Health Management and Policy Section

Turnaround Time and Barriers in Treatment of Newly Diagnosed Cancer Patients: A Research Protocol

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ABSTRACT

Introduction: The journey from cancer diagnosis to treatment initiation is a critical period in a patient's life. Timely treatment is often associated with better outcomes, yet numerous challenges and barriers can impede the process.

Need of the study: This research will hold significant implications for healthcare providers, policymakers, and, most importantly, cancer patients. By uncovering the obstacles and delays in cancer treatment, this protocol will provide the information needed to streamline the process, potentially leading to earlier interventions, improved patient experiences, and enhanced treatment outcomes.

Aim: To comprehensively understand and address the factors influencing the turnaround time and the barriers encountered by cancer patients in accessing treatment.

Materials and Methods: This study will employ a mixed-methods research design, combining both quantitative and qualitative approaches. It will encompass 89 patients at Siddharth Gupta Memorial Cancer Hospital (SGMCH), situated in Sawangi (Meghe), Wardha, Maharashtra, India. The estimated duration for this study is from December 2023 to October 2024. Factors influencing the turnaround time and the barriers encountered by cancer patients in accessing treatment will be evaluated. Primary data will be collected directly from newly diagnosed cancer patients using structured surveys/questionnaires. Secondary data sources include medical records, hospital, and healthcare system data.

Statistical analysis will be done using Chi-square for qualitative measurement, Independent t-test, and Analysis of Variance (ANOVA) for the quantitative measurement. A p-value of <0.05 will be considered significant.

Keywords: Access to care, Cancer diagnosis, Treatment initiation

INTRODUCTION

Efforts to improve accessibility to cancer treatment for newly diagnosed patients have become increasingly important in recent years. Studies have shown that there can be disparities in treatment among patients with cancer due to various socio-demographic factors such as wealth, educational background, and racial/ethnic or sexual discrimination [1]. One of the key factors influencing the turnaround time that acts as a barrier to treatment for newly diagnosed cancer patients is access to care. Access to care plays a crucial role in determining the timely initiation of treatment for cancer patients [2]. While improving access to high-quality specialist treatment has been the focus, other factors such as delayed diagnosis and treatment for symptomatic and screen-detected patients can also contribute to barriers in timely treatment [3]. These barriers can have a detrimental impact on the turnaround time for treatment, as delays in diagnosis and initiation of treatment can result in worse clinical outcomes for patients and contribute to disparities in cancer care. The interventions may include implementing outreach programs to increase awareness about cancer and the importance of early detection, providing resources and support for patients to overcome financial barriers and access necessary treatment and follow-up care, improving access to transportation services for patients who may face difficulties in reaching healthcare facilities, enhancing patient-clinician communication and support systems to ensure clear and effective communication between patients and providers, and implementing strategies to reduce systemic barriers such as improving insurance coverage for all individuals. Prolonged turnaround time - the period between cancer diagnosis and the start of treatment - has been shown to have negative implications for patient outcomes such as increased distress, disease progression, and mortality rates [4]. The total time from diagnosis to initiation of treatment, often referred to as treatment delay, has been identified as a key determinant of cancer outcomes. These findings highlight the importance of minimising turnaround time and addressing barriers to treatment in order to optimise patient outcomes.

This prolongation of the treatment process can result from various factors such as delays in diagnostic procedures, referral processes, and scheduling conflicts [4]. Additionally, the concept of Theragnostic has emerged as a potential approach to reducing mortality rates by minimising the time interval between cancer diagnosis and treatment initiation [5]. Theragnostic combines diagnostic and therapeutic approaches in a single system, allowing for early detection and simultaneous treatment of cancer. There are several factors that can affect the turnaround time in the treatment of newly diagnosed cancer patients [6], including socio-demographic inequalities, lack of insurance coverage, limited transportation options, and challenges in patient-clinician communication. Socio-demographic inequalities can contribute to disparities in access to timely cancer treatment [7].

Patients may face barriers in accessing necessary cancer treatment due to various factors such as limited resources, language barriers, lack of insurance, or limited insurance coverage. This may result in delays in receiving the care they need. Additionally, limited transportation options can also contribute to delays in treatment initiation for newly diagnosed cancer patients. Effective communication between patients and healthcare providers is essential for the timely diagnosis and treatment of cancer [8,9].

Primary objectives:

- To identify several factors contributing to the turnaround time in cancer diagnosis and treatment initiation.

- To explore the barriers faced by newly diagnosed cancer patients, including logistic, financial, and psychological challenges.

Secondary objectives:

- To evaluate the impact of these factors and barriers on the healthcare system's efficiency and patients' outcomes.

- To propose recommendations and strategies for reducing turnaround time and mitigating barriers in cancer treatment.

REVIEW OF LITERATURE

A cohort study was conducted in Boston, Massachusetts, including 2,241,706 patients with breast, prostate, non small cell lung, and colon cancer. Mortality was associated with increased time to treatment, although the degree varied by cancer type and stage. Patients with colon and lung cancer had the highest mortality associated with increased time to treatment. The median {Interquartile Range (IQR)} time to treatment intention by cancer was 32 (21-48) days for breast, 79 (55-117) days for prostate, 41 (27-62) days for Non Small Cell Lung Carcinoma (NSCLC), and 26 (16-40) days for colon. In contrast to current pandemic-related guidelines, more prompt definitive treatment for intermediate-risk and high-risk prostate cancer is needed [7].

A cross-sectional study based on cancer awareness among adolescents was conducted in Britain. In this study, adolescents' cancer awareness was low. Half of all adolescents did not know the most common childhood (51%) or teenage (49%) cancers, and most (69%) believed cancer was unrelated to age. Awareness of cancer symptoms was significantly higher among older adolescents (aged 13-17 years) (p-value=0.003) and those who knew someone with cancer (p-value <0.001) and 'not feeling confident to talk about symptoms' (53%). Endorsement of these emotional barriers was significantly higher among females (p-value ≤0.001) [10].

The issue of delayed presentation and barriers to treatment in newly diagnosed cancer patients has been documented in several studies. For instance, a survey of 2,371 patients with different cancers found that 21% had delayed presentation for three months or more, with socio-economic factors played a significant role in these delays [11]. The pandemic has resulted in newly diagnosed cancer patients presenting with more advanced stages of cancer due to delays in screening [12]. Additionally, many patients postponed their treatment during the height of the pandemic out of fear of contracting Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), leading to a worsened prognosis. Furthermore, the Coronavirus Disease-2019 (COVID-19) pandemic had significant effects on cancer patients, including missed diagnosis and delayed treatments [13]. This can be attributed to patients' reluctance to seek medical care during the pandemic and the strain on healthcare systems. Patients have faced delays in initiating treatment, as they have been hesitant to pursue medical care during the pandemic. These delays in treatment had a significant impact on the prognosis of patients with newly diagnosed cancer. Furthermore, the COVID-19 pandemic has brought about new barriers to treatment for newly diagnosed cancer patients. Additionally, the COVID-19 pandemic has led to disruptions in cancer care and a decrease in resources for treatment [14]. These delays can have detrimental effects on patients' outcomes, as early detection and prompt treatment are crucial in the management of cancer. In line with these findings, a study conducted in 17 European countries during the initial phase of the pandemic estimated approximately 100 million screening tests [15].

In conclusion, this research protocol represents a crucial step towards understanding and addressing the challenges of turnaround time and barriers to treatment faced by newly diagnosed cancer patients. By focusing on patient experiences, healthcare systems, and potential interventions, this study has the potential to contribute significantly to the enhancement of cancer care and the well-being of cancer patients.

MATERIALS AND METHODS

This study will employ a mixed-methods research design, combining both quantitative and qualitative approaches. The study will encompass 89 patients at SGMCH, situated in Sawangi (Meghe), Wardha, providing an appropriate environment at the time of data collection. The estimated duration for this study will be from December 2023 to October 2024. Institutional Ethical Committee (IEC) approval has been obtained from Datta Meghe Institute of Higher Education and Research, IEC Approval Ref. No. DMIHER(DU)/IEC/2023/1161.

Inclusion criteria: Newly diagnosed cancer patients and oncology healthcare workers are often included in cancer research studies for several important reasons: expertise and insight, clinical experience, patient advocacy, clinical trials and treatment development, quality improvement, interdisciplinary collaboration.

Exclusion criteria: Patients who are unable or unwilling to provide informed consent or who have significant cognitive or communication impairments that hinder their participation will be excluded from the study.

Sample size calculation: The sample size will be calculated using the formula:

$$n \geq \frac{Z^2_{1-\alpha/2} \times p(1-p)}{d^2}$$

Z=confidence level at 95% (standard value of 1.96)

Alpha (α)=5%=0.05

Estimated proportion (p)=36%=0.36, 36% barriers at the time of cancer patient diagnostic

(1-p)=1-0.36=0.64 [16]

Estimated Error (d)=10%=0.10

n≥88.510464=89

Minimum sample size required: 89.

Bias: The bias of the study will be minimised as participants will be selected by newly diagnosed cancer patients.

The steps involved:

Step 1: Registration, Triage, and first evaluation

Step 2: Staging investigation

Step 3: Oncology review and treatment prescription

Step 4: Cancer treatment initiation

1. Barriers in treatment initiation

2. Analysis of barriers

3. Investigation delay

4. Procedure delay

To gather cancer information, there are two types of data sources: primary and secondary. Primary data can be collected directly from newly diagnosed cancer patients using structured surveys/questionnaires. Surveys can be conducted through face-to-face interviews, online surveys, or telephone interviews. Additionally, qualitative interviews should also be conducted to gain more insight into the patient's experiences. Primary data collection for research on turnaround time and barriers to treatment of newly diagnosed cancer patients typically involves directly gathering information from patients, healthcare providers, and healthcare facilities.

Primary data will be collected directly from newly diagnosed cancer patients using structured surveys/questionnaires. Here are several methods for collecting primary data in this area:

1. **Patient surveys or interviews:** Conduction structured surveys or interview guides to capture patients' experiences with turnaround time and barriers to treatment. Questions could focus on the time taken from diagnosis to treatment initiation, perceived delays, reasons for delays, and difficulties encountered in accessing care. Surveys can be administered in person, via mail, email, or online platforms, depending on the preferences and accessibility of the target patient population.

2. **Healthcare provider surveys or interviews:** Administering surveys or conduction of interviews with healthcare providers involved in the care of newly diagnosed cancer patients. Gathering insights into factors influencing treatment delays, challenges in care coordination, and perceptions of barriers to timely treatment. Exploring healthcare providers' perspectives on system-level issues impacting turnaround time, such as resource constraints or administrative processes.

3. **Medical records review:** Conduction of retrospective review of medical records to extract data on turnaround time and treatment delays. Collecting information on key milestones in the treatment process, including dates of diagnosis, referrals, consultations, treatment initiation, and completion. Analysing medical records to identify patterns of care delivery, bottlenecks, and factors associated with prolonged turnaround times.

Secondary data sources (including medical records, hospital and healthcare system data, previous studies, and research) will be taken into consideration for several important reasons:

1. Building on existing knowledge
2. Avoiding duplication
3. Methodological guidance
4. Identifying research gaps
5. Supporting hypotheses and predictions
6. Contextualising findings
7. Ethical considerations

1. Quantitative Phase

Data collection: Structured questionnaires will be administered to participants. The questionnaires will include sections on demographic information, medical history, the diagnostic process, perceived barriers to treatment, and satisfaction with healthcare services.

Data collection methods: Participants will be offered the choice of completing the questionnaires through face-to-face interviews, online surveys, or telephone interviews based on their preferences and accessibility.

Data analysis:

- Descriptive statistics: Calculate descriptive statistics, including means, frequencies, and Standard Deviations (SD), to summarise demographic and survey data.

- Inferential statistics: Apply inferential statistical techniques, such as correlations and regression analysis.

2. Qualitative Phase

Data collection: Conduct semistructured interviews with participants using an interview guide designed to explore their cancer journey.

Data recording: Record and transcribe the interviews for analysis.

Thematic analysis: Analyse qualitative data using thematic analysis to identify recurring themes, patterns, and insights related to barriers, turnaround time, and patient experiences.

Integration of data: Combine the quantitative and qualitative findings to triangulate results and provide a comprehensive understanding of the research questions.

Primary Outcome

The primary outcome of studying the turnaround time and barriers to treatment for newly diagnosed cancer patients is to understand the factors that may delay or hinder their access to timely and effective care. By identifying these barriers, we can work towards improving the healthcare system and ensuring that patients receive the treatment they need as quickly as possible. This is an important area of research that can have a significant impact on patient outcomes.

Secondary Outcomes

There can be several secondary outcomes, including evaluating the impact of delays in treatment on patient outcomes, assessing the effectiveness of interventions aimed at reducing barriers, and identifying strategies to improve patient satisfaction and quality of care. By examining these secondary outcomes, we can gain a comprehensive understanding of the challenges faced by patients and develop targeted solutions to address them.

STATISTICAL ANALYSIS PLAN (SAP)

Results of the outcome variables will be tabulated and described using descriptive statistics. Data over the outcome variables will be tested for normal distribution for the mean and standard deviation, median statistics will be used for finding skewed distributions, and Interquartile Range (IQR) will be calculated. Frequency and percentages for binary and categorical variables will be tabulated for descriptive statistics. R-software, the free version, will be used for all statistical analysis.

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