostomies do not rely on sphincters that allow for stool control, as found in the anus, and use of a “pouch” or stoma bag is necessary. Urostomies differ from colostomies and ileostomies as they are much smaller in size, located towards the centre of the lower abdomen, and are used in the case of bladder cancer(11).

Ostomies are a critical surgical intervention in the management of various malignant and benign conditions such as gastrointestinal malignancy, inflammatory bowel disease, perforation or obstruction in the gastrointestinal tract, severe wounds to the perineal region,

as well as end-stage incontinence(7). The most common indicator for ostomy creation is that of bowel, colon, and rectal cancer, with the latter two being jointly referred to as colorectal cancer(6).

Incidence and mortality rates of CRC in low- to-middle income countries (LMICs) are difficult to accurately perceive as low coverage of local cancer registries, insufficient follow-up data, survival data, and the heterogeneity of data collection methods have blurred the actualised disease burden(12). When assessing CRC and ostomy surgery in LMICs, we are presented with prodigious factors that negatively impact a patient's ability to access adequate care(13). These are often presented as limited access to sanitation, stoma care-supplies and equipment, and support services(13). It should be noted that most general surgeons are tasked with performing these colorectal surgeries as specialised colorectal surgeons are rare in LMICs, apart from the exceptions in urban tertiary teaching hospitals or the private sector(14). This, in turn, creates a knock-on effect that further restricts access for impoverished individuals and those in rural areas, who may also be unable to afford medical insurance or the costs of travelling to urban centres where these services are available.(15). Due to under-resourced staffing complements, particularly with stoma therapists, many surgeons would be responsible for educating patients on how to treat their stomas(16). South Africa, India, and Indonesia are rare exceptions in that these LMICs have stoma associations or ostomate associations(15). The South African National Cancer Registry, in 2016, reported CRC as the fourth most diagnosed cancer, the second most common among males, and the sixth leading cause of mortalities in South Africa(17). The South African Society of Stomates (SASS) reported that roughly 60 000 people live with stoma bags in South Africa, and less than 100 qualified nurses can administer this type of specialised care(18).

Ageing populations, sedentary lifestyles, obesity, smoking, urbanisation, and changing reproductive behaviours have all contributed to the increased incidence and prevalence rates of cancer(19). Overall, the increased incidence of CRC is primarily attributed to the increased exposure of populations to environmental risk factors, aligning with societal and cultural shifts following increased global Westernisation(20). The National Bowl Cancer Audit (United Kingdom) had previously published a report in 2022 which found that 37% of CRC patients had required stoma formation after rectal resection and, in a 2020 report, indicated that four out of 10 patients with CRC would require a permanent stoma to be formed(21, 22). Furthermore, Liu et al.(23) conducted a retrospective cohort study of CRC patients and found

that within 30 days of surgery, 19% of patients had experienced complications, and more than 31 days after surgery, 69% of patients had experienced complications with their ostomy. Complications arising from ostomies can be anywhere from 21-70% and is highly dependent on the stage of cancer, comorbidities, and individual patient risk factors(24).

Often, stomates will not contact their respective healthcare professional when complications arise, further exacerbating their complications(25). However, the problems that ostomy patients face are non-discriminatory in their presentation as patients with an ostomy experience at least one of the following: sexual difficulties, feelings of depression, bloating, irregular bowel movements, displeasure with one's physical appearance, alterations in wardrobe, challenges related to travelling, and a sense of fatigue(5). There is also a notable decline in the quality of life that CRC patients experience, with patients reporting stomas further worsening their quality of life(26). The overall impact of colostomy bags and stomas is a “net negative”, as reported by patients(5).

An issue that is not well documented is the financial burdens placed on the patients and their households when seeking stoma care, particularly in South Africa. Health systems extend beyond health improvement to safeguard individuals from the financial impacts of illness and death, ensuring access to medical care without undue financial burden(27). A comparative observation against Malaysia, an upper-middle income country also with a dual health system (public and private), where 51% of cancer-stricken households will experience catastrophic financial expenditures within one year of getting diagnosed, with more than 30% of combined household incomes going to cancer-related expenditure(28). Furthermore, among those patients who seek care in public hospitals and facilities, non-medical expenditures such as goods and services were seen to be key contributors to financial catastrophe.

The research and literature gaps become transparent with limited information about the financial risk protection of South Africans with CRC-related ostomies. The evident need to assess the associations between patient costs, both direct and indirect, how these patients cope with these costs, and how this modifies care-seeking behaviours is fundamental when representing an often-overlooked patient group. Additionally, an increased understanding of particular patient needs and their financial risk protection would undoubtedly influence future implemented interventions and possibly even guide policy decision-making when establishing National Health Insurance (NHI).

1.2. Problem statement

In South Africa, CRC is the third most diagnosed cancer among men and women and the fifth leading cause of cancer-related mortality, with 4 591 deaths reported in 2022(3). There is a liberal estimate of 60 000 people living with a stoma in South Africa, with this figure derived from the number of ostomy products handed out in a year(29). However, this remains questionable as ostomates in the public healthcare system may only receive two monthly bags. In contrast, those in the private healthcare system can receive up to 80 per month, significantly skewing the actual number of ostomates in the country(29). This disparity highlights the inequities in the private and public sector, underscoring the lack of accurate epidemiological and financial data on CRC and stoma care in South Africa. Despite CRC's increasing incidence, limited research exists on its economic burden or the financial coping strategies employed by affected households in low- and middle-income countries (LMICs), including South Africa.. This body of work seeks to add to the sparse research around ostomates in LMICs and to ensure that these individuals have adequate financial risk protection in the public sector as South Africa moves towards NHI and seeks to realise Sustainable Development Goal 3 (SDG 3) and target 3.8, as gazetted by the United Nations. This evidence gap becomes particularly concerning as without robust, context-specific data, policy responses to reduce CHE and support stoma patients may be ineffective or misdirected. This study seeks to address this gap by investigating CHE and coping strategies among CRC patients with stomas in a tertiary public hospital. By generating locally relevant data, this research aims to inform financial risk protection mechanisms and contribute to equitable cancer care policy planning in South Africa.

1.3. Research Aims and Objectives

The overarching aim of this study is to investigate the costs incurred and coping strategies undertaken by patients with ostomies due to CRC at Groote Schuur Hospital, Cape Town, South Africa.

Specific Objectives

1. To investigate catastrophic health expenditure (CHE) at the 10% threshold amongst patients with CRC-related ostomy at Groote Schuur Hospital, Cape Town, South Africa.
2. To investigate the financial coping strategies present in patients with CRC-related ostomy at Groote Schuur Hospital, Cape Town, South Africa.

1.4. Conceptual framework

This study adopts a framework by Pham et al. (31), which describes the socioeconomic impact of cancer. Cancer patients and their households may experience out-of-pocket (OOP) spending or the loss of income due to the financially exhaustive nature of treatments, interventions, and corresponding adverse effects(30). The ongoing nature of cancer treatment and care and the financial implications of this are key underpinnings in understanding how OOP costs affect patients financially(31). The interplay of direct and indirect costs and the knock-on effect on coping mechanisms and psychologically motivated financial decisions are key contributors to these patients' socioeconomic outcomes (31). Thus, employing a robust framework in assessing stoma care and CRC is critical. Hence, the adoption of the socioeconomic impact (SEI) framework by Pham et al. (31) is shown in **Part B; Figure 1**. The SEI framework relies on the four themes of causes, intermediate consequences, outcomes and risk factors.

Direct costs can be defined as the costs due to cancer that are paid OOP by the patients or their households, which can include direct medical costs derived from financial costs of healthcare such as consultation, medicines, hospitalisation, laboratory tests, as well as direct non-medical costs derived from the financial costs of seeking care or to manage the cancer such as transportation, supplements, and dietary changes(32). Indirect costs are defined as the costs indirectly incurred by patients and their households and are typically seen as time loss at work due to cancer but are also inclusive of the time loss experienced by household caregivers and a loss of income for both patient and caregivers attributed to absenteeism, or absconding business meetings(32).

The SEI framework involves the three-themed loop of “intermediate consequences”. These intermediate consequences arise due to the causes, i.e. direct and indirect costs. The psychological financial response is an indicator of the financial stresses that are often present in the diagnosis phase of cancer, signifying the psychological effect as a response to the cost of cancer(31). The psychological financial response is the “psychological perception of the increase in household expenses that must now be managed as patients navigate cancer care”(30). This can be further classified as the financial experience, observing the perception of meeting the costs related to cancer care, or as the financial expectation, the perception of future expectations of financial ability to afford the expenses that come with cancer and stoma care(31). Both classifications can either be positive or negative. However, financial expectations often correlate to negative, worrisome thinking patients can experience when assessing their ability to work or utilising their savings to meet financial expectations(31).

Patients and their household’s financial ability to cope with the cost of cancer care underpin the theme of financial coping ability(32). However, this too is subdivided into the household health expenditure ratio, which is the total OOP health expenditure as a percentage of household income and the household available savings and assets, which assess the liquidity of the available household savings and the corresponding assets that members of the household may possess(31).

Financial coping behaviours are already well established in assessing household expenditure, in the SEI framework, this theme addresses the behaviours patients and their households adopt due to the increased costs attributed to cancer(32). This theme comprises increased liquidity and resources, expenditure reduction, and treatment delinquency. Increased liquidity and resources are often a byproduct of monetary borrowing behaviours, asset sales, welfare/social assistance programs, and the use of savings, a premature return to work(31). Whereas expenditure reduction is the delayed consumption of non-health goods and services, inclusive but not limited to food, leisure activities, education, electricity, and delayed investments(31). Treatment non-adherence is an effect of these increased costs, where patients will take less than their prescribed medications, ignore dietary regiments, or miss physician consults as a means of coping(33).

All three elements in the intermediate consequences loop are tightly linked to one another, the bi-directionality present within each of these themes is caused by the direct and indirect costs of cancer care(31).

The SEI framework also includes the theme of risk factors. Factors inherently contributing to the increased socioeconomic impact of cancer can be discussed as sub-themes, all linked to this increased risk(32). These risk factors range from disease characteristics, individual factors, household factors, societal factors, and contextual factors such as the health system and its policies (31).

Finally, the “socioeconomic outcome” output theme in the SEI framework is a broad, multi-dimensional outcome that seeks to interlink a patient’s financial outcomes along with their experiences and behaviours, as these outcomes do not occur in isolation and typically(31).

1.5. Methodology

1.5.1 Study site

The study site will be the stoma clinic at Groote Schuur Hospital in Cape Town, Western Cape. This site is a large academic tertiary hospital with a wide catchment area and many referrals from primary healthcare clinics and care centres.

1.5.2 Study design and participants

The study will utilise a quantitative methods study approach, collecting information from patients using the attached questionnaire, found in Appendix 4, at a single point in time (cross-sectional survey). This survey will be administered in a quiet, private room at Groote Schuur Hospital after patients receive stoma care. Questions on coping strategies, costs and emotional coping allow for a richer quantitative study, painting a picture of the patient and their household, not only of the financially quantifiable aspects that patients suffering with CRC-related ostomies experience but also the many ways they cope(34). The study participants are patients who present with an ostomy to the stoma care clinic at Groote Schuur Hospital, Cape Town. These participants will be recruited using the following eligibility criteria:

Inclusion criteria: Patients over 18 years of age, diagnosed with CRC, clinically staged, currently receiving stoma care and or treatment, and who are more than 30 days post stoma formation.

Exclusion criteria: Patients who are less than 18 years of age, who may be diagnosed with CRC but do not have a stoma, or who have a stoma for less than 30 days, and those who are unwilling or unable to provide consent.

Patients who are less than 30 days post-stoma formation are excluded as is part of the immediate post-operative phase, as such costs related to stoma care and other financial coping strategies would not be fully incurred or experienced. Selecting patients beyond this threshold ensures that there is sufficient time for a patient to engage with stoma care practices, incur relevant costs, and develop coping mechanisms providing more accurate and meaningful data for the study's objectives.

1.5.3 Sample size and sampling procedure

Given the limited population of stoma patients, particularly those confined to the Western Cape who seek care at Groote Schuur Hospital, the study acknowledges that a low sample size will likely be achieved. After consultation with the colorectal cancer division's lead surgeon, we agreed upon a sample size of around 20 to 30 patients.

Due to the specificity of our inclusion criteria, the unique context of the hospital clinic, and the niche research area, a small sample size is anticipated. The selection of participants is based on the available population within the defined criteria, as well as the feasibility of conducting the study, given the hospital's available resources.

A purposive sampling methodology will be employed to select participants for this study. Purposive sampling allows for the deliberate selection of participants who meet the specified criteria, ensuring that the sample reflects the characteristics of the target population within the hospital's stoma care facilities. By employing purposive sampling, we aim to capture the experiences and perspectives of stoma patients within the criteria we have set despite the limited population size.

1.5.4 Data

This study will utilise primary data, which will be collected at Groote Schuur Hospital in Cape Town, Western Cape. All data collected will be from patients who are post-operative and who already have a stoma due to, but are not limited by, either colon, rectal, or colorectal cancer. To our knowledge, this is the first study to be conducted in South Africa. All data will be collected using a survey adapted from the World Health Organization's Tuberculosis Patient cost survey, a validated instrument widely used in global health research. The survey will be reviewed and adapted to ensure cultural and linguistic appropriateness for the South African context.

1.5.5 Variables

Dependent Variables

The dependent variable of this study is CHE, which would be derived through calculations involving the household income and total OOP health expenditure. For this study, we use the 10% income threshold(35).

Independent Variables

The independent variables of this study are seen as the direct and indirect costs that patients incur in seeking stoma care. For direct costs, these variables include medical consultations, medicines, and stoma supplies, including bags and transport. Similarly, variables generated from indirect costs impact employment, income, and care responsibilities in the household. The complete list and specifications are presented in Appendix 5.

Control Variables

The control variables in the study included age, gender, socioeconomic status, education status, marital status, employment status, stage of cancer and insurance status.

1.5.6 Data Analysis and Model specification

First, a simple descriptive analysis, such as frequencies and means, will be performed on binary, categorical, and discrete variables, respectively. Univariate analysis will be performed to compare average mean costs, followed by a penalised logistic regression analysis on Catastrophic healthcare expenditure, which will be performed by dividing total OOP healthcare expenditure by the total household expenditure, assessed at the 10% level. The penalised logistic regression is necessary as the sample size in the study is small. All analyses will be conducted in STATA 15.1.

1.5.7 Research Limitations

The proposed study is not immune to limitations. As this study utilises a cross-sectional study design and purposive sampling, the generalisability of the findings may be scrutinised. This limitation was acknowledged upfront, and the study is positioned as exploratory, aiming to provide contextual insights rather than population-wide estimates. Future research could adopt multi-site sampling or longitudinal study designs to strengthen external validity. This can be compounded by the contextual setting being a tertiary academic hospital in the Western Cape, which may not indicate the patient experiences shared by other ostomates in other provinces. Hence, findings are interpreted cautiously, and recommendations are made with recognition of this contextual specificity. Future studies could extend recruitment to rural settings and multiple provinces. The limited sample size due to the small number of ostomy patients utilising the stoma care clinic may also detract from the generalisability of the study findings. As this study is a purposive sample, there is the risk of selection bias, leading to misrepresenting the sample and the corresponding results. To minimise this risk, clear inclusion criteria were applied and recruitment procedures were transparently reported. Future research may benefit from randomised or stratified sampling where feasible. As this study is collecting data through validated surveys, both quantitative and qualitative, there is the risk that self-reporting bias may occur as patients may not accurately recall or report their behaviours and experiences. To mitigate this, validated tools were used and patients were assured of confidentiality, thereby encouraging honest reporting. Triangulation with clinical records in future studies could further reduce self-reporting bias. Finally, given the inherently complicated nature of stomas, the patients may face challenges regarding their participation,

discomfort, and overall sensitivity around the topic, resulting in decreased participation rates and the possibility of incomplete data sets. This was addressed through sensitive interviewing techniques, provision of privacy, and the option to withdraw at any time without consequence. Future studies could incorporate additional psychosocial support or involve stoma associations in recruitment to enhance participation.

1.6. Ethical considerations

In conducting our study on the costs incurred and care-seeking behaviours among stoma patients, we are committed to upholding stringent ethical standards to safeguard the rights and well-being of our participants.

Central to our approach is informed consent, where participants will be fully informed about the study's objectives, procedures, and potential risks and benefits before deciding if they would like to participate and then providing their consent if they want to continue. We will explain that they are free to withdraw at any stage without consequence to their care. We recognize the importance of privacy and confidentiality in preserving the dignity and anonymity of our participants. Thus, all data collected will be anonymized and securely stored in a locked drawer at the Health Economics Unit at the University of Cape Town to prevent unauthorized access.

Moreover, we hold utmost respect for the autonomy and decision-making of our participants, ensuring that they have the right to withdraw from the study at any time without facing repercussions. In our endeavour to minimize harm, we are sensitive to the potential emotional impact of discussing stoma care experiences and have implemented measures to be as mindful and cautious with the line of questioning and how we conduct patient interviews.

Furthermore, we are committed to ensuring that our study has tangible benefits for both participants and society, focusing on improving stoma care services and informing healthcare policies.

Application of this proposal will be made to the University of Cape Town Human Research Ethics Committee (HREC), which will then be followed by submission to the Western Cape Department of Health to obtain ethical approval for the initiation of this study at Groote Schuur Hospital.

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2. PART B: Structured Literature Review

This section provides a concise literature review on CRC-related stomas covering key aspects related to the global burden of disease that CRC poses, stoma formation and CRC management, the economic impact of CRC and stoma care, financial coping strategies employed by patients and applicable to health economics, frameworks used to guide this research, as well as a methodological review of CHE, indirect and direct costs, as well as an empirical review of existing literature.

There are three main sections: 2.1 Conceptual/Theoretical Literature Review, 2.2 a Methodological Literature Review and 2.3 an Empirical Literature Review.

2.1. Conceptual/Theoretical Literature Review

2.1.1 Introduction to CRC

Global Epidemiology of CRC

Colon and rectal cancer, colloquially referred to as colorectal cancer (CRC), is the third most diagnosed and second most fatal cancer globally in both men and women (1). Moreover, CRC is the second leading cause of Disability Adjusted Life Years (DALYs) globally amongst all cancers (2). The incidence and mortality rates associated with CRC have more than doubled from 1990 to 2019 (2). CRC was responsible for approximately 9.3% of all cancer-related deaths in 2022 (3). Historically, CRC has shown trends indicating increased incidence in high-income countries (HICs), with low incidence reported in low-income countries (LICs) (4).

The last three decades have shown that temporal incidence patterns of CRC have either shown no change or decreases in higher socio-demographic index (SDI) countries, while low-income and transitioning global economies have shown to be steadily increasing (5). The SDI is a combined index measuring educational, economical, and fertility rates globally, often with health outcomes tied to this measure (6). CRC is ranked among the top five in incidence and mortality across these SDI regions (very high, high, medium, and low). However, transitioning countries typically display a three to four times lower incidence rate when compared to those countries that have already transitioned, although mortality does not display such variance as these transitioning countries experience higher case fatalities (3). The decrease in incidence in these developed countries can be attributed to the adoption of healthier diets (i.e., fruits and fibre) and screening initiatives, whereas the increase in incidence in developing countries can be attributed to behavioural and dietary changes whereby physical inactivity, increased consumption of processed foods, smoking and alcohol use have become more widely observed (7).

CRC is a disease historically linked to age, with disease incidence occurring typically in those above the age of 50 (8). Nevertheless, there is an observable global trend in both incidence and mortality rates of early-onset CRC in individuals younger than 50 years old, with a

particularly concerning increase in high-income countries (9). In the United States of America, early-onset CRC is projected to nearly double by 2030 (10), while Europe has seen an increasing incidence of CRC in people aged 20-49, particularly those aged 20-39 (11). Australia also experienced a rise in CRC cases among those under 40, with rates stabilizing or declining in older adults (12). Between 1990 and 2019, CRC incidence grew significantly in East Asia and Latin America among individuals aged 15-49 (13).

A study from North America has shown that the incidence of CRC in North America increases by 2-fold every 5 years until 50, whereas after 55 years of age and beyond, there is a 30% increase every 5 years (14). However, the incidence rate in individuals aged 55-59 is 15% higher compared to those aged 50-54 (68.4 vs 59.5 per 100,000 population), which can be partly attributed to the interruption of the natural age-related risk by the initial CRC screening and the detection of existing cancers in the younger age group (14).

More significant disparities exist within the current CRC epidemiology, sex, racial/ethnic, and geographic factors, all of which influence the overall epidemiological burden of disease. The lifetime risk for developing CRC among men and women is roughly similar, 4.4 to 4.1%, respectively, with the overall incidence among men being 31% higher than in women (14). These sex disparities become further emphasised when factoring in age as incidence in men and women can be comparable up to age 45 but present a 40 to 50% higher incidence among men aged 55 to 74 years old compared to women (15). The reasons for the sharply increased incidence are unknown but can be assumed to be the complex interaction of cumulative risk factor exposure and sex hormones (15).

CRC incidence is 3 to 4 times lower in LMICs than in HICs (3). This trend is shifting as CRC incidence has steadily increased, partly due to increased risk factor exposure and ageing populations (16). However, the mortality to incidence ratio is significantly higher in LMICs, with this imbalance being partially explained by the high levels of risk factor exposure in HICs and the low rates of screening in LMICs (17, 18). When looking at Africa, the second largest and most populous continent with roughly 16% of the global human population, there is limited data on regional specificity for CRC epidemiological trends (19). A meta-analysis by Arhin et al. (16) showed annual age-standardised incidence rates for Africa at 6.30%, with incidence rates higher among men than women. When stratified by subgroups, North Africa had higher incidence rates than Sub-Saharan Africa (SSA), while West and North Africa had higher

incidences than Western and Southern Africa (16). However, there are no country-level population screenings or guides in Africa, so the estimates are much lower than the actualised disease burdens in Africa (20).

These epidemiological disease burdens can be further explained through risk factors. Non-modifiable risk factors are the inherent characteristics, such as age, sex, and genetic predisposition, that cannot be altered, whereas modifiable risk factors encompass lifestyle and environmental determinants, including diet, physical activity, and tobacco use, which may be addressed to reduce the risk of colorectal cancer.

Non-modifiable risk factors

Ethnicity/race

As per a 2017 Centre for Disease Control report, CRC incidence and mortality rates vary based on sex, race, and ethnicity (22). Black men and women have the highest incidence and mortality rates, followed by white individuals, Asian or Pacific Islanders, and American Indians or Alaska Natives (22). Non-Hispanic men and women experience higher incidence and mortality compared to their Hispanic counterparts (22). In some Asian American groups, such as Korean, South Asian men and women, and Chinese women, late-stage CRC incidence is 30 to 60% lower (22, 23). Compared to white individuals, black individuals had lower rates of rectal cancer but higher rates of distal and proximal CRC (24). African Americans are more likely to have tumours and proximal tumours compared to white individuals (25, 26).

In South Africa, the 2022 national cancer registry has shown that the incidence of CRC differs between ethnic groups. Age-standardised incidence rates show that the highest rates of CRC are present in White, Asian and Coloured communities. When further stratified, we see that White males (25.91 per 100 000 population), White females (19.04 per 100 000 population), Asian males (18.21 per 100 000 population), Coloured males (14.87 per 100 000 population) and Asian females (11.47 per 100 000 population) were the most significant contributors to CRC incidence (27). Interestingly, Coloured females (9.72 per 100 000 population), Black males (5.25 per 100 000 population) and Black females (3.54 per 100 000 population) were the lowest contributors to CRC incidence rates (27). However, something not well discussed

in literature is the confounding nature of ethnicity in a South African context, particularly for CRC and how cultural beliefs and access to care could impact incidence rates.

Gastrointestinal Disorders

Chronic conditions affecting the gastrointestinal tract, such as IBD, Crohn's disease and ulcerative colitis, present a higher risk of developing gastrointestinal and extra-gastrointestinal malignancies (28). The mechanism for which this occurs can be attributed to mucosal inflammation, sporadic mutations, and increased cell turnover (29). A 2013 meta-analysis examining more than 45 000 patients across 13 trials in the United States had shown that the risk of CRC among patients with IBD was three times higher than those without IBD (30). This is further compounded by findings of a 2019 retrospective study also in the United States, which included 269 early-onset CRC patients, 2802 late-onset CRC patients, and 1122 controls had shown that early-onset CRC patients had a 3 times higher chance of developing IBD (31).

Diabetes

Patients who have type 2 diabetes mellitus (T2DM) are at an increased risk of developing CRC (1). A Sub-Saharan Africa (SSA) case-control study demonstrated that T2DM was independently linked to CRC development (32). The findings of this study are consistent with the findings of a study carried out in the USA that had explored the association between CRC and T2DM where 22 000 CRC patients were assessed, the findings of which indicated increased prevalence among those patients with proximal malignancy as compared to those with distal or rectal malignancy (24). The proposed underlying mechanism for the link between T2DM and CRC can be attributed to hyperinsulinemia acting on the colon to cause rapid cell proliferation (1).

Family History and genetics

When assessing family history, we take the definition as one direct first-degree relative who has/had CRC (30). A study observing the site-specific risk of CRC in the Korean population

showed that a familial history of cancer had a strong association with the development of proximal and distal colon tumour formation (33). A meta-analysis, including 8091 cases of CRC over 16 North American studies, has shown that the mean risk of CRC among individuals with a family history of CRC was almost 2 times higher than those with no family history of CRC (30). In a 2020 retrospective study looking at the US population and risk factors associated with developing CRC, findings showed that patients who presented with early-onset CRC and a family history of CRC were at a higher risk for developing CRC than those who did not have a family history of CRC (31).

The two most common forms of hereditary CRC are that of familial adenomatous polyposis (FAP) and Lynch syndrome (34). Lynch syndrome is the most common hereditary CRC, accounting for 24% of all CRCs (35). Gene carriers increase their lifetime risk of developing CRC by over 60% (34). FAP, on the other hand, is a rare genetic disease which in which there is uncontrolled formation of gut tumours and if untreated, the risk of developing CRC is 100% (34).

Age and Gender

Young individuals may develop malignancies, but there is a far greater risk of developing CRC over the age of 50 (1). Men and women do not present with CRC at the same timeframes; the mean age of colon cancer diagnosis in the USA for men is 68 years old, whilst women are likely to be diagnosed around 72 years old (36). Similarly, the average age of diagnosis for rectal cancer in both men and women in the USA is 63 years old (37). An increase in age is a risk factor in the development of CRC. A study by Steele et al. (37) of almost 8000 CRC patients found that 77% ranged from 50 to 79 years old. Although both men and women are at risk for developing CRC, men are disproportionately more likely to develop CRC than women (26). A USA comparative study showed that patients with early-onset CRC were more likely to be males (31). Notably, when comparisons are made with SSA, we see the proportion of early-onset CRC incidence up to 38%, whereas in the USA, only 1.9% of CRC patients are classified as early-onset (38). The rise in early-onset diagnosis, typically in patients under 40, could be attributed to the largely youthful population dynamics in SSA countries, which these countries could also be experiencing rising incidence (39).

Modifiable risk factors

Although early-onset CRC development is linked to non-modifiable risk factors, CRC presentation is often sporadic and linked mainly to dietary and lifestyle patterns (40). This can be further substantiated by evidence from the USA and UK, which have shown that 47% and 45% of CRC cases are attributed to modifiable risk factors (40). In Africa, the dynamic nature of diet and lifestyles, particularly in highly urbanised settings, have seen increased adoption of diets consumed in developed nations, with high levels of CRC incidence, accompanied by the sedentarism of urbanisation resulting in a CRC incidence in SSA being primarily attributed to modifiable risk factors (41).

Obesity and Body Mass Index

A meta-analysis investigating the relationship between CRC and the body mass index (BMI) of more than 66 000 CRC patients in 23 studies from both LMICs and HICs found that the risk of developing CRC had increased by 10% every 8 kg/m2 of BMI (30). This evidence is compounded by a prospective study of more than 184 000 participants, which assessed the waist circumference and BMI in relation to CRC, showing that increasing waist circumference was directly proportional to the increased risk of developing CRC in both men and women (42). The mechanism responsible for the relationship between CRC and BMI is explained by the insulin-resistive properties of obesity, which typically include hyperinsulinemia, oxidative stress, chronic inflammation, IGF-1 elevation, and DNA damage (43). Physical activity, or rather physical inactivity, has shown to increase the risk of CRC development, whereas physical activity has been shown to increase the survival rates of patients with CRC. This is correlated with the findings from a meta-analysis across 52 studies that found an inverse relationship between the intensity and frequency of physical activity and a patient's CRC risk (44).

Diet and Alcohol Consumption

A systematic review concluded that processed and red meat, including lamb, beef, and pork, convincingly increased the risk of developing CRC by 20 to 30% (45). A USA meta-analysis showed that five servings per week of red meat presented a 13% increased risk of developing CRC (30). Furthermore, findings from a cohort consisting of 4000 patients elucidated that the relationship between frequent red meat consumption and proximal and rectal cancer incidence in males and females, respectively, was directly proportional (30). Recommendations on the daily consumption of red meat are 500g per week or 70g per day (45). Conversely, white meat such as poultry and fish are deemed safe and have no associated risk with the development of CRC (46). The mechanism behind the association of CRC with excessive red and processed meat consumption is unknown but can be inferred through carcinogenic compounds that are produced during the cooking process (47).

The regular consumption of alcohol, whether daily or weekly, has a significant association with the risk of developing CRC (36). Individuals with moderate alcohol consumption (up to 4 drinks per day) are at a 21% increased risk of developing CRC, whilst those with heavy alcohol consumption (more than four drinks per day) are at a 52% increased risk of developing CRC (48). This relationship between alcohol consumption and CRC is time-dependent, where the longer the consumption periods, the higher the risk for CRC (49). A Danish population cohort study which had followed up participants for more than 14 years had shown that drinkers who had consumed more than 40 drinks per week were at twice the relative risk for rectal cancer as compared to those who were non-drinkers (50). Similarly, a cohort of the Korean population with more than 1000 women and 3000 men had shown that heavy and moderate alcohol consumption was associated with an increased risk of distal colon cancer in men and rectal cancer in women (33). The mechanism by which alcohol influences CRC is based on ethanol metabolism and the production of metabolites that have a carcinogenic effect on the colon (51). The carcinogenesis of CRC is primarily attributed to the formation of acetaldehyde, a metabolite occurring through ethanol metabolism, and impacts many biochemical and cellular processes (52). Typically, alcoholics are more susceptible to having bad diets, often lacking in fibre and folate, contributing to the development of CRC (51).

Smoking

Cigarette smoking is a modifiable risk factor in the development of CRC, with the risk of CRC increasing with the number of cigarettes smoked (30). When compared to non-smokers, smokers had presented with a relative risk for CRC of 1.06 for five pack-years, 1.11 for 10 pack-years, 1.21 for 20 pack-years, and 1.26 for 30 pack-years (30). Active smoking shows an associated decrease in CRC survival rates, along with an increased likelihood of the development of rectal malignancy as opposed to distal or proximal malignancy (24). When compared to non-smokers, males who smoke had a 39% higher risk of distal cancer, while female smokers had a 20% higher risk of developing proximal cancers when compared to non-smokers of their respective genders (53). It should also be noted that female smokers were more susceptible to developing rectal cancer when compared to their smoking male counterparts (53). Of all the harmful compounds found in cigarettes, nicotine is the most well-studied, and its metabolites are highly carcinogenic, being responsible for enhancing the proliferation of CRC carcinoma cells by the upregulation of acetylcholine and noradrenaline receptors (54, 55).

2.1.2 CRC in the South African Context

CRC is a significant health concern in South Africa, estimated as one of the country's top five malignancies, with a projected increased incidence due to population growth, ageing and numerous risk factors (56). The age-standardised incidence and mortality rates per 100 000 people in Africa for 2022 are said to be 8.2 and 5.6, respectively (57). In SSA, South Africa is the leader in CRC incidence, strongly marked by ethnic disparities (58). In a prospective longitudinal study, findings showed that black South Africans tended to develop CRC at a younger age than their white counterparts (59). This was further substantiated by a South African study in which young black South Africans (under 50 years old) were more likely to present with CRC compared to their white counterparts, particularly with proximal malignancy that can be due to mismatch repair deficiencies or methylation promoters (60). The cumulative lifetime risk for developing CRC in South Africa is 0.81 and 1.31 for females and males, respectively (27). At the time of CRC diagnosis, it is said that up to 25% of patients will have metastatic tumours, typically in the liver (61, 62). More than 50% of patients who experience curative surgical resection are expected to have a recurrent tumour either as a local site or

metastatic disease (63). This becomes further exacerbated when assessing the projected age-standardised incidence and mortality rates in South Africa, which are expected to increase by more than 80 and 100%, respectively, by 2045 (64).

Evidence around CRC presentation is limited. However, a study conducted at Charlotte Maxeke Johannesburg Academic Hospital found that within a cohort of 162 patients, 37% of patients had presented with non-metastatic stage 3 CRC, whilst 63% of patients had presented with metastatic CRC at stage 3 or 4 (65). The five-year overall survival rates for clinically staged CRC are; 93.2% for stage 1, 72.2% for stage 2, 52.3% for stage 3, and 8.1% for stage 4, with these patients having roughly 12 months of chemotherapy treatment alone (66, 67). Surgical resection of the primary tumour would result in the most significant survival benefit for the patient, should resection be possible (68). A study assessing the 5-year survival rates of South African CRC patients utilising private healthcare services reported that one-third of patients would present with either liver or pulmonary metastasis, with 7% of these patients being eligible for metastatectomy (69). However, of these patients who underwent metastasectomy, the survival rates had considerably declined once liver or pulmonary metastasis was present, survival rates for CRC only, CRC with liver metastasis, CRC with pulmonary metastasis, and CRC with liver and pulmonary metastasis were 71.7%, 57.3%, 31.5% and 26.0%, respectively (69). Resections performed were in line with international outcomes, but the number of resections performed in South Africa on these patients lagged heavily compared to international literature.

CRC prevention programs such as screening are common in HICs, in South Africa, these programs have a very low likelihood of being implemented due to the complexity within care pathways that would affect the execution of screening programs (70). Hence, no programs exist for early detection and screening in South Africa.

2.1.3 Treatment and care

Historically, the pathway for cancer patients involves either surgery, chemotherapy, radiation, or a combined treatment plan involving a mix of these treatments. Although patients with metastatic disease have a much poorer prognosis when it comes to CRC, the use of adjuvant and primary therapies has increased the survival rates of patients, allowing for prolonged life

should surgical removal of the tumour not be possible (71). Radio/chemotherapy can be used in tumour stabilisation before or after surgery (71). Globally, more than a quarter of all CRC cases are identified at the advanced stage (stages 3 and 4), with metachronous metastases affecting 20% of the remaining cases, making curative surgical resection challenging and often life-threatening (40).

The most common chemotherapy treatment regimen that is globally accepted includes the use of either single agent, i.e., fluoropyrimidine, and multiple agent therapies, these are commonly a mixture of fluoropyrimidine, capecitabine, irinotecan, or oxaliplatin, and are widely used as the primary mainstream approaches in CRC chemotherapy (1). Patients at low risk of deterioration or those who have poor performance on alternative treatments have suggested adherence to single-agent therapies, similarly, the addition of additive agents shows comparable efficacy but presents with irreversible side effects such as decreased tumour selectivity, systemic toxicity, variable immune resistance, and unsatisfactory treatment response (72). However, novel approaches to CRC treatment, such as gene, adjuvant, nano, monoclonal antibody, and natural or traditional therapies, have gained significant traction over the past few years but have yet to be integrated into the existing standard of care model for CRC (1).

2.1.4 Ostomy Formation in CRC Management

Types of Ostomies and Indicators

The term "ostomy" originates from the Greek word "stoma" (st?µa), signifying "mouth", and in the medical context, stoma/ostomy denotes the surgical establishment of an opening in a hollow organ on the body's surface to facilitate the discharge of waste products (73). Ostomies can be temporary or permanent and allow the waste matter to be eliminated effectively (74). There are three main types of ostomies: colostomies, ileostomies and urostomies. A colostomy is the diversion of the large intestine connected to the left or right abdominal wall, depending on the part of the colon being affected (75). Colostomies are used in the case of diversion or decompression, whereas colonic diversion is often performed in the case of trauma or distal elective surgery involving the rectum (76). Decompression is required if colonic obstruction

has occurred, typically through sigmoid volvulus and left-side tumours (77, 78). Colostomies are used in the case of rectal cancer, obstruction in the large intestine, a birth defect, faecal incontinence, perineal fistulas, or abdominal infections (79).

Similarly, an Ileostomy is the diversion of the ilium to the lower right side of the abdominal wall (80). This can be due to irritable bowel disease such as Crohn's disease or ulcerative colitis (79). Both ileostomies and colostomies do not rely on sphincters that allow for stool control, as found in the anus, and use of a "pouch" or stoma bag is necessary. Urostomies differ from colostomies and ileostomies as they are much smaller in size, located towards the centre of the lower abdomen, and used in the case of bladder cancer (81).

Ostomies are a critical surgical intervention in the management of various malignant and benign conditions such as gastrointestinal malignancy, inflammatory bowel disease, perforation or obstruction in the gastrointestinal tract, severe wounds to the perineal region, as well as end-stage incontinence (74). The most common indicator for ostomy creation is that of bowel, colon, and rectal cancer, with the latter two being jointly referred to as colorectal cancer (73).

Incidence rates for the construction of a stoma occur as two peaks. However, at varying ages, the first being the formation of an ileostomy at 20 to 40 years of age in treating inflammatory bowel disease, with the second being colostomy formation occurring from 60 to 80 years of age due to CRC (82). However, the increased incidence of CRC has pushed this to become earlier as CRC infiltrates the age groups between 40 and 60 years old, often with the development of a definitive permanent stoma (82). Indicators necessitating a stoma will vary based on the geographic location and the disease burdens in those countries, for example, if IBD is not common in a particular region of the world, then the early development of an ileostomy may not be required. Similarly, the other indications for stoma construction are that of Hirschsprung's disease and imperforate anus (82).

Surgical Practices and Outcomes

CRC management, particularly late-stage malignancies, requires the creation of colostomies and ileostomies. The creation of these ostomies is often associated with the increased

likelihood of surgical complications, especially when compared with other surgeries (83). A study assessing the National Surgical Quality Improvement Program in the USA showed 37% and 55% unadjusted complication rates for elective ostomy cases and emergency operations, respectively (84). The complications that were commonly experienced were prolonged postoperative ventilation, sepsis, pneumonia, myocardial infarctions, acute renal failure and a mix of superficial, deep, and organ space surgical site infections, with patients experiencing a median hospital stay time of 10 days (84). Of these, the unadjusted morbidity rates for patients were higher in emergent procedures as compared to elective cases, similarly, unadjusted mortality rates were seen to be higher in emergent cases as opposed to elective surgery (84). However, these findings are not solely due to the diverse patient characteristics, demographics of populations, specific procedures, or hospital characteristics. It should be noted that although these pre-existing conditions correlate to increased post-surgical risk of complications, the variation of a hospital setting and the surgeons' practices contribute significantly to these varying morbidity and mortality rates, as even when adjusted, they remained significant (84).

In the United States, more than 1 million people have a history of CRC, making this patient group one of the largest in its respective geographic location (85). Of this patient group, it is estimated that around 20-35% of patients have received either a temporary or permanent stoma throughout their illness (86). Implementing bowel screening and enhanced perioperative patient care has increased the percentage of patients surviving 5 to 10 years post-diagnosis (87). However, existing literature has highlighted a minimum of at least 20 to 30% of patients having non-resectable or inoperable tumours at laparotomy due to comorbidities or the tumour burden presented by the patient (88, 89). It is estimated that the median survival rate for metastatic CRC is roughly 6 months for those who do not receive palliative chemotherapy (90). Typically, patients presenting with advanced-stage disease present as elective or for emergencies such as haemorrhage, perforation, or bowel obstruction (89). Those patients presenting in the elective setting with advanced-stage disease often undergo palliation via radio/chemotherapy, colonic stenting, surgical faecal diversion by a stoma or bypass, and noncurative resection (89). The use of noncurative surgical resections can prolong the initiation of chemotherapy and radiotherapy, proven to provide significant value for patients with stage IV CRC (91). However, noncurative surgery in the form of ostomy formation is a necessary procedure in the symptomatic control of perianal disease,

obstructions, or fistulas (89). Ostomy formation may also be required prophylactically to prevent obstruction when patients are undergoing chemo or radiation therapy.

These patients who present with these malignancies are subsequently placed on aggressive treatments inherently designed to cure their disease. However, when curative treatments prove ineffective and continued metastasis, palliative treatment is the only remaining option.

Impact of Ostomies on Quality of Life

Ostomies present significant challenges and significantly impact a patient's quality of life, which spans physical, psychological, social, financial, and even spiritual domains (92). Patients presenting with CRC-related ostomies present with a myriad of complications, such as stenosis, prolapse, dermatitis and parastomal hernias (93). Some of the complications that these patients experience go untreated for years, often due to ostomates contacting their healthcare professionals too late or not at all (94). Quality of life (QoL) can be understood as the subjective measure of a patient's satisfaction level in terms of their well-being and overall health, with this metric being critical in the outcomes related to cancer survivorship owing heavily to the psychological, social and physical QoL (95). Grant et al. (96) found in several studies that intestinal ostomies, both cancer-related and non-cancer-related, significantly contributed to a patient's concerns regarding their QoL. In a study by Anaraki et al. (97), the overall QoL of patients decreases with the presence of a stoma, with just over 70% of patients reporting issues with depression and sexual activity, whilst this becomes further exacerbated by the underlying disease resulting in the stoma, location of their stoma, and whether the ostomy was permanent or temporary.

Krouse et al. (98) also found that colostomy presence had negatively affected their QoL between non-cancer and cancer patients. However, other studies have shown that up to 80% of long-term colostomates have depicted acceptable QoL scores when measured by the Short Health Scale (SHS), indicating that the effects of long-term ostomy on QoL are feared by patients but not as bad as they expected showing no significant impact (99, 100). When assessing the social well-being and complications that these ostomates experience, Gooszen et al. (101) found that the primary determinant of social isolation in patients was attributed to leakage of their stoma and subsequent skin irritation. Adaptations enforced psychosocially are

critical, as demonstrated by the psychosocial adaptation to a stoma, which has been studied prospectively in patients with a permanent stoma (102). Self-efficacy is defined as one's confidence in one's capability to perform specific social functioning tasks; in this case, stoma care plays an essential role in fostering compliance (102). However, self-efficacy is often not noticed as the majority of patients rely on their relatives for stoma care, highlighting a gap in fostering independence in this critical aspect of adaptation as well as the cultural nuances that exist between different regions not only within a macro-level country perspective but also at a micro-level in households (100).

Despite the difficulties and challenges that are present, ostomies are a crucial and life-saving procedure, often necessitating a balance between treatment benefits and QoL considerations, with healthcare providers playing a pivotal role in supporting these patients and addressing their ostomy-related concerns to improve overall QoL (103).

2.1.5 Economic Impact of CRC and Ostomy Care

Direct and Indirect Costs of CRC Treatment

CRC presents a substantial burden both to a patient and the health system, this burden is not just resource-intensive but also financially strenuous (104). The total healthcare costs that patients are exposed to are direct and indirect. These direct costs comprise medical costs, including all medical costs involving diagnosis, treatment, rehabilitation, and ambulatory, often seen as physician consults, medication, hospital stays, diagnostic tests, and medical equipment (i.e., stoma bags) (105). Direct non-medical costs can be understood as the costs patients are privy to in seeking or accessing care but not in the medical care itself, this is often seen as transportation fees, accommodation fees if they have to stay overnight to access the healthcare facilities, or other patient-related costs (105). Indirect costs are categorised as tangible and intangible costs. Tangible costs are linked to the financial impact that patients and their families experience due to premature death, disability, or disease (105). Macroeconomically, these tangible costs are usually quantified as lost productivity and expressed anywhere from days to years. Lastly, intangible costs indicate burdens greater than

finances; these include the quality of life of a patient, the pain and suffering an individual may endure, and psychological burdens borne by the family or caregivers of the patient (105).

Catastrophic Health Expenditure

Catastrophic Health Expenditure (CHE) encompasses the expenditures that jeopardise a household's financial stability and safety (106). CHE does not necessarily arise due to exorbitant or extraordinary medical costs but instead exists as a significant proportion of a household's income eroded due to medical costs, typically benchmarked at a 10% threshold where total health-related expenditures exceed 10% of the household's total income (106). However, the World Health Organisation (WHO) has explained that CHE arises when out-of-pocket healthcare costs equal or exceed a household's capacity to pay, as this is a relative measure of financial capacity, certain households experience catastrophic healthcare spending even when their out-of-pocket expenses, though not necessarily exorbitant, surpass their capacity to pay (107). While there is no universally agreed-upon threshold for categorizing healthcare expenses as catastrophic, the WHO recommends a benchmark of 40% of household payment capacity after subsistence needs are met for developed countries whilst acknowledging that this threshold may vary depending on the specific circumstances and economic context of the country being assessed (107). Subsistence needs are understood as the minimum requirements for a household to sustain basic living standards, including necessities like food, shelter, clothing, and essential household items. Non-subsistence income, by contrast, refers to the residual income available after deducting the amount required to cover these essential needs. This is calculated by subtracting the subsistence threshold, represented by the poverty line, from the household's total income (108). Thus, any remaining income after satisfying subsistence requirements constitutes the household's non-subsistence income (109). According to the WHO, CHE is incurred when the OOP healthcare expenditure is either greater than or equal to the payment capacity threshold for that household (107).

Universal Health Coverage and Coping Mechanisms for High Healthcare Costs

The evolution of health systems occurred in such a way that users were protected from the financial hardships they may experience when paying for care (110). Despite this, OOP payments for healthcare are still the reality for millions of people around the world, with these OOP payments being the most regressive form of financing for a health system, hence the focus of universal health coverage (UHC) in mitigating the impact of these payments is heavily influenced by the actualised burdens these patients experience (111). Financial hardship/catastrophe is often representative of the extent to which health systems affect individuals in non-medical scenarios, as households may experience financial hardship or impoverishment due to accessing medical care, further emphasising the importance of UHC in a health system (111).

The concept of financial risk protection (FRP), or rather the absence of financial hardship, is a key pillar in achieving UHC, as the capacity of a health system to protect the people who use it from financial hardship due to OOP payments is critical across all countries and income levels (112). FRP often directly reflects how patients engage in trade-offs, particularly around paying for medical treatment and their subsistence needs, such as groceries and childcare (113).

When experiencing illness, either dread disease or chronic, many individuals, particularly in LMICs, are unable to meet the intensely high OOP expenditures required for their care, often forcing them to adopt coping strategies that are financially underpinned (114). LMICs present a unique case in which many individuals cannot pay large sums of money from their current incomes or savings and must often resort to other strategies to cope with these financial costs, such as borrowing money or selling assets (115, 116).

However, when assessing FRP, metrics such as these financial coping strategies are short-term in the way they address healthcare costs and often overlook the hidden costs that may be present in other long-term coping strategies, such as high interest rates on loans or the lost returns after the sale of a productive asset (114). The economic and non-economic effects of these consequences could be severe and may even limit the patient's ability to pay for timeous necessary medical treatments, food and education whilst prematurely returning to work to meet these financial obligations (117, 118).

The parallel economic burden that has accompanied the growing non-communicable disease burden further inflicts financial risk onto households as modern medicines long-term, life-sustaining treatments often result in households having regular, life-long OOP payments for drug treatment and follow-up consultations (114).

2.1.6 Theoretical Framework

The theoretical framework used for this study utilises the socioeconomic impact (SEI) framework by Pham et al. (119), which describes the socioeconomic impact of cancer. Cancer patients and, moreover, their households may experience OOP spending or the loss of income due to the financially exhaustive nature of treatments, interventions, and corresponding adverse effects (119). The ongoing nature of cancer treatment and care and the financial implications of this are key underpinning in understanding how OOP costs affect patients financially (120). The interplay of direct and indirect costs and the knock-on effect this has on the coping mechanisms and psychologically motivated financial decisions are key contributors to these patients' socioeconomic outcomes (120). Thus, employing a robust framework in assessing stoma care and CRC is critical. Hence, the adoption of the SEI framework, as shown in Figure 1, relies on the four themes of causes, intermediate consequences, outcomes and risk factors.

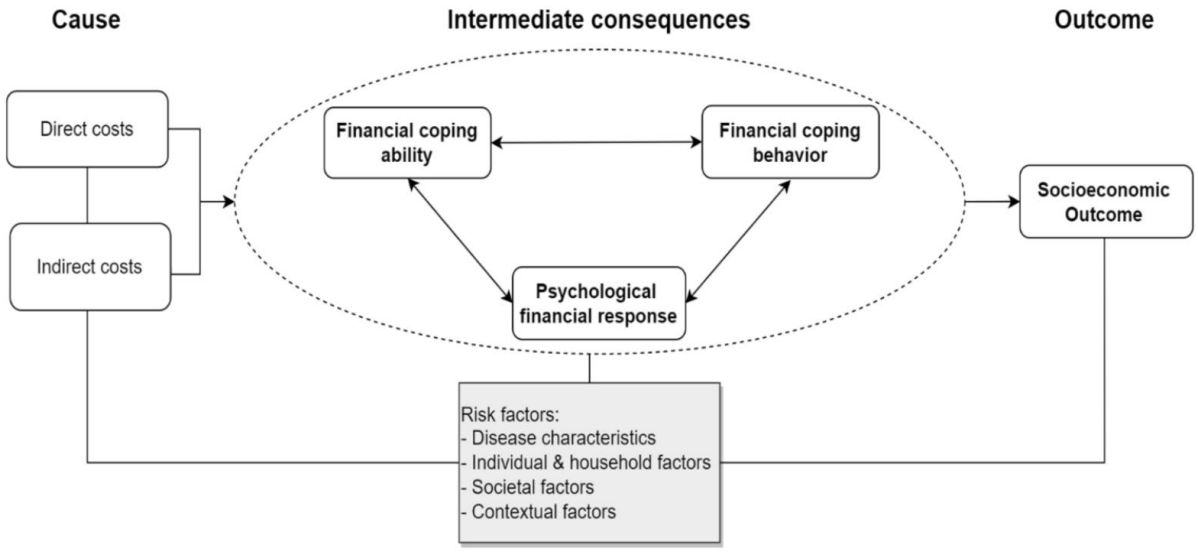

Figure 1: The Socioeconomic Impact Framework by Pham et al. (119)

Direct costs can be defined as the costs due to cancer that are paid OOP by the patients or their households, which can include direct medical costs derived from financial costs of healthcare such as consultation, medicines, hospitalisation, laboratory tests, as well as direct non-medical costs derived from the financial costs of seeking care or to manage the cancer such as transportation, supplements, and dietary changes (121). Indirect costs are defined as the costs indirectly incurred by patients and their households and are typically seen as time loss at work due to cancer but are also inclusive of the time loss experienced by household caregivers and a loss of income for both patient and caregivers attributed to absenteeism, or absconding business meetings (121).

The SEI framework involves the three-themed loop of “intermediate consequences”. These intermediate consequences arise due to the causes, i.e. direct and indirect costs. The psychological financial response is an indicator of the financial stresses that are often present in the diagnosis phase of cancer, signifying the psychological effect as a response to the cost of cancer (120). The psychological financial response is defined as the “psychological perception of the increase in household expenses that must now be managed as patients navigate cancer care” (119). This can be further classified as the financial experience, observing the perception of meeting the costs related to cancer care, or as the financial expectation, the perception of future expectations of financial ability to afford the expenses

that come with cancer and stoma care (120). Both classifications can either be positive or negative. However, financial expectations often correlate to negative, worrisome thinking patients can experience when assessing their ability to work or utilising their savings to meet financial expectations (120).

Patients and their household's financial ability to cope with the cost of cancer care underpins the theme of financial coping ability (121). However, this too is subdivided into the household health expenditure ratio, which is the total OOP health expenditure as a percentage of household income and the household available savings and assets, which assess the liquidity of the available household savings and the corresponding assets that members of the household may possess (120).

Financial coping behaviours are already well established in assessing household expenditure, in the SEI framework, this theme addresses the behaviours patients and their households adopt due to the increased costs attributed to cancer (121). This theme comprises increased liquidity and resources, expenditure reduction, and treatment delinquency. Increased liquidity and resources are often a byproduct of monetary borrowing behaviours, asset sales, welfare/social assistance programs, and the use of savings, a premature return to work (120). At the same time, expenditure reduction is the delayed consumption of non-health goods and services, including food, leisure activities, education, electricity, and delayed investments (120). Treatment non-adherence is an effect of these increased costs, where patients will take less than their prescribed medications, ignore dietary regimens, or miss physician consults as a means of coping (122).

All three elements in the intermediate consequences loop are tightly linked to one another, the bi-directionality present within each of these themes is caused by the direct and indirect costs of cancer care (120).

The SEI framework also includes the theme of risk factors. Factors inherently contributing to the increased socioeconomic impact of cancer can be discussed as sub-themes, all linked to this increased risk (121). These risk factors range from disease characteristics, individual factors, household factors, societal factors, and contextual factors such as the health system and its policies (120).

Finally, the “socioeconomic outcome” output theme in the SEI framework is a broad, multi-dimensional outcome that seeks to interlink a patient's financial outcomes along with their experiences and behaviours, as these outcomes do not occur in isolation and typically (120).

2.1.7 Conclusion

This theoretical and conceptual literature review examined the epidemiological, risk factor, economic, and health-related challenges that CRC and stoma care present in LMICs. Exploration of the SEI framework allows us to assess the complex interplay between costs, financial coping strategies, and broad economic and psychological consequences for CRC patients and their households.

Increasing early onset-onset CRC cases have marred the increasing global epidemiologic incidence. With some HICs benefitting from their screening programs and infrastructure, LMICs face significant deficiencies in early detection and accessibility. Those in the most vulnerable socioeconomic strata are privy to the CHE that arises due to seeking care for their illness. These patients must often cope with this burden through borrowing, selling assets, or reducing essential household expenses, contributing to long-term household financial instability.

2.2. Methodological Literature Review

In this section, we will discuss the Methodological underpinnings of the study by examining the literature on CRC-related ostomy and describing each of these in detail and how they contribute to the overall formation of the study itself. Previous study designs assessing CHE were examined, along with the different data collection tools, how defining CHE differs from study to study, how studies compute OOP expenditure and cost variables, sample size differences, the associations and determinants of CHE, and the statistical analysis used.

2.2.1 Study Design

To our knowledge, there are no studies that exist that assess CHE for CRC ostomy, for this reason, we assess the existing literature around the design of studies assessing CHE for cancer, which tend to use longitudinal, cohort or cross-sectional studies. Many of these studies are retrospective cohort studies or observational and tend to assess these patient groups in HICs, where existing and established national health insurance schemes or large patient registries allow for collecting data linked to these ostomates with CRC (123-125). Cross-sectional studies are commonly used as these are much more feasible in resource-constrained settings and allow CHE assessment at a specific point in time (126). The benefit to cohort studies, although not commonly utilised in resource-constrained settings, is the forecasting of CHE, as the dynamic nature of cancer care may impact the overall financial well-being of households (127). However, there are studies in LMICs assessing CRC care and financial catastrophe, and these tend to be retrospective cohorts that utilise secondary data obtained from patient registries.

It should also be noted that there is a greater prevalence of screening in HICs and upper-middle-income countries, which allows for the appropriate care pathways for these patients to be elucidated. However, a prospective longitudinal study from Malaysia, an LMIC with a well-developed UHC system, collected primary data through a validated questionnaire assessing CHE amongst CRC patients and their families (128).

2.2.2 Data Collection Tools

Primary data collection through household surveys has remained prevalent in CHE research, primarily due to the detailed insights that can be gathered for a specific disease or treatment area regarding healthcare access, income, and expenditure patterns (129). The living standards and measurements study (LSMS) household survey is a well-documented example. Secondary data sources such as national registries for cancer or national health insurance records (should a country have an established national health insurance system) are commonly used globally when estimating CHE prevalence and its predictors (126). However, the trade-off when using these registries and other large data sources is the lack of granularity when assessing indirect costs such as lost productive work hours (130).

2.2.3 Defining and assessing CHE

The definition of CHE varies from country to country, as well as the context in which the study is conducted. Typically, CHE is defined as either 10% of the household income or 40% of the household's ability to pay once subsistence expenditure is accounted for (131). From this definition, subsistence expenditure refers to the minimum level of household spending required to meet basic needs, commonly estimated based on food expenditure and other essential living costs. The household's ability to pay is therefore the remaining financial resources available after the subsistence expenditure is deducted from total household expenditure. The 40% ability-to-pay threshold is widely used and recommended by the WHO as it aligns with international poverty metrics allowing for comparability with international studies but may underestimate financial hardship in low-income settings. Conversely, the 10% household income threshold is prevalent in regions that are typically under-resourced and would require broader financial burdens to be captured but can reduce comparability and overestimate catastrophic spending in wealthier populations (132). It should also be noted that the use of a 25% threshold is also common, as this was included in the WHO's SDG3, although it has previously been criticised for lacking a strong empirical basis (133). Hence, selection of a threshold requires careful consideration of the study's context, balancing the need of international comparability and good practice to the lived local economic realities.

2.2.4 Computing OOP cost variables

Typically, studies define direct costs as an aggregate of direct medical and non-medical costs; indirect costs are aggregated as tangible and intangible indirect costs (105). Country-specific contexts and study designs play a role in the selection and computation of costs, with authors often deciding not to explore indirect costs that affect patients, keeping to the direct costs only, as these indirect costs are often difficult to quantify, risk losing methodological robustness, or are not aligned with the study perspectives (134, 135). These specific country contexts are further expanded if studies assess the role of NHI on the computation of these variables, as seen in a Korean study that excluded transportation costs, as the Korean NHI does not allow for subsidisation of these costs (135). Furthermore, a 2017 study from China defined these OOP payments as any expenditure not covered through NHI and non-medical expenditure that patients had to pay (136). A study in Nigeria calculated OOP costs by summing all costs that were not reimbursed by insurance, including deductibles, copayments, and services not covered, as well as costs of procedures, consultation fees, administrative fees, medication, laboratory/pathology costs, imaging costs, and chemo/immunotherapy costs (137). However, it is worth noting that this study assessed costs at a private hospital where these patients are typically privately insured. A 2013 American study assessing the costs of cancer care for Medicare beneficiaries computed OOP payments as the direct medical payments that patients had to make and their unpaid healthcare-related liabilities (138). Some studies do not elaborate on how these OOP costs were computed, often due to these studies utilising hospital or national databases (106, 139, 140).

In the case of CRC, direct medical expenditure can be computed as the sum of payments made for pharmacy, nursing services, dressings, colostomy bags, hospitalisation inclusive of inpatient costs, outpatient services, laboratory testing and radiation oncology services (128, 133, 141). Direct non-medical costs consistently assess transportation, lodging, and food or supplement expenses (128, 133, 142).

2.2.5 Sample Sizes

Study sample sizes differ significantly from one another. The WHO has set out a standard for health research, which suggests a sample size of 200 people (143). However, some studies do not conform to this baseline due to factors such as time, financial and resource constraints.

A cross-sectional exploratory study assessing CHE due to CRC in Malaysia utilised a universal sampling approach to recruit participants (128). However, a large cross-sectional multi-hospital study in China assessed expenditure and financial burden in CRC diagnosis and treatment, 3120 CRC patients were forecast across 13 different hospitals, whilst the study managed to enrol 2356 patients (136). The use of retrospective study designs with registry or hospital databases is common. In a retrospective study from Nigeria assessing the costs of treating CRC at a private cancer clinic, there were 92 CRC patients surveyed over 10 years, no power calculations were done as the study was limited to the sample of patients using the facility (137).

2.2.6 Determinants of CHE

CHE predictors are extremely similar and carefully aligned to global literature on CHE (144). The most common predictors for a household are residence type (i.e., rural or urban), family size, elderly persons within a family, presence of children under five years of age and economic status (145). Furthermore, the most common predictors when assessing the household head are gender, age, employment status, educational status, and hospitalisation (128).

Most studies agree that living within a rural area is a risk factor for developing CRC, particularly within LMICs. This finding does not often reflect well in HICs as a non-significant or non-applicable relationship exists between CHE and those residing in a rural area (146, 147). The size of a family is often a debated association with CHE as studies with large family sizes can be seen as a risk factor in CHE or, conversely, as protective against CHE (148, 149). The presence of an elderly person is also considered to be a risk factor for CHE, whilst the presence of a child under the age of five is said to be either non-significant or a risk depending on the country's context (145).

Wealth quintile assessment within many studies has shown that the presence of individuals within the lowest or lower quintiles increases the risk of experiencing CHE, whilst this finding can be argued against high quintile households having higher healthcare spend and, in turn, surpassing their capacity to pay thresholds (150-153).

In a meta-analysis of household head associations, 16 out of 27 studies had assessed that household head gender was a non-significant risk factor in the prediction of CHE, when applied to a low-income setting such as Kenya, there was a significant association among the non-poor but not among the poor (109, 145). From the same meta-analysis, when assessing age, 7 studies out of 12 found significance in the age being a determinant of CHE, along with 11 papers of 17 which found that unemployed household heads are at a greater risk for CHE, as well as 15 of 22 papers reporting low education being linked to increased prediction of CHE (145).

2.2.7 Analysis techniques

The analytical approaches taken in studies assessing CHE vary, and these can range from simple descriptive statistics to complex econometric modelling. Typically, most studies will utilise regression analysis, either logistic or probit, in estimating the burden of CHE and its predictors in the population of interest (154, 155). However, these studies typically use larger data sets obtained from national surveys and existing registries, making the exploratory primary data analysis difficult. The Firth logistic regression allows for regression analysis with small sample size data, introducing a penalty term to prevent overfitting and reducing the complexity of the model (156). This applied penalty term discourages overly complex models with numerous predictors and few outcomes. Firths penalised logistic regression ensures that the model retains generalisability and robust results not disturbed by “noise” in the data (157). Multicollinearity, which often occurs in complex datasets, occurs due to highly correlated predictors, causing unreliable and inefficient coefficients. These unstable coefficients are regularised by the Firth logistic regression and reduce the influence of the predictors, ensuring that the results are interpretable (157).

2.2.8 Conclusion

This review highlights the methodological variations in assessing CHE among cancer patients, particularly CRC patients with a stoma. Cross-sectional and retrospective cohort designs are common, especially in LMICs due to feasibility constraints. While primary data collection through household surveys provides detailed cost insights, secondary data from registries and

insurance databases offer broader population-level insights but lack granularity and “richness” in the data.

CHE definitions and OOP cost computations vary across studies, with thresholds of 10%, 25%, and 40% of household income or ability to pay being the most used. These thresholds are heavily dependent on the context and setting of a study. Calculating OOP expenditure differs with some studies choosing to look exclusively at direct costs, while others incorporate non-medical expenditures like transport and lodging, there is also a significant gap within this already minimal pool of data as the assessment of indirect costs that CRC patients incur due to their illness.

Several determinants of CHE are consistent among most studies with these involving rural or urban residence, socioeconomic status, household size, and the employment and education of the household head, as well as the presence of an elderly individual in the household. Analytical approaches predominantly use logistic regressions for the assessment of CHE and its predictors. However, studies with small sample sizes might employ the use of Firth logistic regression helps address this sample bias and model instability.

In light of the methodological variations and challenges, the current study adopts a cross-sectional design with primary household survey data, allowing for comprehensive assessment of direct costs and predictors of CHE among CRC ostomates. This design balances feasibility in a resource-constrained setting with methodological rigor, addressing the gap in existing literature on this specific patient group while mitigating challenges such as small sample sizes and incomplete indirect cost data.

2.3 Empirical Literature Review

The following section evaluates, synthesises and contextualises the related prior studies. It should be noted that some studies may not directly include CRC and may separately assess this as colon and rectal cancer, as well as assessing cancer with no specificity on sub-classification. Studies included here are from the following databases: PUBMED, PLOS, OPEN ACCESS, GOOGLE SCHOLAR, ELSEVIER, SPRINGER LINKS, TAYLOR AND FRANCIS, and KOREASCIENCE. The search terms included catastrophic expenditure or, CHE or, colorectal cancer or, ostomy or stoma or, out-of-pocket expenditure or financial coping strategies. Supplementation of literature had occurred by manually searching references from the included articles. The inclusion of studies was based on associations of CHE with cancer, CRC, and social determinants, as well as the associations of CRC or cancer with OOP payments and financial coping strategies. Studies were excluded if they were not written in English, if the full studies were not accessible, and did not focus on the above-mentioned inclusion criteria. Regression analysis is the most common method for assessing CHE and its determinants, with a plethora of studies showing strong and significant associations at the household and individual levels.

This review is stratified by geographical region, threshold levels, financial burdens and OOP payments for stoma care, and financial coping strategies.

2.3.1 By Geographical Region

LMICs typically show high CHE incidence rates, often accompanied by a lack of FRP (158). HICs oftentimes have increased social protection and existing FRP mechanisms but will incur CHE at lower rates and intensity when compared with LMICs (145). For instance, Portugal, a HIC, over a period of 10 years had reduced the incidence of CHE from 2.57 to 0.46% (159). Although this is commendable, the 10% poorest and most marginalised accounted for almost 60% of CHE experienced at the 40% threshold (159). It is also worth noting that these were not CRC or disease-specific rates of CHE but rather CHE as a general measure. Furthermore, the assessment of other European countries, such as Czechia and Georgia, showed 0% and 9% CHE incidence at the 25% threshold, respectively (160).

The pattern of incidence in LMICs could be explained by these households in these countries choosing not to seek care and, in turn, avoiding financial hardship due to healthcare payments, which are substantiated by studies from Iran and Burkina Faso where a directly proportional relationship exists between healthcare usage and CHE (145, 149, 161).

The existing body of work for CRC-related CHE or ostomy-related CHE is sparse. However, several studies in LMICs have quantified these risks, particularly in Asian and African contexts. The following studies will be interpreted and grouped as African or Asia regions. A study from India found that CHE incidence among 226 CRC patients had been reported at 90.1% at a 25% threshold (133). The high rate of CHE can be attributed to India's existing NHI program. This program does not provide full subsidisation or reimbursement for medical treatments due to the large number of users on the program (133). Health expenditure accounts for 2% of India's gross domestic product (GDP), with 6.53% of the population experiencing CHE (162). With there being non-existent support for cancer care and with patients having to pay for their own chemotherapy drugs prior to visiting a clinic, this elucidates the high burden of OOP payments patients must incur in seeking care (162).

Studies assessing CHE among CRC patients in China and Malaysia have also provided insights into the extent of FRP in LMICs. A study from Malaysia found 47.8% CHE at the 40% threshold for 138 CRC patients after the first year of diagnosis (128). Interestingly, even with the Malaysian healthcare system having achieved UHC whereby care is free at the point of care and only nominal charges are levied against particular services, there is still a strong indicator that the FRP that exists for prolonged diseases such as cancer are not sufficient to protect these patients from these high OOP payments that are greater than their capacity to pay (128).

A study from China of almost 2400 patients found the CHE rate due to CRC to be 75% at the 40% threshold (136). Notably, 60% of CRC patients' household income was spent on a year's worth of treatment and diagnosis, indicating how intense OOP payments are for these patients (136). NHI does exist in China, but it does not sufficiently cover those patients in the lowest income quintiles, further pushing them into an unmanageable financial catastrophe.

In Africa, evidence assessing CHE in CRC is sparse, further exacerbating the insufficiency of evidence in LMICs. A study from Ethiopia assessing catastrophic expenditure and coping strategies of cancer patients found that out of 352 patients, 74.4% of them experienced CHE

at the 10% threshold level (134). When stratifying this burden for CRC, 32 out of 46 CRC patients experienced CHE (134). The average expenditure for these patients on CRC was more than half of their annual household income (unadjusted), this means that when compared to the average income in Ethiopia, these patients experience financial catastrophe; subsequently, a large uncounted number of patients are avoiding seeking medical care to avoid these OOP payments (134). The authors emphasized that the high level of CHE could be due to a myriad of reasons, such as the lack of diagnostic centres, increasing transportation and accommodation costs, and unavailability of medicines, resulting in more significant expenditures when seeking these services (134).

To the best of our knowledge, the only other country in Africa that had assessed CHE due to CRC was Nigeria, in which this study had not been able to find the absolute incidence of CHE but rather the risk of CHE as the data collection tools had not accounted household income (137). Hence, the reported outcome was the risk of CHE based on the OOP payments patients had to make, measured against the 2022 per capita GDP (137). Nevertheless, 92 patients in this study were sampled, and the risk of these patients experiencing CHE was estimated to be 62% at the 20% threshold, with these patients spending an average of 35 000 United States Dollars (USD) annually for treatment (137). While not an accurate measure of CHE incidence as no patient-specific income was collected, it provides valuable information on the cost of care at a private cancer care facility and how this would affect patients if assessed as per capita GDP.

2.3.2 By Threshold Level

The payment for healthcare is deemed to be catastrophic when it exceeds a certain threshold of household income, this threshold is usually defined based on a particular country or regional context as well as the scope of the study (163). To better quantify the global burden of CHE, utilising the standardised threshold of 40% non-food consumption expenditure, 150 million people worldwide are said to experience CHE (108). Although the thresholds at which to examine CHE may be debated, the understanding is that even unexpected or argumentatively low levels of healthcare expenditure could tip a household into financial catastrophe (113). For this reason, when assessing CHE, the set thresholds must account for that particular country's context.

The countries with the highest thresholds in which CHE incidence was calculated were Iran, China, and Malaysia at 40% (128, 136, 141). Of these countries, Iran and Malaysia present with a fully functional NHI system that has achieved UHC. However, the rate of CHE for the Iranian study had shown 67.9% CHE at this 40% threshold, whilst the rate of CHE in Malaysia was 47.8%, indicative of the high OOP payments that must be made at the point of care by patients even though subsidisation mechanisms are in effect (141).

When assessing the incidence of CHE at the 20 to 25% threshold, particularly for CRC or cancer care, studies from India, Colombia, and Nigeria formed part of this literature. As discussed above, the study of Indian CRC patients who experienced financial catastrophe at the 25% threshold was 90.1% of the sampled population (133). The study out of Nigeria assessed CHE at the 20% threshold and found that 62% of patients risked CHE (137). When looking at Colombia, findings from this study had shown that households experienced 9.6% CHE at this 20% threshold. However, Colombia has a well-established NHI that aids in the FRP for these patients through an efficient cross-subsidisation mechanism (139).

At the 10% threshold, countries such as the USA, Korea, Malaysia, India, South Africa and Ethiopia produced literature that deals with CHE for cancer and CRC. It is worth noting that although the literature on financial catastrophe due to CRC is sparse, inferences can be made when looking at the overall costs of cancer care and how these can relate to the burden of OOP expenditure when seeking out cancer care. Other studies assessing the costs of cancer care, particularly in the USA, Korea, Malaysia and India, had shown varying levels of CHE at the 10% thresholds, observed at an incidence of 49.9%, 28.57%, 54.4% and 74%, respectively (106, 138, 142, 164). When comparing literature assessing CHE due to CRC against CHE due to any cancer diagnosis, the incidence rates are higher at higher thresholds, particularly in India (90.01% at 25% vs 74% at 10%); this is not the case for Malaysia (47.8% at 40% vs 54.4% at 10%) as this threshold set at 40% we can infer that lowering this threshold would increase the incidence of patients who experience CHE (106, 128, 133, 142). A study from South Africa assessing CHE among surgical patients showed an incidence rate of 1.9% CHE at this 10% threshold, elucidating the level of FRP provided by the health system (165).

2.3.3 Financial Burden and OOP Payments for Ostomy Care

Living with an ostomy poses not only a clinical risk to a patient but also leaves them privy to significant financial expenditure that may leave them in significant debt. In a study assessing German claims data of 1589 ostomates, findings had shown that these patients incur higher financial burdens with a mean spend of 16 523,50 USD compared to a matched population which experienced spending of 5 644.59 USD (166). A similar pattern is seen in a study by Andersen et al. (125), which assessed patients with an ileostomy or colostomy and found that patients with an ileostomy experience higher costs of care than those with a colostomy, 30 851.31 USD and 29 350.31 USD, respectively. Furthermore, ileostomy creation due to CRC caused patients to experience higher costs per year than those who did not have cancer, 34 048.55 USD (125). Similarly, in a study by LeBlanc et al. (167), patients with an ostomy were experiencing a minimum spend of 1000 USD per year, with 58% of this spending being OOP payments, oftentimes causing patients to sacrifice non-medical expenses such as food, clothing, travel and leisure expenses. Furthermore, 25% of respondents in this study indicated that paying for ostomy supplies and care caused them financial burden. It should be noted that these ostomies were not specific to CRC but accounted for other gastrointestinal issues such as IBD.

The most significant driver for total healthcare costs had been that of inpatient admission, disproportionately increasing for those who had their ostomies created due to CRC. The cost per patient inpatient admission ranged from 16 097.43 USD to 21 047.58 USD (125). The total healthcare costs that are incurred can typically be attributed to the care required for CRC due to the cost-intensive nature of the disease, which is further compounded by the presence of an ostomy and its inherent complications, adding to higher healthcare resource utilisation (125).

Financial burdens experienced by ostomy care are non-selective and will disproportionately affect a household. This can be seen in a study by Shauq et al. (168) in which 79.9% of mothers of child ostomates ranging from 1 to 4 years old in Iraq were economically burdened. A study by Sina et al. (169) reported that patients with rectal cancer requiring stoma formation had experienced great financial distress due to caring for both their cancer and stoma.

Although limited research exists on the direct and indirect costs of CRC in LMICs, Tran et al. (170) found that the average cost per patient in Vietnam for CRC was roughly 2000 USD, with

males typically having to pay more than their female counterparts. At a national level, the direct medical costs in treating CRC are estimated to be 17.933 million USD, assuming there are 9481 CRC patients in Vietnam according to 2018 GLOBOCAN guidelines (170). Interestingly, these direct costs only comprise 16.4% of the total economic burden, whilst indirect costs comprise 82.61% (170).

There are no studies that we are aware of that quantitatively assess the financial burden of ostomy care in SSA, let alone South Africa.

2.3.4 Financial Coping Strategies

Although linked to financial burden and OOP payments, financial coping warrants separate examination to better understand the empirical literature on how households may respond to high costs of cancer care. This distinction is particularly important given that financial coping strategies remain under-researched especially in the context of CRC, despite being a central focus of this study. In a study assessing the economic burden of breast cancer on households in India, a combination of coping strategies was observed, where most households were able to borrow money at low interest rates from banks or family members, although these households also had to pawn jewellery, utilise high-interest loans, sell assets such as gold and even economically productive assets like cattle (171). A study assessing cancer-related CHE and coping strategies from Ethiopia reported that a significant proportion of households (85.5%) utilise household savings in their payments for healthcare, followed by patients receiving support from family, friends, non-governmental organisations as well as various religious groups (43%), whilst selling of household assets such as land, livestock, property, jewellery, while borrowing from financial institutions contributed 12% and 8.5% respectively (134)

2.3.5 Conclusion

This review of empirical evidence has shown a noticeably glaring gap in the number of studies assessing CHE for CRC, not only for LMICs but also for SSA. Of the two studies in Africa, neither assessed CRC explicitly but rather cancer care with the inclusion of CRC alongside other high-incidence forms of cancer.

Some studies had assessed CHE but did not comprehensively analyse OOP payments, and vice versa. Including this missing information would allow for a more holistic view of the risk protections made available in specific country contexts. Furthermore, only one study assessed coping strategies for cancer patients and provided key insights into the observable ways patients seek to cope with the costs of cancer care. The inclusion of financial coping strategies would allow for a comprehensive assessment of how patients may deal with increasing costs, even if they are not experiencing CHE.

2.3.6 Conclusion of the structured literature review

This review of the theoretical, methodological, and empirical literature has underscored the significant burden of CRC and stoma care on patients, particularly in LMICs. The Socioeconomic Impact model emphasises the complex interplay between costs, coping, psychological, financial responses, and socioeconomic outcomes, further reinforcing the multidimensional challenge of CHE and not just a financial measurement. The studies assessing CHE in cancer patients are typically retrospective cohorts and cross-sectional studies, which leverage large data sets and samples from HICs, leaving a notable context-specific gap for primary investigations in LMICs. The empirical evidence further highlights this disproportionate financial burden on households with CRC as CHE often exceeds global thresholds, particularly in LMICs. However, the research on the costs of care associated with CRC and stomas remains sparse, especially in South Africa. Given the absence of comprehensive assessments of CHE and financial coping strategies among CRC ostomates in SSA, this study seeks to close the knowledge gap by providing empirical insights into the economic burden faced by CRC patients with stomas, informing policy interventions to mitigate financial hardship and to improve healthcare equity and access.

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3. PART C: JOURNAL MANUSCRIPT

Proposed Journal: BMC Public Health

Catastrophic Health Expenditure and Financial Coping Strategies Among Patients with Colorectal Cancer (CRC) and Stomas: A Cross-sectional Study at Groote Schuur Hospital, Western Cape, South Africa

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3.1. ABSTRACT

Background

Colorectal cancer (CRC) is the second leading cause of cancer mortality globally, with an increasing burden in low- and middle-income countries (LMICs) like South Africa. CRC, often accompanied by stoma formation, imposes significant out-of-pocket (OOP) expenses for patients. However, limited research exists on the financial and socio-economic impacts of CRC and CRC-related stoma care in LMIC contexts. This exploratory study investigated the extent of catastrophic health expenditure (CHE) among CRC patients with stomas and the financial coping strategies they employ.

Methods

A cross-sectional observational study was conducted at Groote Schuur Hospital in Cape Town, South Africa, from October to November 2024. A questionnaire was administered to 21 patients with CRC and stomas to gather data on demographics, direct and indirect costs, and coping mechanisms. Statistical analysis included descriptive statistics, computing CHE and penalised logistic regression models to identify determinants of CHE. Cost-coping strategies were also examined.

Results

Transportation costs accounted for the largest share of OOP expenditure (48.9%) and followed by medicines (27.8%). CHE, defined as annual OOP costs exceeding 10% of household expenditure, affected 38% of participants, with a disproportionate burden on poorer households and patients with late-stage CRC. Among the poorest households, 60% experienced CHE compared with 50% of poor households, similarly 50% of stage 3 and 33.33% of stage 4 CRC households reported CHE. Financial coping strategies were reported by 81% of households, most commonly reducing household expenditures (47.7%) and taking on additional work (19%). A notable proportion (19%) reported employing no coping mechanisms.

Conclusion

This study highlights the significant financial burden faced by CRC patients with stomas. To mitigate this burden, policymakers should prioritize expanding financial protection measures, such as subsidies for essential medications and transport assistance programs. Integrating CRC care into existing universal health coverage (UHC) frameworks can also enhance affordability and accessibility. Adopting early screening initiatives may also play a crucial role in alleviating late-stage disease burdens and the accompanying likelihood of financial catastrophe.

Keywords: Colorectal cancer, CRC, Catastrophic Health Expenditure, CHE, South Africa, Stoma, Household costs, Financial protection

3.2. Background

Globally, colorectal cancer (CRC) is the third most frequently diagnosed cancer and the second leading cause of cancer mortality, with nearly two million new cases and almost one million deaths annually (1). While CRC has historically been more prevalent in high-income countries (HICs), low- and middle-income countries (LMICs) are experiencing rapidly rising incidence rates, with projections estimating an 87% increase in LMICs by 2045 compared to 36% in HICs (2–4). In South Africa, CRC is the fourth most commonly diagnosed cancer, the second among men, and the sixth leading cause of cancer-related deaths, with age-standardised incidence and mortality rates of 13.5 and 8.9 per 100,000, respectively (4,5).

Rising CRC incidence in LMICs is attributed to epidemiological transitions and increasing exposure to environmental and lifestyle-related risk factors, such as urbanisation, obesity, smoking, and sedentary behaviour (6,7). An estimated 40% of CRC patients will require a stoma as part of their treatment pathway (8). Ostomy creation—derived from the Greek stoma, meaning “mouth”—is a critical surgical intervention used in gastrointestinal malignancies, inflammatory bowel disease, traumatic injuries, and incontinence, with CRC being the most common indication (9,10).

In LMICs, ostomy care is often hindered by systemic health inequities. Limited numbers of specialised colorectal surgeons, scarce stoma care services, and poor access to sanitation and medical supplies disproportionately affect patients in rural and low-income communities (11,12). In South Africa, this challenge is compounded by the uneven distribution of healthcare resources: specialist services are concentrated in urban tertiary hospitals and the private sector, while most patients rely on general surgeons for stoma creation and education (12,13). Fewer than 100 specialised stoma nurses are available to serve an estimated 60,000 South Africans living with a stoma (14,15). Although patient-led organisations, such as the South African Society of Stomates (SASS), provide support, significant care gaps remain.

While these access issues are well documented, less attention has been given to the financial strain experienced by CRC patients and their households in LMICs, particularly in South Africa. Financial risk protection is a core function of health systems and a pillar of universal health coverage (UHC), yet cancer care remains a major source of catastrophic health expenditure (CHE) worldwide (16). Evidence from Ethiopia shows that nearly 70% of CRC patients experience financial catastrophe (17), while studies from other LMICs, such as Malaysia,

report that over half of cancer-affected households face CHE within a year of diagnosis (18). Non-medical costs, such as transport, food, and accommodation, are significant contributors to this financial burden, particularly for patients dependent on public-sector care.

In South Africa, where the public health system serves the majority of the population and private health insurance coverage is low, little is known about the economic implications of CRC and stoma care for households. Understanding these costs, coping mechanisms, and the adequacy of financial protection is crucial to informing UHC efforts under the proposed National Health Insurance (NHI) framework (19).

This exploratory study addresses this gap by investigating catastrophic health expenditure among South African patients with CRC-related stomas and describing household coping strategies.

3.3. Conceptual framework

This study utilized the Socio-economic Impact of Cancer (SEI) framework (**Part B; Figure 1**), developed by Pham, Schlander et al. (18), to analyse the financial burden of colorectal cancer CRC and stoma care. The framework comprises four interconnected themes: causes, intermediate consequences, risk factors, and outcomes. Causes encompass direct out-of-pocket (OOP) expenditures and indirect costs, such as income loss and time spent on care, which contribute to the overall socio-economic impact of the disease. Intermediate consequences form a dynamic loop involving financial coping ability (households' capacity to manage CRC and ostomy-related costs), financial coping behaviour (strategies adopted to address financial strain), and psychological financial response (emotional and mental stress due to rising costs). These components are bi-directionally linked and influenced by CRC and stoma-related expenses. Risk factors include disease characteristics (CRC stage, ostomy type, treatment regimen, and side effects), individual and household factors (demographics, health status, socio-economic status, insurance coverage, family size, dependents, and social support), societal factors (social relationships, financial and emotional support), and contextual factors (health system structures and policies).

The overarching outcome of this study is the socio-economic impact of CRC and stoma care, with a particular focus on catastrophic health expenditure (CHE). By applying the SEI

framework, we assess the household-level financial burden of CRC and stoma care, guided by patient-reported expenditures collected through a questionnaire. The SEI framework also provides valuable insights into the financial coping strategies employed by patients and enables a comprehensive understanding of how household, disease, societal, and contextual factors interact to shape the economic consequences of CRC and stoma care.

While the SEI framework provides a strong conceptual basis for assessing the household-level economic consequences of CRC and stoma care, its application in the South African context warrants reflection. The framework was initially developed in high-income settings, and some of its assumptions, such as consistent access to health insurance, robust social safety nets, and formal care structures, may not fully reflect South Africa's dual health system and pronounced socio-economic inequalities. The lack of integration of informal care dynamics and community-based support networks also presents challenges in capturing the full financial and social burden experienced by households. Additionally, while the framework's structured approach is valuable, it may oversimplify the complex, non-linear interactions between healthcare utilisation, financial strain, and coping mechanisms in lower- and middle-income contexts. These limitations are acknowledged, and findings from this study may help inform future adaptations of the SEI framework to improve its applicability and sensitivity to settings with resource constraints and high levels of inequality.

3.4. Methods

3.4.1 Study Design

This study was a cross-sectional observational study with an in-person interview allowing the questionnaire to be administered. The survey was adapted from the WHO generic TB costing survey to apply to CRC-related stoma. Adaptations included the addition of questions on stoma-related medical supplies, colorectal cancer treatment modalities (such as chemotherapy, radiotherapy, and surgical interventions), oncology-specific outpatient and inpatient visits, and cancer-related support services while excluding all TB-specific questions. The final survey comprises 82 questions under the following headings (20): (1) Demographic and Socio-economic Status, (2) Household Expenditure Patterns, (3) Diagnosis and Treatment History, (4) Direct Costs, (5) Indirect Costs, (6) Coping Strategies. Patient responses were recorded directly on Google Forms (Google LLC, 2024) for ease of use, access and security.

3.4.2 Study site

This study was conducted from October – November 2024 at Groote Schuur Hospital, an urban tertiary academic hospital in Cape Town, Western Cape, South Africa, at the hospital's stoma clinic and the radiation oncology unit.

3.4.3 Study Population and Eligibility Criteria

All patients older than 18 years of age, diagnosed with colorectal cancer, clinically staged, with a stoma, who were currently receiving stoma care and or treatment, and who were more than 30 days post-stoma formation were invited to participate. Exclusion of participants occurred if patients were less than 18 years of age, with a diagnosis of colorectal cancer but without a stoma, or had a stoma for less than 30 days, as well as patients who were not fluent in English and those who were unwilling or unable to provide consent. The exclusion of those participants who were not fluent in English was necessary due to resource constraints and a lack of translation services at the study site. Although this criterion was included for feasibility, all of

the patients approached were able to converse in English and no participants were excluded on this basis.

3.4.4 Sample size

Being an exploratory study, only 21 patients were recruited over the study period. This sample size reflected the strict eligibility criteria required for inclusion as well as the limited time in which this research could take place. As an underrepresented patient group with no known prior research on this population in South Africa, an exploratory study provides crucial insights to inform future research. Its findings highlight the need for more extensive studies to better understand the unique challenges faced by this patient population.

3.4.5 Ethical considerations

Ethical approval was granted by the University of Cape Town (UCT) Human Research Ethics Committee (HREC), HREC: 649/2024 and institutional approval was obtained from the Western Cape Department of Health, WC_202410_053. Informed consent was obtained from all participants prior to interviews and data collection.

3.4.6 Measurement variables

Direct Costs

Direct costs were defined as the OOP expenses a patient must cover when seeking CRC and stoma-related care. These costs were categorized into direct medical costs and direct non-medical costs. Direct medical costs included general practitioner consultations, medicines, vitamins or food supplements, diagnostic procedures such as MRI scans, CT scans, laboratory tests, radiation and chemotherapy expenses, stoma bags, and other stoma care products. Direct non-medical costs encompassed transportation to healthcare facilities, accommodation expenses, and any additional costs incurred during the care-seeking process.

Total household expenditure was calculated by summing up a household's monthly spending on food, transport, rent or mortgage, utilities, clothing, childcare and education, leisure, alcohol and tobacco, and other miscellaneous expenses.

All costs were taken from the perspective of the patient. OOP expenditure, direct costs, and total household expenditure were annualised to allow for representative average costs and easy comparison with national indicators for income and expenditure. The recall period for these costs was one month to ensure capture of those frequently recurring expenses. To reduce event-driven cost inflation during interviews patients were instructed to report on a "typical month" to exclude once off costs that could skew the data. While annualisation of one-month recall data introduces potential variability especially in low-income settings where household income and expenditure may seasonally fluctuate, this approach was chosen to facilitate comparability with published national statistics, which are typically reported annually. Future studies with larger samples and longitudinal data collection could provide sensitivity analyses or multi-month recall to better capture temporal variability. All cost variables are measured in South African Rands (ZAR) value at October 2024.

Catastrophic Health Expenditure

The primary outcome variable for this study was CHE. It was assessed utilizing the approach taken by Wagstaff and Van Doorslaer (16). In this study, CHE was computed using a 10% threshold, which defines households as experiencing catastrophic health expenditure if their annual out-of-pocket healthcare costs exceed 10% of their annual total household expenditure.

$$CHE_{10} = \frac{Annual\ OOP\ health\ Expenditure}{Annual\ Total\ Household\ Expenditure} \geq 0.10$$

Predictor variables

Age, gender, status as the household head, education level, occupation, household wealth, Uniform Patient Fee Schedule (UPFS) and CRC stage were all predictor variables for CHE (Table 1). These variables were selected after a comprehensive review of the literature (17, 21-26). The inclusion of these variables ensures that key sociodemographic and clinical information allows for predictive accuracy in the factors that could contribute to household CHE.

Uniform Patient Fee Schedule (UPFS)

The South African public sector makes provision for patients by providing a tiered subsidised user fee system called the UPFS. This is classified on a scale ranking participants from H0 to H3 and is shown as follows (27):

- H0: Full subsidisation – typically, social pensioners who collect the following grants qualify for full subsidisation: Old age, child support, Veterans, care dependency, social relief of distress grant, disability grant, foster care, grant-in-aid and the formally unemployed, which means persons supported by the Unemployment Insurance Fund (UIF) who can produce a formal document issued by the Department of Labour.

- H1: Partial subsidisation [income <R70 000 per annum for a single person and <R100 000 per annum for a family unit].

- H2 Partial subsidisation [income <R250 000 per annum for a single person and <R350 000 per annum for a family unit].

- H3: Partial subsidisation [income >R250 000 per annum for a single person and >R350 000 per annum for a family unit].

Although UPFS is partly determined by income, its inclusion was intentional because it is a formal government classification used in South African public sector healthcare financing and resource allocation. Unlike self-reported income or household wealth, which may be under- or over-reported, UPFS represents a standardised and validated measure of patient affordability used nationally to determine healthcare subsidies. Including both UPFS and other SES indicators enabled triangulation and exploration of whether formal government classifications align with household-level measures of socioeconomic vulnerability in predicting CHE.

Household Wealth Quintile Computation

The wealth quintiles for this study were computed through a set of multiple-choice questions in the patient questionnaire (Appendix 4) guided by the WHO TB patient cost questionnaire. These questions included but were not limited to the type of dwelling participants lived in, the materials of their floors and walls, sources of drinking water, the type of toilet facilities they have access to, whether their households have gas or electric stoves, refrigerators, cell phones, internet connectivity, cars, or if they owned livestock.

Once compiled, this information was summed up and analysed using principal component analysis (PCA). PCA was used to reduce the dimensionality of this data whilst still retaining as much information as possible. The PCA of 23 asset and housing variables allowed for the first component to explain 33.1% of the total variance and was used to construct a wealth index. Variables with the highest loadings included household delivery services (0.333), washing machine ownership (0.314), and internet access (0.281), indicating strong differentiation by household assets. The wealth index scores were divided into quintiles (poorest, poor, middle, rich, richest) to create five wealth categories."

Table 1; Table of Variables

Variable	Type of variable	Variable coding
Outcome variables		
OOP expenditure	Continuous	
CHE	Binary	0 = Did not face CHE 1 = Faced CHE
Predictor variables		
Age	Continuous	
Gender	Binary	0 =Female 1 = Male
Marital status	Categorical	0 = Single, never married 1 = Married/Cohabiting 2 = Divorced/Widowed
Household Head	Binary	0 = No 1 = Yes
Education Level	Binary	0 = Secondary School 1 = More than Secondary School
Occupation	Categorical	0 = Unemployed 1 = Employed 2 = Self-employed 3 = Pensioner/Retired
Household Wealth Quintile	Categorical	0 = Poorest 1 = Poor 2 = Middle 3 = Rich 4 = Richest
Colorectal Cancer Stage	Binary	0 = Early stage (stage 2) 1 = Late stage (stage 3 and stage 4)

3.4.7 Statistical analysis

Data analysis was conducted using Stata 15.1 (StataCorp, version 15.1, 2017). Descriptive statistical analysis was performed on categorical and continuous variables, respectively. CHE was computed as the annualised one-year patient household OOP expenditure on their CRC and stoma care exceeding 10% of total annual household income.

The determinants of CHE were assessed using logistic regression. However, separation had occurred where the outcome had been perfectly predicted by more than one of the predictor

variables. Thus, penalised maximum likelihood regression analysis, also known as the firth logit, was employed. The Firth logit is best suited for small sample sizes (28, 29). The study's small sample size contributed to the perfect prediction that was observed, further supporting the use of Firth logit as opposed to typical regression analyses. Univariate Firth logit regression analysis was performed on independent variables against CHE, followed by a multivariate Firth logit.

The penalized log-likelihood function used in Firth logistic regression is expressed as:

$$\ell * (\beta) = \ell(\beta) + \frac{1}{2}\log | F(\beta) |$$

Where:

- $\ell(\beta)$ is the standard log-likelihood for logistic regression.
- $|F(\beta)|$ is the determinant of the Fisher information matrix, representing the curvature of the likelihood surface.

The penalty term, $\frac{1}{2}\log | F(\beta) |$reduces the bias in the estimates by incorporating the uncertainty associated with the parameters.

Results were statistically significant when the p-value ≤ 0.05 at the 95% confidence interval.

3.5. Results

3.5.1 Descriptive statistics

21 participants were enrolled for the study. As shown in **Table 2** these participants had an average age of 58 years, with 11 females and 10 males. Most participants were married or cohabiting (52.38%), and the rest were single (19.05%) or divorced/widowed (28.57%). A significant proportion of participants had identified as the household head, with most only completing secondary school (71.43%) and 28.57% pursuing education beyond this level. Regarding employment status, 42.86% were pensioners/retired, while 23.81% were unemployed. Notably, only one participant (4.76%) reported having medical aid coverage. Household wealth distribution revealed an even spread across quintiles.

Table 2; Characteristics of study participants

Variable	Categories	Frequency	Proportion (%)
Age in years (mean, ±SD)	(58 ±11)		
Gender	Female	11	52.38
	Male	10	47.62
Marital status	Single never married	4	19.05
	Married/Cohabiting	11	52.38
	Divorced/Widowed	6	28.57
Household head	No	6	28.57
	Yes	15	71.43
Highest education	Secondary school	15	71.43
	More than secondary school	6	28.57
Employment status	Unemployed	5	23.81
	Employed	4	19.05
	Self-employed	3	14.29
	Pensioner/retired	9	42.86
Has medical aid	No	20	95.24
	Yes	1	4.76
Household wealth quintile	Poorest	5	23.81
	Poor	4	19.05
	Middle	4	19.05
	Rich	4	19.05
	Richest	4	19.05
Colorectal Cancer Stage	Stage 2	2	9.52
	Stage 3	10	47.62
	Stage 4	9	42.86
Household income	ZAR 0 - 1000	2	9.52
	ZAR 1001 - 2000	2	9.52
	ZAR 2001 - 3000	1	4.76
	ZAR 4001 - 5000	3	14.29
	ZAR 5001 - 10000	5	23.81
	ZAR 10001 - 15000	3	14.29
	ZAR 15001+	5	23.81
UPFS	H0	7	33.33
	H1	10	47.62
	H2	3	14.29
	H3	1	4.76

3.5.2 OOP Expenditure analysis

The components of participant OOP expenditure, as shown in **Table 3** below, revealed transportation costs as the primary contributor (48.9% of total expenses), with a mean (±SD) expenditure of ZAR 137.19 per month (±96.49). Expenditure on medicines accounted for 27.8%, averaging ZAR 223.33 per month (±453.16). Other notable expenditures included vitamins (10.3%) and, interestingly, stoma bags (4%), with the latter averaging ZAR 85.71 per month (±298.81). Diagnostic tests (0.9%), doctor fees (3.5%), and accommodation expenses (2.4%) contributed minimally to overall costs, averaging ZAR 14.28 per month (±65.46), ZAR 35.95 per month (±144.48) and ZAR 38.09 per month (±174.57) respectively.

Table 3; Components of Out-of-pocket (OOP) expenditure

Component of OOP expenditure	**Proportion (%)**	**Mean (SD)**
Doctor's fee	3.5	35.95 (144.48)
Diagnostic tests	0.9	14.28 (65.46)
Medicines	27.8	223.33 (453.16)
Transport	48.9	137.19 (96.49)
Accommodation	2.4	38.09 (174.57)
Chemo/radiation therapy	0.7	4.52 (20.73)
Vitamins	10.3	39.76 (75.01)
Stoma bags	4	85.71 (298.81)
Miscellaneous	1.5	23.81 (109.11)
Total OOP expenditure per patient	**4.76**	**602, 64**

Stratification of OOP expenditure by colorectal cancer stage, shown in **Table 4**, indicated that participants in Stage III incurred the highest mean costs (ZAR 732, ±867.84), compared to ZAR 577.33 (±593.08) for Stage IV and ZAR 70 (±14.14) for Stage II. These disparities suggest a significant cost burden associated with late disease stages.

Table 4; Out-of-pocket expenditure stratified by stage of disease

Stage of Colorectal Cancer	Mean OOP expenditure
II	**70 (14.14)**
III	**732 (867.84)**
IV	**577.33 593.08)**

3.5.3 Catastrophic Health Expenditure

38% of the patient population in this study were shown to experience CHE at the 10% threshold level. As shown in **Table 5**, the prevalence of CHE varied across wealth quintiles, with the poorest households experiencing the highest rate at 60%, followed by poor households at 50%. CHE was lowest among the "wealthier" quintiles, in this case, the middle to richest households, with each at 25%. The overall mean OOP expenditure was ZAR 655.05 (±714.93), but the median was significantly lower at ZAR 250, indicating a skewed distribution driven by a subset of participants with exceptionally high costs.

Table 5; Total out-of-pocket expenditure and proportion of households experiencing catastrophic health expenditure according to wealth quintiles.

Wealth quintile	OOP Monthly Expenditure Mean (SD)/Median	Households That Experienced Catastrophic Health Expenditure (CHE) *n* (%)
Q1 – Poorest	668 (1028.94) / 200	3 (60)
Q2 – Poor	716.25 (833.90) / 450	2 (50)
Q3 – Middle	530 (383.41) / 510	1 (25)
Q4 – Rich	507.75 (437.16) / 345.50	1 (25)
Q5 – Richest	850 (925.56) / 650	1 (25)
Total	**655.05 (714.93) / 250**	**8 (38%)**

When stratified by cancer stage, households of stage III patients bore the highest CHE prevalence at 50%, when compared to 33.33% for stage IV (**Table 6**)**.** Stage II households did not report any CHE. These results highlight the disproportionate financial burden borne by stage III households despite similar OOP costs in later stages.

Table 6; Catastrophic Health Expenditure stratified by stage of illness

Stage of Colorectal Cancer	**Households That Experienced Catastrophic Health Expenditure (CHE)** ***n* (%)**
II	0 (0)
III	5 (50)
IV	3 (33.33)

Note: Stage I absent as no patients in the study presented with stage I CRC

CHE stratified by levels of subsidisation

The analysis of the UPFS revealed significant disparities in CHE prevalence. Households in UPFS categories 1 and 2 (H1 and H2) exhibited the highest CHE rates (75% and 25%, respectively) (**Table 7**). A statistically significant chi-square test corroborated this finding (Pearson chi2 (3) = 7.9962, Pr = 0.046), demonstrating an association between UPFS classification and CHE prevalence. UPFS 1 and 2 (H1 and H2) patients qualify for partial healthcare subsidisation due to household incomes lower than ZAR 100 000 and 350 000, respectively. Those in category 1 are often unemployed or without income but do not qualify for certain grants that allow them to be in the fully subsidised category 0 (H0).

Table 7; Contingency table showing the relationship between Catastrophic Healthcare Expenditure (CHE) and the Universal Patient Fee Schedule (UPFS)

		UPFS				**Total**
CHE (10%)		**0**	**1**	**2**	**3**	
0 - No	**Frequency (%)**	7 (100)	4 (40)	1 (33)	1 (100)	13 (62)
1- Yes	**Frequency (%)**	0 (0)	6 (60)	2 (67)	0 (0)	8 (38)
Total	**Frequency (%)**	7 (100)	10 (100)	3 (100)	1 (100)	21 (100)
Pearson chi2(3) = 7.9962			**Pr = 0.046**			

3.5.4 Determinants of CHE

Univariate and multivariate Firth regression models explored associations between sociodemographic and clinical characteristics against CHE at the 10% threshold level (**Table 8**). Analysis revealed a clear but non-statistically significant trend: late-stage colorectal cancer (Stages III and IV combined) demonstrated a higher likelihood of CHE, with a crude odds ratio (OR) of 3.70 at a 95% confidence interval (95% CI) of 0.16–87.38, though the association was reduced in the multivariate adjusted model (OR=1.28; 95% CI: 0.04–46.58). Wealth quintiles showed an uneven distribution. In the univariate model, the association between the poorest (Q1) showed an increased risk of CHE, whilst the other wealth quintiles showed a decreased risk associated with CHE. However, the adjusted multivariate model showed that the poor (Q2) and the rich (Q3) were at greater risk of CHE, as indicated by OR values over two for these groups. Notably, adjusted models yielded non-significant results, reflecting a combination of wide confidence intervals and sample size limitations.

Surprisingly, univariate analysis showed that secondary education appeared to lower the risk of CHE compared to those with higher education. However, this trend was not statistically significant in the adjusted multivariate model (adjusted OR=1.56, 95% CI: 0.17–14.5). Gender and age similarly lacked significant associations. Overall, while the regression models highlight important trends, particularly the financial vulnerability of late-stage patients and lower-income households, larger sample sizes are needed for precise estimates.

Table 8: Predictors of CHE using univariate and multivariate Firth regression analysis

Variable	Categories	Univariate Crude Odds Ratio (95% Confidence Interval)	P value	Multivariate Adjusted Odds Ratio (95% Confidence Interval)	P value
Age	Continuous	0.91 (0.82 – 1.02)	0.112	0.95 (0.82 – 1.10)	0.494
Gender	Female ***(Reference)***	1.18 (0.38 – 3.68)	0.773		
	Male	0.25 (0.04 – 1.52)	0.132	0.30 (0.03 – 2.97)	0.301
Household head	No ***(Reference***)	1 (0.23 – 4.40)	1.00		
	Yes	0.52 (0.09 – 3.19)	0.483	1.27 (0.08 – 19.26)	0.861
Highest Education	Secondary School ***(Reference)***	0.52 (0.19 – 1.47)	0.219		
	More than secondary school	1.91 (0.31 – 11.61)	0.483	1.56 (0.17 – 14.5)	0.694
Occupation	Unemployed ***(Reference)***	1.4 (0.28 – 7.10)	0.685		
	Employed	0.31 (0.02 – 3.76)	0.355	0.22 (0.01 – 9.10)	0.426
	Self-employed	1.19 (0.09 – 15.94)	0.895	0.71 (0.02 – 20.98)	0.841
	Pensioner/Retired	0.24 (0.03 – 2.07)	0.194	0.48 (0.04 – 6.44)	0.577
Household Wealth Quintile	Poorest ***(Reference)***	1.40 (0.28 – 7.10)	0685		
	Poor	0.71 (0.07 – 7.79)	0.783	2.24 (0.09 – 57.92)	0.626
	Middle	0.31 (0.02 – 3.76)	0.355	1.78 (0.05 – 59.92)	0.747
	Rich	0.31 (0.02 – 3.76)	0.355	2.98 (0.04 – 228.21)	0.621

	Richest	0.31 (0.02–3.76)	0.355	1.14 (0.03 – 40.26)	0.943
Colorectal Cancer Stage	***Early stage (Reference)***	0.20 (0.01 – 4.17)	0.299		
	Late Stage (3 & 4)	3.70 (0.16 – 87.38)	0.418	1.28 (0.04 – 45.63)	0.894
			Cons_	17.14 (0.00 - 300596.9)	0.569

3.5.5 Coping Strategies for Financial Stress

Most participants (81%) reported adopting coping strategies to mitigate financial hardship. As shown in **Table 9**, the most common strategy was reducing household expenditure (47.7%), followed by taking on extra work (19%) and borrowing from friends or relatives (9.5%). Surprisingly, 19% did not report any coping strategy, potentially reflecting barriers to resource access or a lack of viable options. Patients did not report the use of bank loans and sales of household assets.

Table 9; Cost-coping strategies

Type of cost-coping strategy	**Frequency/Proportion (%)**
Use of savings	1 (4.8)
Borrowing from friend/relative	2 (9.5)
Reduced household expenditure	10 (47.7)
Take on extra work	4 (19)
No cost-coping strategy adopted	4 (19)
Total	21 (100)

3.6. Discussion

To the best of our knowledge, this is the first study in South Africa to assess the incidence of CHE, its determinants and financial coping strategies for CRC patients with stomas. Our findings show that the most significant cost drivers are transportation (48.9%) and medication (27.8%), whilst stoma bags (4%) contributed minimally to patient OOP expenditure. CHE was observed for 38% of participants, with a higher prevalence among poorer households and

patients with late-stage CRC. This implies that although substantial progress has been made in providing and accessing healthcare through free and subsidised public healthcare in South Africa, it does not necessarily mean that the care is affordable to all patients and often plunges patients into catastrophic spending (27, 30).

Other LMICs, such as India, have shown that transportation and lodging costs of CRC patients accounted for 20% of OOP expenditure (31). This was attributed to the large distances patients had to travel in seeking care, with some travelling up to 500km to access cancer care services (23). A study assessing OOP expenditure for cancer patients in rural Australia found that the most significant cost drivers for patients were transport, consultation fees, and co-payments for medication (32).

High transportation costs seen across studies can have varied causes, yet all have to do with the centralisation of care and, in turn, the high cost of travelling when individuals live outside large cities and metropoles (33). Public transportation in South Africa can become quite costly, with an over-reliance on personal vehicles such as cars, limiting access to publicly subsidised transport. This is further substantiated in a South African study addressing CHE amongst patients with diabetes, in which the most significant cost driver of their OOP expenditure was that of transport, with more than 50% of household spending going towards travelling (30). Other studies out of South Africa have also corroborated these findings with high levels of OOP expenditure going towards transport and travelling expenses (34-36). Very few studies have reported high OOP expenditure on medication. Stoma bags, including ostomy products, equipment, and consumables, only accounted for 4% of the patient OOP expenditure. This was surprising as we had anticipated higher OOP expenditure on stoma bags and supplies. When discussing this with the head of the stoma clinic, it was discovered that patients often have a surplus of stoma supplies as the clinic “over-dispenses” these bags to post-operative stoma patients to ensure they are sufficiently prepared for frequent bag changes. Once these patients are then referred out to their community clinics, the bags that are specific to that patient's needs are provided, and any extra bags from the visits made to the Groote Schuur Hospital stoma clinic are kept for emergency use should these patients run out or require more frequent bag changes, as such, these patients are well stocked. However, while this system has appeared to reduce the financial burden on patients, it is unknown whether this support is provided across other stoma clinics. This highlights the need for more research on the consistency of stoma supplies and their distribution and any potential discrepancies patients

may experience accessing these clinics. Furthermore, as this is merely anecdotal evidence and based upon informal conversation, this should be interpreted cautiously.

This study established CHE incidence at 38% for patients with CRC-related stomas. Similarly, a study from South Korea investigating CHE amongst households with a cancer patient had shown the rate of CHE for households was 39.8%, also at the 10% threshold. This finding is similar to ours, albeit with a much larger sample size. Similarly, a study conducted in Malaysia assessed CHE among CRC patients, reporting CHE at 47.8% (25). A study from India assessing CRC patients and their risk of financial catastrophe had shown 90% CHE (31). This result is significantly higher than not only this study but most of the existing literature around CHE due to cancer and could be attributed to cancer patients in India facing higher OOP expenditure due to limited subsidisation for radio and chemotherapy, as well as patients being required to purchase their own medication, including anaesthetic for surgical procedures (21).

A study conducted in Cape Town assessing the CHE amongst surgical inpatients (including those with cancer diagnoses and requiring surgery) found 1.9% CHE at the 10% threshold (37). The differing degrees to which CHE affects these individuals could be due to the costly nature of cancer and stoma care, where patients who do not incur user fees or experience fee subsidisation would require more significant OOP expenditure for a greater period when compared to surgical costs. It should be noted that these patients with CRC and stoma must undergo surgery to form the stoma and incur further costs for oncology services, medicines, and stoma supplies. Evidence from South Africa's income and expenditure surveys in 2010 found CHE to be just under 10% (38). Interpretation of this should err on the side of caution as the inclusion of transportation and indirect medical and non-medical expenditures were not accounted for in this calculation, underestimating the burden of CHE, particularly as more than half of poor households deemed seeking medical care too expensive due to the cost of transport (39). The estimated incidence of CHE in Sub-Saharan Africa (SSA) is 23% at the 10% threshold (40). Although this is lower than the findings from our study, CHE had been interpreted in terms of general healthcare services and diagnostic testing across SSA and specific rates of CHE related to cancer care were not accounted for. The costs associated with CRC are typically intense and require increased OOP expenditures to pay for treatments (25).

Although minimal data assesses CHE in terms of CRC in South Africa, we can compare it with other non-communicable and infectious diseases. A study assessing the incidence rate,

determinants, socio-economic inequalities of CHE and impoverishment of diabetes patients in Tshwane, Johannesburg, had found 25% CHE at the 10% ability to pay threshold (30). A South African study assessing health expenditure and Catastrophic spending for older individuals living with HIV reported that less than 10% of respondents had incurred CHE at the 40% level (41). This is significantly lower than the results of our study but is indicative of existing social protection for those who are above the age of 60, as well as the subsidisation mechanisms that exist in South Africa for HIV-related treatment and funding for infectious diseases. From these findings, we can infer that the South African public health system, due to its subsidisation mechanisms, protects a large number of patients who seek care (42).

Although not statistically significant, secondary education was shown to be associated with a lower risk of CHE compared to tertiary education. This almost counterintuitive finding may indicate a potential buffering effect due to simplified care-seeking behaviour associated with basic education levels. Other studies have reported on the importance of tertiary education as a mechanism to reduce the risk of CHE (31, 43). However, this finding could also be due to a small sample size bias and would require further investigation, which is out of the scope of this study.

CHE had also shown variation among wealth quintiles, where those in the first two quintiles (“Poorest” and “Poor”) experience the highest rates of CHE, although not statistically significant at a 95% CI in our study. Other studies substantiated our findings, showing that CHE disproportionately affects those in the lowest income quintiles (“poorest” and “poor”) (44-46). Although not statistically significant, the univariate analysis of wealth quintiles and CHE supported these findings. Interestingly, the multivariate analysis showed that those in the “rich” quintile were at greater risk of CHE than those in the “poor” and “middle” quintiles. This could be attributed to a greater proportion of OOP medical expenses these patients are privy to as they do not have the same social protection that those in lower quintiles may have. However, when assessing UPFS and CHE, patients on the UPFS system were listed as partial subsidisation, and categories 1 and 2 were the only patients experiencing CHE. In this analysis, 60% of H1 and 67% of H2 patients experienced CHE, which is statistically significant ($p = 0.046$) at the 95% CI. This may indicate that those who do not qualify for full subsidisation and those considered to have some ability to pay for care in terms of the UPFS system are the most susceptible to financial catastrophe. This differs from our findings, which show that wealth quintiles 1 (poorest) and 2 (poor) were the most likely to experience CHE. Further

research is also required to assess the variance in the degrees at which CHE occur in terms of the UPFS system and actual patient income, but this is beyond the scope of this research.

Although not statistically significant, regression analysis had shown a trend with disease staging and CHE, where patients with late-stage CRC were more likely to incur financial catastrophe than those with an early-stage diagnosis. A study in Ethiopia assessing cancer-related CHE used stages/rounds of chemotherapy as a proxy for disease staging, where treatment failures, retreating, and altered treatment regiments would result in unjust increased financial burdens (17). Similarly, other studies have also found that late-stage CRC (stage III and stage IV) increases the financial burden of households as the cost of managing late-stage CRC is significantly higher than early-stage CRC (25). Interestingly, when stratifying CHE by disease stage, 50% of stage III and 33.33% of Stage IV patients had experienced CHE. A possible explanation for this could be that CRC patients are typically diagnosed at later stages of disease progression; bowel resection and stoma formation typically occur shortly after confirmation of the diagnosis and may lead to a sudden “financial shock” increasing a patients OOP expenditure. These findings highlight the importance of early diagnosis interventions to reduce healthcare resource utilisation rates as well as the risk of financial catastrophe for the patient. However, these findings must be interpreted with caution, the small sample size may not be representative of the true distribution between these late stage groups, prompting the need for a larger study to be conducted.

More than 80% of patients had employed financial cost-coping strategies, where patients had reduced household spending due to their illness and reported borrowing from friends and family members, which had been noted in other studies (17, 47, 48). Interestingly, the selling of household assets, a commonly reported cost-coping mechanism, was not reported by patients (49, 50). During the interviews with patients, a commonly echoed sentiment by most patients is that they do not have anything of value to sell or that the things they have are necessities. It was further noted that patients did not want to use institutional banking services as they felt they could not pay back loans and did not want to burden their spouses or their children with debt when they passed. However, given that the sample was not necessarily representative of the total population, this cannot be generalised and only applies to the specific patient population enrolled in the study. Furthermore, the variation in socio-economic status and cultural saving/borrowing norms may differ from household to household, affecting the coping behaviours implemented by other CRC patients with a stoma (51).

The household sociodemographic characteristic assessment allowed for the discovery of patient household head self-identification, typically from the eldest individuals in the household, which did not translate to these patients being the financial head of the household or the breadwinners. This underlines the cultural nuances within households in South Africa, as most senior members see themselves as the household head, even if their children are the household's primary breadwinners and financial heads. Future research assessing financial catastrophe should clarify whether the head of the household is the cultural or the financial head.

3.7. Strengths and limitations.

As this study is the first in South Africa, it provides novel insights into the financial burden of CRC and stoma care, particularly in the Western Cape. Thus, contributing to and starting to address the significant gaps in the literature regarding the CHE that this patient group may experience.

This study adopted a comprehensive analysis of patient costing, which evaluated direct costs and financial coping strategies associated with CRC and stoma care, presenting a robust understanding of these patients' economic burden.

Lastly, the addition of financial coping strategies provided a more holistic view of the burden of CRC and stoma care and elucidated the real-world, tangible impacts that this disease can have on households.

The study is not free from limitations, as it was exploratory in nature, and formal sample size and power calculations were not possible due to feasibility and time constraints. As such, the study leveraged a pragmatic approach to sample size calculation. This low sample size also contributed to the non-significance of the regression analysis results, although the trends provide meaningful insight. It should also be noted that while exclusion criteria included non-English speakers, in practice all participants were able to converse in English, so this did not impact recruitment. This criterion was retained for transparency and feasibility rather than as a source of bias.

Although this study is unique and detailed in terms of medical expenses that CRC patients incur, there is the possibility that patients could underreport their household income and

overreport expenditures. Furthermore, many patients had classed themselves as household heads in the study, but in some cases, this may be in a cultural sense rather than being the breadwinners at home. Often, the children of these patients would support them alongside any grants, pensions, or retirement funds they draw on.

3.8. Conclusion

Although exploratory and yielding non-statistically significant results, this study shows that CHE prevalence among patients with CRC and stomas is comparatively low when measured against other LMICs. This phenomenon could be attributed to the social protection afforded by user fee subsidisation against direct health-related expenses. However, this cannot be stated with certainty due to the small sample of the study but may allow for insight into a possible mechanism Although CHE affected less than half the number of patients enrolled in the study, most patients had to employ financial coping strategies when dealing with their illness, mainly through decreased household expenditure, whilst many households had to employ varied financial coping behaviours given their unique circumstances. Findings from this study underscore the significance of financial barriers in accessing CRC stoma care, particularly the role of transportation costs and medication expenses, which collectively exacerbate household economic vulnerability. Late-stage diagnoses and limited healthcare access in resource-constrained settings further highlight the necessity of prioritizing preventive care and early diagnosis to mitigate long-term financial and clinical outcomes for patients. Integrating CRC care into existing UHC frameworks, particularly as the NHI program gains traction in South Africa, can also enhance affordability and accessibility for these patients. Furthermore, adopting early screening initiatives may also play a crucial role in alleviating late-stage disease burdens and their accompanying likelihood of financial catastrophe.

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Availability of data and materials

The data sets for this study can be made available upon request.

Authors' contributions

KG designed the study, wrote the paper, analysed results, reviewed the paper and submitted it for publication. DO supported data analysis and review of drafts. LC offered strategic guidance in all stages of this research.

Ethics approval and consent to participate

Consent was obtained from participants of the study prior to data collection. Ethical approval was granted from the Human Research Ethics Committee (HREC) at the University of Cape Town (HREC REF: 649/2024) and from the Western Cape Department of Health (WC_202410_053).

Competing interests

No competing interests.

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4 PART D: POLICY BRIEF

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CATASTROPHIC HEALTH EXPENDITURE (CHE) AND COST-COPING STRATEGIES AMONG PATIENTS WITH COLORECTAL CANCER (CRC) AND STOMAS IN THE WESTERN CAPE, SOUTH AFRICA

This policy brief reports on;

1. *Catastrophic health expenditure faced by patients with CRC and stomas.*
2. *The determinants of financial catastrophe.*
3. *Financial coping strategies adopted by patients with CRC and stomas.*

KEY MESSAGES

- Transportation (48.9%) and Medication expenses (27.8%) were the largest contributors of out-of-pocket spending.
- 38% of patients with CRC in this study experienced catastrophic health expenditure, highlighting the significant financial burden of CRC care, for patients with late-stage CRC (Stage 3 and 4) significantly more likely to experience CHE
- The financial burden was greater among poor households, with 60% of the poorest and 50% of poor households likely to face catastrophic health expenditure.
- Expansion of transport subsidies and medication assistance programs and improving access to early CRC screening could mitigate the financial impacts on vulnerable households

Understanding CRC in South Africa

Colorectal cancer (CRC) is among the top five cancers in South Africa, with nearly 7,400 cases and over 4,500 deaths reported in 2022. CRC incidence and mortality are rising, projected to increase by 81% and 104%, respectively, by 2045. South Africa's mortality rate (8.9 per 100,000) exceeds that of the United States of America (8.2 per 100,000). Many patients with CRC require a stoma, a surgically created opening in the abdomen to direct waste. CRC care imposes significant financial burdens on households, particularly for patients requiring stoma care.

Research gap

In South Africa, there is currently no literature on CHE for CRC patients with a stoma, making this research the first of its kind. In Africa, some studies have assessed CHE due to cancer care and stratified this by the site of cancer to include CRC, but none explicitly assessed CRC patients with a stoma.

Research overview

Research approach

With the approval from the University of Cape Town Human Research Ethics Committee (HREC) and the Western Cape Department of Health, this cross-sectional exploratory study was conducted at Groote Schuur Hospital (GSH) in the Western Cape, South Africa. Primary data collection occurred through a validated questionnaire that was administered to patients with CRC and stomas over the age of 18 who had had their stomas for more than one month at minimum. CHE was interpreted as health-related out-of-pocket expenditure that exceeded 10% of that household's income.

Key results

The most significant cost drivers for patients were transportation costs (48.9%) and medication costs (27.8%). Evidence for high transport costs is well documented in South Africa, attributable to the centralisation of healthcare facilities and hospitals. Minimal literature around high medication costs exists within an African context and for patients with CRC and stomas. Stoma care supplies accounted for 4% of patient costs.

CHE affected 38% of participants, primarily those with late-stage CRC. Stage 3 and 4 patients faced a 50% and 33% CHE risk, respectively **(Figure 2)**. The poorest (60%) and poor (50%) were most impacted, compared to the higher wealth quintiles experiencing 25% CHE each **(Figure 3).**

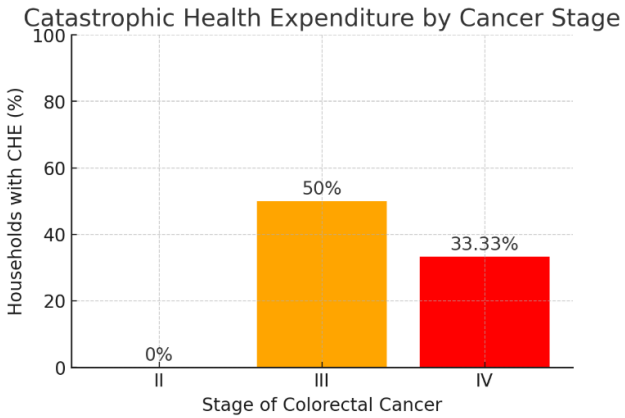

Figure 2: CHE by stage of cancer

Source: Authors' computations

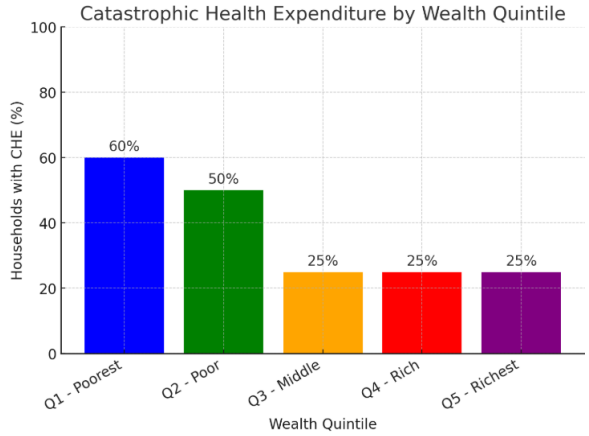

Figure 3: CHE stratified by wealth quintile
Source: Authors' computations

To manage CRC care costs, 47.7% of patients reduced household expenses, 19% took on extra work, and nearly 10% borrowed from friends or family. These findings highlight the significant financial strain cancer care imposes on households and the coping strategies they adopt. However, it should be noted that all findings are preliminary and require further research in larger studies.

Current debates

The National Health Insurance (NHI)

South Africa's NHI Act aims to achieve universal health coverage through a centralised insurance fund, purchasing services from both the public and private sectors. To prevent exclusion, it is crucial to justify the inclusion of vulnerable groups like CRC patients. This study highlights their significant out-of-pocket costs, which hinder equitable access. Without comprehensive coverage, CRC patients risk worsening financial distress, exacerbating the current 38% catastrophic health expenditure rate.

CRC prevention

Rising CRC incidence in South Africa underscores the importance of screening and early diagnosis in improving life expectancy. However, population-based screening remains limited due to complex care pathways. Expanding these programs could enhance survival and reduce advanced-stage diagnoses and the associated high risk of CHE.

Policy insights

1) Subsidies for transport costs.
With nearly half of out-of-pocket expenses allocated to transport, targeted subsidies are essential to improve healthcare accessibility and reduce the financial burden on patients.

2) Coverage expansion on essential CRC medications.
Integrating essential CRC medications into the public healthcare fee schedule could reduce out-of-pocket costs and ease patients' financial burden.

3) CRC Awareness and Screening.
This study found that those who are in late-stage progression of their disease are more likely to experience CHE than those in the early stage. We recommend implementing early screening programmes alongside awareness interventions to protect these patients. In doing so, identifying early-stage CRC could protect patients from financial catastrophe.

Conclusion
Colorectal cancer poses a substantial financial burden, particularly for advanced-stage patients and low-income households. The high prevalence of catastrophic health expenditure highlights the urgent need for more substantial financial protection under the NHI, broader screening access, and subsidies for medication and transport. Strengthening these measures will reduce financial hardship, enhance health outcomes, and advance equity in cancer care. More research is needed in clinics and hospitals that supply patients with stoma care.

Key literature

1. Bray F, Laversanne M, Sung H, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2024; 74(3): 229-263. doi:10.3322/caac.21834

2. Chen WC, Van Wyk A, Algar U, Muchengeti M, Buccimazza I, Malherbe F, Mbatani N, Ramesar R, Goldberg P. Reducing colorectal cancer mortality in South Africa: experiences and progress from the South African National Cancer Prevention Services. South African Health Review. 2023 Dec 1;2023(1):60-8.

3. Negin J, Randell M, Raban MZ, Nyirenda M, Kalula S, Madurai L, Kowal P. Health expenditure and catastrophic spending among older adults living with HIV. Glob Public Health. 2017 Oct;12(10):1282-1296.

4. PART E: Appendices

Appendix 1: Plagiarism declaration

DECLARATION

I, *Kairav Gokool*, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature: 

Date: 13/02/2025

Appendix 2: Ethical Approval

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

E-52 – Room46, E-Floor, Old Main Building
Groote Schuur Hospital
Observatory 7925
Email: hrec-submissions@uct.ac.za
Website: https://health.uct.ac.za/home/human-research-ethics

2 October 2024

HREC REF: 649/2024

Dr Lucy Cunnama
Health Economics Unit and Division
School of Public Health
UCT Faculty of Health Sciences
Email: lucy.cunnama@uct.ac.za
Student email: GKLKAI001@myuct.ac.za

Dear Dr Cunnama

PROJECT TITLE: THE COST OF STOMA CARE IN COLORECTAL CANCER: A PATIENT PERSPECTIVE AT GROOTE SCHUUR HOSPITAL IN CAPE TOWN, SOUTH AFRICA. (MASTER DEGREE – KAIRAV GOKOOL)

Thank you for submitting your study and PI response dated 17 September 2024, 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 only granted for one year until the 30 October 2025.

Please submit a progress report, using the standardised Annual Progress Report Forms (FHS016) **or** (FHS 017) if the study continues beyond the approval period. Please submit a Standard Closure form (FHS 010) when the study has been completed, this includes after publication or thesis submission and final completion.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that Master's Degree student: Mr Kairav Gokool will also be involved in this study.

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.

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

Please quote the HREC Reference number 649/2024 in all your correspondence.

Yours sincerely

PROFESSOR MARC 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.

Radiation Oncology

Professor Jeannette Parkes
Head of Division

Groote Schuur Hospital, Observatory, 7925, South Africa

Tel: +27 (0) 21 404 4263/5, +27 (0) 21 406 6801 Fax: +27 (0) 21. 404 5259
E-mail: Jeannette.parkes@uct.ac.za

07 October 2024

Dr L Cunnama
Cancer Research Initiative

Dear Dr Cunnama

Permission is hereby granted for the following study to be conducted in the department of Radiation Oncology:

RESEARCH PROJECT HREC REF: 612/2024
The cost of Stoma care in Colorectal cancer: A Patient Perspective at Groote Schuur Hospital in cape Town, South Africa (student GKLKAI001 Kairav Gokool)

Please note that permission is also required from Dr Eick through Lionel Naidoo's institutional research committee, and from Ethics committee before the trial may commence.

Kind regards

Prof Jeannette Parkes
Radiation Oncology Department

Western Cape Government

GROOTE SCHUUR HOSPITAL

Enquiries: Lionel Naidoo
e-mail: GSHResearch.Request@westerncape.gov.za

Dr L. Cunnama
Division of Human Economics Unit

E-mail: lucy.cunnama@uct.ac.za

Dear Dr Cunnama

RESEARCH PROJECT: The Costs of Stoma Care Following Colorectal Surgery at Groote Schuur Hospital, Western Cape, South Africa

Your recent letter to the hospital ~~refers~~.

You are granted permission to proceed with your research, which is valid until **30 August 2025**

Please note the following:

a) Your research may not interfere with normal patient care.
b) Hospital staff may not be asked to assist with the research.
c) **Confidentiality must always be maintained.**
d) No additional costs to the hospital should be incurred as indicated in your Annexure 2 i.e. Lab, consumables or stationery. **If access to TRACK Care/NHLS is required, kindly attach our letter of approval to the application form and approach Information Management to assist with data.**
e) **No patient folders may be removed from the premises or be inaccessible.**
f) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
g) **Should you at any time require photographs of your subjects, please obtain the necessary indemnity forms from our Public Relations Office (E45 OMB or ext. 2187/2188).**
h) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
i) Please discuss the study with the HOD before commencing.
j) Please introduce yourself to the person in charge of an area before commencing.
k) On completion of your research, please forward any recommendations/findings that can be beneficial to use to take further action that may inform redevelopment of future policy / review guidelines.
l) If the researcher is not ~~GSH~~ staff member, a supernumerary contract is required before commencement of the research.
m) Please contact Michelle Riley (Patient Fees) at ext. 2276 to ascertain if there will be charges for conducting the Research and to obtain a quote or to discuss charges
n) **Kindly submit a copy of the publication or report to this office on completion of the research.**
o) **At no time should any posters encouraging patients to ~~partake~~ in research, be displayed within a clinical area.**
p) **Please adhere to ALL COVID-19 regulations and Groote Schuur Hospital policies.**
q) **All Clinical Trials to be registered on ~~Clinicom~~ with Michelle Riley. michelle.riley@westerncape.gov.za**

I would like to wish you every success with the project.

Yours sincerely

LIONEL NAIDOO
HEAD: ALLIED HEALTH
Date: 25 September 2024
C.C. Mr. L. Naidoo, Mr. A. Mohamed, Dr B. Jacobs, Professor L. Cairncross

Appendix 3: BMC Public Health (Author's guide)

Criteria

Research articles should report on original primary research or new experimental or computational methods, tests or procedures. Manuscripts reporting results of a clinical trial must conform to CONSORT 2010 guidelines. Authors of randomized controlled trials should submit a complete CONSORT checklist alongside their manuscript, available at www.consort-statement.org. Research articles may also report on systematic reviews of published research provided they adhere to the appropriate reporting guidelines which are detailed in our editorial policies. Please note that non-commissioned pooled analyses of selected published research and bibliometric analyses will not be considered. Studies reporting descriptive results from a single institution or region will only be considered if analogous data have not been previously published in a peer reviewed journal and the conclusions provide distinct insights that are of relevance to a regional or international audience.

Data sharing

BMC Public Health strongly supports open research, including transparency and openness in reporting. Further details of our Data availability policy can be found on the journal's About page.

Professionally produced Visual Abstracts

BMC Public Health will consider visual abstracts. As an author submitting to the journal, you may wish to make use of services provided at Springer Nature for high quality and affordable visual abstracts where you are entitled to a 20% discount. Click here to find out more about the service, and your discount will be automatically be applied when using this link.

Preparing your manuscript

The information below details the section headings that you should include in your manuscript and what information should be within each section.

Please note that your manuscript must include a 'Declarations' section including all of the subheadings (please see below for more information).

5. Title page

The title page should:

- present a title that includes, if appropriate, the study design e.g.:
    - "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review"
    - or for non-clinical or non-research studies a description of what the article reports
- list the full names and institutional addresses for all authors
    - if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please

include this information in the “Acknowledgements” section in accordance with the instructions below

    - Large Language Models (LLMs), such as ChatGPT, do not currently satisfy our authorship criteria. Notably an attribution of authorship carries with it accountability for the work, which cannot be effectively applied to LLMs. Use of an LLM should be properly documented in the Methods section (and if a Methods section is not available, in a suitable alternative part) of the manuscript.
- indicate the corresponding author

6. Abstract

The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. Reports of randomized controlled trials should follow the CONSORT extension for abstracts. The abstract must include the following separate sections:

- **Background:** the context and purpose of the study
- **Methods:** how the study was performed and statistical tests used
- **Results:** the main findings
- **Conclusions:** brief summary and potential implications
- **Trial registration:** If your article reports the results of a health care intervention on human participants, it must be registered in an appropriate registry and the registration number and date of registration should be stated in this section. If it was not registered prospectively (before enrollment of the first participant), you should include the words 'retrospectively registered'. See our editorial policies for more information on trial registration

7. Keywords

Three to ten keywords representing the main content of the article.

8. Background

The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field.

9. Methods

The methods section should include:

- the aim, design and setting of the study
- the characteristics of participants or description of materials
- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
- the type of statistical analysis used, including a power calculation if appropriate

10. Results

This should include the findings of the study including, if appropriate, results of statistical analysis which must be included either in the text or as tables and figures.

11. Discussion

This section should discuss the implications of the findings in context of existing research and highlight limitations of the study.

12. Conclusions

This should state clearly the main conclusions and provide an explanation of the importance and relevance of the study reported.

13. List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.

Declarations

All manuscripts must contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Consent for publication
- Availability of data and materials
- Competing interests
- Funding
- Authors' contributions
- Acknowledgements
- Authors' information (optional)

Please see below for details on the information to be included in these sections.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

Ethics approval and consent to participate

Manuscripts reporting studies involving human participants, human data or human tissue must:

- include a statement on ethics approval and consent (even where the need for approval was waived)
- include the name of the ethics committee that approved the study and the committee's reference number if appropriate

Studies involving animals must include a statement on ethics approval and for experimental studies involving client-owned animals, authors must also include a statement on informed consent from the client or owner.

See our editorial policies for more information.
If your manuscript does not report on or involve the use of any animal or human data or tissue, please state "Not applicable" in this section.

Consent for publication

If your manuscript contains any individual person's data in any form (including any individual details, images or videos), consent for publication must be obtained from that person, or in the case of children, their parent or legal guardian. All presentations of case reports must have consent for publication.

You can use your institutional consent form or our consent form if you prefer. You should not send the form to us on submission, but we may request to see a copy at any stage (including after publication).
See our editorial policies for more information on consent for publication.
If your manuscript does not contain data from any individual person, please state "Not applicable" in this section.

Availability of data and materials

All manuscripts must include an 'Availability of data and materials' statement. Data availability statements should include information on where data supporting the results reported in the article can be found including, where applicable, hyperlinks to publicly archived datasets analysed or generated during the study. By data we mean the minimal dataset that would be necessary to interpret, replicate and build upon the findings reported in the article. We recognise it is not always possible to share research data publicly, for instance when individual privacy could be compromised, and in such instances data availability should still be stated in the manuscript along with any conditions for access.

Authors are also encouraged to preserve search strings on searchRxiv https://searchrxiv.org/, an archive to support researchers to report, store and share their searches consistently and to enable them to review and re-use existing searches. searchRxiv enables researchers to obtain a digital object identifier (DOI) for their search, allowing it to be cited.
Data availability statements can take one of the following forms (or a combination of more than one if required for multiple datasets):

- The datasets generated and/or analysed during the current study are available in the [NAME] repository, [PERSISTENT WEB LINK TO DATASETS]
- The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
- All data generated or analysed during this study are included in this published article [and its supplementary information files].
- The datasets generated and/or analysed during the current study are not publicly available due [REASON WHY DATA ARE NOT PUBLIC] but are available from the corresponding author on reasonable request.
- Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.
- The data that support the findings of this study are available from [third party name] but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of [third party name].
- Not applicable. If your manuscript does not contain any data, please state 'Not applicable' in this section.

More examples of template data availability statements, which include examples of openly available and restricted access datasets, are available here.
BioMed Central strongly encourages the citation of any publicly available data on which the conclusions of the paper rely in the manuscript. Data citations should include a persistent identifier (such as a DOI) and should ideally be included in the reference list. Citations of datasets, when they appear in the reference list, should include the minimum information recommended by DataCite and follow journal style. Dataset identifiers including DOIs should be expressed as full URLs. For example:

Hao Z, AghaKouchak A, Nakhjiri N, Farahmand A. Global integrated drought monitoring and prediction system (GIDMaPS) data sets. figshare.
2014. http://dx.doi.org/10.6084/m9.figshare.853801
With the corresponding text in the Availability of data and materials statement:

The datasets generated during and/or analysed during the current study are available in the [NAME] repository, [PERSISTENT WEB LINK TO DATASETS].[Reference number]
If you wish to co-submit a data note describing your data to be published in *BMC Research Notes*, you can do so by visiting our submission portal. Data notes support open data and help authors to comply with funder policies on data sharing. Co-published data notes will be linked to the research article the data support (example).

Competing interests

All financial and non-financial competing interests must be declared in this section.

See our editorial policies for a full explanation of competing interests. If you are unsure whether you or any of your co-authors have a competing interest please contact the editorial office.

Please use the authors initials to refer to each authors' competing interests in this section.

If you do not have any competing interests, please state "The authors declare that they have no competing interests" in this section.

Funding

All sources of funding for the research reported should be declared. If the funder has a specific role in the conceptualization, design, data collection, analysis, decision to publish, or preparation of the manuscript, this should be declared.

Authors' contributions

The individual contributions of authors to the manuscript should be specified in this section. Guidance and criteria for authorship can be found in our editorial policies.
Please use initials to refer to each author's contribution in this section, for example: "FC analyzed and interpreted the patient data regarding the hematological disease and the transplant. RH performed the histological examination of the kidney, and was a major contributor in writing the manuscript. All authors read and approved the final manuscript."

Acknowledgements

Please acknowledge anyone who contributed towards the article who does not meet the criteria for authorship including anyone who provided professional writing services or materials.

Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements section.

See our editorial policies for a full explanation of acknowledgements and authorship criteria.
If you do not have anyone to acknowledge, please write "Not applicable" in this section.

Group authorship (for manuscripts involving a collaboration group): if you would like the names of the individual members of a collaboration Group to be searchable through their individual PubMed records, please ensure that the title of the collaboration Group is included on the title page and in the submission system and also include collaborating author names as the last paragraph of the “Acknowledgements” section. Please add authors in the format First Name, Middle initial(s) (optional), Last Name. You can add institution or country information for each author if you wish, but this should be consistent across all authors.

Please note that individual names may not be present in the PubMed record at the time a published article is initially included in PubMed as it takes PubMed additional time to code this information.

Authors' information

This section is optional.

You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

References

Examples of the Vancouver reference style are shown below.

See our editorial policies for author guidance on good citation practice
Web links and URLs: All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, as well as the date the site was accessed, in the following format: The Mouse Tumor Biology Database. http://tumor.informatics.jax.org/mtbwi/index.do. Accessed 20 May 2013. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

Appendix 4: Stoma patient cost questionnaire

- Complete this interview for patients:
  - who have visited the stoma clinic for stoma care subsequent to a diagnosis of colorectal cancer
  - who are 18 years of age or older
  - who have provided written consent after the project has been explained to them, as well as the ability to cease the interview at any point without consequence to their care

- Ask each question in the order it appears on the form and choose the *best possible response* from the options provided.
- Do not skip questions unless told to do so by the skip logic.
- After the interview is complete review the form to ensure all questions were answered ***before ending the interview with the participant.***

PART A: DEMOGRAPHIC AND SOCIOECONOMIC STATUS			
The following questions are about your background information and socioeconomic status			
1.1	Unique Identifier		
1.2	Date of Interview *dd/mm/yyyy*		
1.3	Place of Interview (Facility Name)		
1.4	Gender	0 = Male 1 = Female 2 = Other	
1.5	Age		
1.6	What is the highest level of education you have completed?	0 = None 1 = Grade 1/Standard A 2 = Grade 2/Standard B 3 = Grade 3/Standard 1 4 = Grade 4/Standard 2	

		5 = Grade 5/Standard 3 6 = Grade 6/Standard 4 7 = Grade 7/Standard 5 8 = Grade 8/Standard 6 9 = Grade 9/Standard 7 10 = Grade 10/Standard 8 11= Grade 11/Standard 9 12 = Grade 12/Standard 10 (Matric) 13 = Attended some tertiary education (University/College) 14 = Completed tertiary education	
1.7	What is your marital status?	1= Single, never married 2 = Cohabitating 3 = Married 4 = Divorced 5 = Married and currently separated 6 = Widow/Widower	
1.8	Relationship of patient to household head	1 = Head 2 = Brother/Sister 3 = Partner/Spouse/Wife/Husband 4 = Parent 5 = Daughter/Son 6 = Other relative 7 = Other	
1.9	What is your current occupation?	1 = Unemployed 2 = Student	

		3 = Employed full-time 4 = Employed part-time 5 = Self-employed 6 = Pensioner/Retired	
1.10	Other than yourself, does anyone else in your household have a job?	1 = Yes 2 = No	
1.11	On average, what is your household's monthly income?	1 = < ZAR 5000 2 = ZAR 5 001 – 10 000 3 = ZAR 10 001 - 15 000 4 => ZAR 15 001	
1.12	What type of dwelling do you live in?	1 = House or brick/concrete block structure on separate stand or yard or on a farm 2 = Traditional dwelling/hut/structure made of traditional materials 3 = Flat or apartment in a block of flats 4 = Cluster house in complex 5 = Townhouse (semi-detached house in a complex) 6 = Semi-detached house 7 = House/flat/room in backyard 8 = Informal dwelling (shack in backyard) 9 = Informal dwelling (e.g. in an informal squatter settlement or on a farm) 10 = Room/flatlet on a property or a larger dwelling, or granny flat 11 = Caravan/tent 12 = Homeless	

		13 = Other, specify: _____	
1.13	What is the main material of your floor?	1 = Natural floor (earth/sand/dung) 2 = Rudimentary floor (bare wood planks) 3 = Finished floor (parquet/polished/ceramic tiles/cement/carpet)	
1.14	What is the main material of your walls	1 = Plastic/cardboard 2 = Prefab/wood 3 = Mud 4 = Bare brick/cement blocks 5 = Mud and cement 6 = Plaster/finished 7 = Corrugated iron/zinc 8 = Other, specify: _____	
1.15	What is the main source of drinking water for members in your household?	1 = Piped (tap) water inside dwelling 2 = Borehole 3 = Piped (tap) water inside the yard 4 = Piped (tap) water on community stand 5 = Open source (river or stream) 7 = Other, specify: _____	

1.16	What kind of toilet facilities does your household have?	1 = Flush toilet connected to sewage 2 = Pit toilet without ventilation 3 = Pit toilet/latrine with ventilation (VIP) 4 = Flush toilet connected to septic tank 5 = Bucket toilet 6 = Chemical toilet 7 = None 8 = Other, specify: _____	

1.17	Does your household have any of the following in working condition?	18a. Electric/gas stove: *1=Yes, 0=No*	
		18b. Vacuum cleaner: *1=Yes, 0=No*	
		18c. Washing machine *1=Yes, 0=No*	
		18d. Satellite television (DSTV): *1=Yes, 0=No*	
		18e. DVD player: *1=Yes, 0=No*	
		18f. Working motorcar: *1=Yes, 0=No*	
		18g. Mail Post box/bag: *1=Yes, 0=No*	
		18h. Mail delivery at home: *1=Yes, 0=No*	
		18i. Radio: *1=Yes, 0=No*	
		18j. Television: *1=Yes, 0=No*	
		18k. Laptop/Tablet/Computer: *1=Yes, 0=No*	
		18l. Refrigerator: *1=Yes, 0=No*	

		18m. Landline telephone *1=Yes, 0=No*	
		18n. Cell phone (no internet): *1=Yes, 0=No*	
		18o. Cell phone with Whatsapp: *1=Yes, 0=No*	
		18p. Internet/WiFi: *1=Yes, 0=No*	
		18q. Bicycle: *1=Yes, 0=No*	
		18r. Motorcycle or scooter *1=Yes, 0=No*	
1.18	Does any member of your household own:	19a. Donkey/horse *1=Yes, 0=No*	
		19b. Livestock (sheep, cattle or goats) *1=Yes, 0=No*	
1.19	Do you currently have any form of health insurance/medical aid	1= Yes, 0=No	
1.20	If yes, what		

PART B: HOUSEHOLD EXPENDITURE PATTERNS	
This section asks you to provide an estimate of your monthly household expenditure on the following items.	
ITEM	**EXPENDITURE (ZAR)**
Food	
Transport	

Rent/Bond/Mortgage (including interest payments)	
Utilities (Water, Gas, Electricity)	
Clothing expenses	
Childcare and education expenses	
Health care expenses (excluding medical aid)	
Medical aid	
Leisure expenses (eating out/travel/entertainment)	
Alcohol and tobacco	
Miscellaneous expenses	

PART C: DIAGNOSIS AND TREATMENT HISTORY			
The following questions are about your diagnosis and treatment history			
2.1	What stage of colorectal cancer do you have?	1 = Stage 1 2 = Stage 2 3 = Stage 3 4 = Stage 4	
2.2	Date that you had your stoma formed? *dd/mm/yyyy*		□□/□□/□□□□
2.3	What date did you first visit the stoma clinic? *dd/mm/yyyy*		□□/□□/□□□□
2.4	What was the main mode of transport taken on this visit to the hospital?	1 = Bike 2 = Car 3 = Bus/taxi 4 = Walking 5 =Train 6 = Other, specify: _____	

In this section we are asking you some questions about the use of health care providers during the last month		
Type of facility	**No. of visits/days of stay**	
Public clinic (outpatient visits)		
Private clinic (outpatient visits)		
General Practitioner/Doctor (outpatient visits)		
Traditional healer (outpatient visits)		
Public hospital emergency department (outpatient visits/inpatient days)		
Public hospital outpatient department (outpatient visits)		
Public hospital inpatient stay (inpatient days)		
Private hospital emergency department (outpatient visits/inpatient days)		
Didn't seek care		

PART D: DIRECT COSTS	
Including today, in the last month, how much have you spent in total on the following items because of colorectal cancer and your stoma?	
Item	**Cost (ZAR)**
Consultations at GP/Traditional Healer	
Drugs/medicines at the pharmacy	
Vitamins/food supplements	
Diagnostic costs including laboratory tests, MRIs or CT scans?	
Transport to health facility	
Accommodation (if applicable for you and any accompanying member of your household)	
Chemotherapy or radiation therapy	
Stoma bags and stoma care products	
Other costs (specify)	

Part E: Indirect Costs			
The following questions are about how your economic circumstances have changed since your diagnosis.			
3.1	In what ways has the illness affected your income?	1 = I was too sick to work 2 = I work less time now 3 = I lose income when I seek treatment 4 = I spend more money on drugs and special food 5 = I was fired 6 = It has not affected my income 7 = Other, (Specify)	
3.2	Were you employed at the time you were diagnosed with colorectal cancer?	*1=Yes, 0=No*	
	If yes, are you still working now?	*1=Yes, 0=No*	

	If no, are you working now?	*1= Yes, 0=No*	
3.3	Are you looking after anyone else in your household, including any children, elderly or disabled people?	*1=Yes, 0=No*	
	If yes, how many?		
3.5	Since you were diagnosed with colorectal cancer, were you are unable to work at your job?	*1=Yes, 0=No*	
	Was anyone else in your household able to take over your job-related tasks?	*1= Yes, 0= No*	

	If yes, who?		
3.6	Since you were diagnosed with colorectal cancer, how many hours had to be covered by members of your household because you were unable to do your job-related tasks?		
3.7	When you are unable to work, is anyone else in your household able to take over your household-related tasks?	*1=Yes, 0=No*	
3.8	Has anyone in your household had to care for you because of your cancer illness and stoma?	*1=Yes, 0=No*	
	If yes, who?	1 = Spouse 2 = Child 3 = Other relative 4 = Other (specify)	

3.9	Since you were diagnosed with colorectal cancer, how many hours did this person have to care for you?		
3.13	When was the last time that you were seriously ill?		
3.14	Did somebody else have to take care of you the last time you were seriously ill?	*1=Yes, 0=No*	
	If yes, for how many days did they have to look after you?		
3.15	When was the last time you were so ill that you had to be hospitalised?		
3.16	How many days did you spend in hospital?		
3.17	Did you have to pay?	*1=Yes, 0=No*	
	If yes, how much?		

Part E: Coping Strategies			
The following questions are about how your cope with health care costs			
4.1	How did you pay for the treatment that you received the last time?	1 = Paid for by medical aid 2 = Use of household savings 3 = Sold valuables 4 = Borrowed money 5 = Other specify	
4.2	Since you were diagnosed with colorectal cancer, did you have to borrow any money due to income losses associated with your colorectal illness?	*1=Yes, 0=No* If no, skip to Question 4.4	
4.3	If YES, whom did you borrow from?	1 = A household member 2 = A community leader 3 = Relatives 4 = Friends within the community 5 = Friends outside the community (work colleagues) 6 = Money lender 7 = A commercial bank 8 = Other (specify)	
4.4	Since you were diagnosed with colorectal cancer, did you have to sell any assets (like the list in 1.18) to pay for seeking treatment?	*1=Yes, 0=No*	
4.5	Have any household members started to increase the number of jobs/work hours since the onset of your illness?	*1=Yes, 0=No*	

4.6	Has any household member of less than eighteen years old currently had to start working to contribute to the household income?	*1=Yes, 0=No*	
4.7	Has anybody dropped out or abandoned school/studies in your household since the onset of your illness?	*1=Yes, 0=No*	
4.8	If YES, please specify type of asset sold		
4.9	Since you were diagnosed with colorectal cancer, did you reduce spending on other items in order to pay for health care?	*1=Yes, 0=No*	
	If YES, please specify the category in which you reduced spending	1 = Food 2 = Children's education e.g. change of school or drop out 3 = Health care treatment for other family members (e.g. to use cheaper facility) 4 = Clothing e.g. winter clothes 5 = Other (Specify)	
4.10	Before you were diagnosed with colorectal cancer, did you receive any grants?	*1=Yes, 0=No*	

	If yes, what type of grant did you receive?	1 = Disability grant 2 = Child support grant 3 = Old age/pension grant 4 = Other (specify)	
	Since you were diagnosed with colorectal cancer, did you receive any grants?	*1=Yes, 0=No*	
	If yes, what type of grant did you receive?	1 = Disability grant 2 = Child support grant 3 = Old age/pension grant 4 = Other (specify)	
4.11	What is the total income from these grants?		

Is there anything else that you would like to share with me about your experience of colorectal cancer or stoma care?

Appendix 5: Table showing direct and indirect cost variables with corresponding descriptions.

Direct Costs		
Question	**Type of variable**	**Description**
Consultations at GP/Traditional healers	Discrete	0 - ∞
Drugs/Medicines at the Pharmacy		
Nutritional Supplements/Vitamins		
Diagnostic costs including laboratory tests, MRI's or CT scans		
Transport to health facility		
Accommodation (if applicable for you and any accompanying member of your household)		
Chemotherapy or radiation therapy		
Stoma bags and stoma care products		
Other costs (please specify)		

The Indirect Costs that are explored are as follows:

Indirect costs		
Question	**Type of Variable**	**Description**
In what ways has the illness affected your income?	Categorical	1 = I was too sick to work 2 = I work less time now 3 = I lose income when I seek treatment 4 = I spend more money on drugs and special food 5 = I was fired 6 = It has not affected my income 7 = Other, (Specify) .....
Were you employed at the time you were diagnosed with Colorectal Cancer?	Binary	1= Yes 0= No
If yes, are you still working now?	Binary	1= Yes 0= No
If no, are you working now?	Binary	1= Yes 0= No
Are you looking after anyone else in your household, including any children, elderly or disabled people?	Binary	1= Yes 0= No
If yes, how many?	Discrete	0 - ∞
Since you were diagnosed with colorectal cancer, were you are unable to work at your job?	Binary	1=Yes 0=No

was anyone else in your household able to take over your job-related tasks?	Binary	1= Yes 0= No
Since you were diagnosed with Colorectal Cancer, how many hours had to be covered by members of your household because you were unable to do your job-related tasks?	Discrete	0 - ∞
When you are unable to work, is anyone else in your household able to take over your household-related tasks?	Binary	1= Yes 0= No
Has anyone in your household had to care for you because of your cancer illness?	Binary	1= Yes 0= No
If yes, who	Categorical	1 = Spouse 2 = Child 3 = Other relative 4 = Other (specify)
Since you were diagnosed with colorectal cancer, how many hours did this person have to care for you?	Discrete	0 - ∞
Have any household members started to increase the number of jobs/work hours since the onset of your illness?	Binary	1= Yes 0= No

Has any household member of less than eighteen years old currently had to start working to contribute to the household income?	Binary	1= Yes 0= No
Has anybody dropped out or abandoned school/studies in your household since the onset of your illness?	Binary	1= Yes 0= No
Did somebody else have to take care of you the last time you were seriously ill?	Binary	1= Yes 0= No
If yes, for how many days did they have to look after you?	Discrete	0 - ∞