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The Burden of Cancer in the General Surgical Population in the Eastern Region of Ghana

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The Burden of Cancer in the General Surgical Population in the Eastern Region of Ghana

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25 Abstract

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30 Objective: To estimate the surgical burden of malignant disease in the Eastern Region
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33 of Ghana
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37 Design: Descriptive cross-sectional study
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41 Setting: Regional hospital in the Eastern Region of Ghana
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44 Participants: Patients treated by the surgery department at Eastern Regional Hospital in
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47 Koforidua, Ghana
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51 Interventions: None
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4 Primary and Secondary Outcome Measures: Primary outcome was incidence of
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6 malignancy and secondary outcomes descriptive differences between patients who had
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8 a benign indication for surgery compared to those with a malignant indication for
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14 surgery.

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17 Results: A total of 1,943 inpatient surgical procedures were performed from 2015-2017
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20 with 13.4% (261) of all procedures ultimately performed for malignancy. Of all breast
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Results: A total of 1,943 inpatient surgical procedures were performed from 2015-2017 with 13.4% (261) of all procedures ultimately performed for malignancy. Of all breast procedures performed, 95.2% of procedures resulted in a malignant diagnosis. The remaining subtypes of procedures had rates ranging from <1% to 41.2% of procedures performed for malignant disease. Additionally, this study found over 13% of patients admitted to the surgical service for breast cancer ultimately did not undergo a surgical procedure.

Conclusion: This is the first study investigating the burden of malignant disease in the Eastern Region of Ghana. We found a substantial prevalence of malignant disease in the surgical population in this region. This information can be used to aid in future medical resource planning in this region.

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4 Trial Registration: Not Applicable
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7 Article Summary:
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- 10 • Strengths:
 - 11 ○ The burden of malignant disease in the Eastern Region of Ghana is
 - 12 currently unknown and this study represents the first study to characterize
 - 13 the incidence, distribution, and demographics of patients with malignant
 - 14 disease in this region.
 - 15
 - 16 ○ This study represents a novel method to estimate cancer burden in low-
 - 17 resource communities without comprehensive cancer registries using
 - 18 surgical log books and pathology records
 - 19
 - 20 ○ This study contains important results that can be used for resource
 - 21 allocation and capacity building of oncologic care programs.
 - 22
 - 23 • Limitations
 - 24 ○ Given the lack of cancer registries there is no way to characterize detailed
 - 25 oncologic, treatment, and overall survival data in this population.
 - 26
 - 27 ○ This study includes only patients treated by general surgery given limited
 - 28 records of other specialties and does not include patients with obvious
 - 29 advanced or metastatic disease who are not considered surgical
 - 30 candidates.
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7 Keywords:

8 Cancer, Ghana, Sub-Saharan Africa, Eastern Regional Hospital, Surgery
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14 Funding Statement:

15 This research received no specific grant from any funding agency in the public,
16 commercial or not-for profit sectors.
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21 Competing Interests:

22 None Declared
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31 Background

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35 Cancer is a major cause of morbidity and mortality worldwide with low-and-middle
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38 income countries (LMIC) such as those in Sub-Saharan Africa shouldering a majority of
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41 the burden of cancer related mortality (1). In 2016, out of 9 million cancer related
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44 deaths, 70% occurred in LMIC (2). Historically, the burden of cancer has been
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48 overshadowed in LMICs countries by infectious and neonatal mortalities. However, as
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51 life expectancy has been progressively increasing in countries such as Ghana, attention
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55 has been shifted toward preventing cancer-related deaths (3, 4). In Ghana, cancer-
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3 related disease is currently the fifth leading cause of death at 58 deaths per 100,000
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7 population annually (5) . While the current burden of cancer in Ghana is significant, the
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10 International Agency for Cancer Research (IARC) estimates that cancer incidence and
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13 mortality to double by 2040 (6), reinforcing the importance of understanding and
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17 addressing burden of cancer related mortality in this region.
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21 Contributing to this disproportionate burden of cancer in Ghana and other parts of
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24 Sub-Saharan Africa is inadequate data and lack of centralized cancer registries. Cancer
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27 registries are a basic but essential tool for understanding patterns of cancer and
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31 developing effective programs regarding resource utilization (7). High quality cancer
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34 registries such as the Cancer Incidence in Five Continents have provided valuable
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38 information for high income continents such as North America, where over 95% of the
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41 population is included in existing cancer databases. Data is inadequate for continents
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44 such as Africa, where the proportion of population covered is less than 2% (8). While
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47 attempts have been made to develop sustainable population based cancer registries
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51 (PBCR) in Ghana, inadequate funding, lack of personnel, insufficient coordination of
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55 reporting sources and the lack of available census data have made it difficult to
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4 implement (9, 10). Currently the only existing PBCR in Ghana is the Kumasi Cancer
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7 Registry, which was established in 2012 and collects cancer data from Komfo Anokye
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10 Teaching Hospital and Kumasi South Regional Hospital (11). In the absence of PBCRs,
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12
13 the majority of cancer incidence estimates for Ghana are based on mathematical
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16 modelling which includes prevalence of risk factors and the use of data from other
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19 countries in Sub-Saharan Africa (12).
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25 Despite the known growing burden of cancer in Sub-Saharan Africa, the lack of
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28 cancer registries along with limited understanding of the incidence and distribution of
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31 different tumor types makes it difficult to allocate resources for early detection and
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34 treatment (10, 13). Limited existing research has shown that a majority of patients with
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37 cancer in Ghana present with advanced disease (14-16), and often require surgical
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40 intervention. In fact, an existing cancer registry found that over 50% of cancers treated
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43 at Komfo Anokye Teaching Hospital in Kumasi were treated by surgical resection only
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46 and never received medical or radiation oncology treatments (10, 17). This is
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49 concerning as the cancer registry initially collected information only from the medical
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3 oncology department, resulting in a majority of the cancer cases inadvertently being left
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7 out of the registry.
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10 Given both the unknown burden of cancer outside of large cities in Ghana, as well
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12 as the likely significant surgical burden of cancer related disease, the aim of this study
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14 was to investigate the surgical cancer burden in the suburban/rural setting of Ghana's
15
16 Eastern Region. We hypothesized that there is a high burden of cancer related disease
17
18 affecting the population of Ghana's Eastern Region, and that a substantial proportion of
19
20 general surgery resources are currently being utilized to treat malignant disease. By
21
22 using data obtained from the inpatient general surgical service at Eastern Regional
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24 Hospital (ERH), a large referral center for the Eastern Region of Ghana, our study aims
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26 to estimate the incidence and burden of cancer related surgeries from 2015-2017 at this
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28 institution.
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49 **Methods:**

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52 **Data Source:**
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4 Surgical logbooks and the electronic medical record at Eastern Regional Hospital
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6
7 (ERH) in Koforidua, Ghana were reviewed for all surgical admissions from 2015-2017 to
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9
10 create a database of surgical patients. Demographic information including age, sex,
11
12
13 admitting diagnosis and surgical procedure performed were available within the
14
15
16 database. Primary surgical procedures for potentially malignant disease were grouped
17
18
19 into one of seven categories including gastric, soft tissue, biliary/hepatic, colon/rectal,
20
21
22 breast, thyroid, or other. Any patient admitted to the inpatient surgical service at ERH
23
24
25 between 2015-2017 and who had a procedure with general surgery was included in the
26
27
28 database. Men, women and children were included in this study. Patients having
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30
31 gynecological or urologic surgery were excluded. Patients who did not have surgery or if
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34 the procedure was not recorded were excluded (**Figure 1**).

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42 Data regarding pathologic information was obtained directly from pathology
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45 records. All pathology for ERH is performed at the neighboring hospital, St. Joseph
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48 Orthopaedic Hospital. After any surgical procedure that results in a specimen that is
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51 appropriate for pathologic evaluation, patients are asked to transport the specimen and
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54 must pay an additional fee to St. Joseph Orthopaedic Hospital. Pathologic results are
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3 then given directly to the patient or family member and must be physically brought to
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7 their subsequent follow-up appointment with the operating surgeon at ERH. There is
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10 inconsistent inclusion of pathology reports in medical records, thus all pathology reports
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13 recorded at St. Joseph Orthopaedic hospital for procedures performed at ERH were
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16 examined from 2015-2017. Any pathologic reports of malignancy were obtained and
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19 included in this study except for gynecological and urologic tumors. Only patients
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22 admitted to the surgical ward were included in this study, with all outpatient procedures
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24
25 and patients admitted to medical, gynecological, and pediatric wards excluded from this
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28 study. Approval for use of the data was given by the institutional review board at The
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31 Pennsylvania State University College of Medicine (STUDY00011242) as well as by
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34 ERH ethical review board.
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45 Patient and Public Involvement:

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48 It was not appropriate or possible to involve patients or the public in the design, or
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Statistics:

Descriptive statistics including mean and standard deviation or median and interquartile range for normally distributed and skewed continuous data were reported. Categorical variables were expressed as frequencies and percentages. The incidence of cancer diagnosis by type of procedure was calculated by determining the number of malignancies identified by pathology report divided by the overall number of surgical procedures performed during the same time period.

Results:

There were 4,014 admissions to the surgical service from 2015-2017. After excluding gynecological and urological procedures, a total of 3,713 admissions for the general surgical service occurred during this time period, with 1,943 having recorded surgical procedures. The 1,943 patients with recorded surgical procedures included 56 gastric procedures, 253 soft tissue procedures, 57 biliary/hepatic procedures, 119 colon/rectal procedures, 83 breast procedures, 136 thyroid procedures, and 1,239

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3 classified as other, most commonly hernia repair or appendectomy. The mean age,
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7 gender, and insurance status distribution can be seen in **Table 1**.
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10 Information obtained from pathology reports is presented in **Table 2**. A total of
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14 261 pathology reports during 2015-2017 revealed a definitive malignant diagnosis. This
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16
17 indicates that 134 per 1000 surgeries performed at EHR during this time period were
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20 performed due to a malignant diagnosis with confirmed pathologic evaluation. When
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23 including all patients admitted to and treated by the surgical service, with or without
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26 documented surgical intervention, this study found that 70 per 1000 surgical admissions
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29 had a diagnosis of malignancy that was pathologically confirmed.
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35 When further investigating categories of surgical procedure, the highest
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38 incidence of malignancy was found to be in those undergoing inpatient breast
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41 procedures. 95.2% (79/83) of all breast procedures resulted in a diagnosis of breast
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44 cancer. Of those with a diagnosis of breast cancer, 97.5% were female with an average
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47 age of 54 years old (SD 13.44).
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52 A total of 119 colon, rectal, and anal procedures were performed from 2015-2017
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56 resulting in 49 with a confirmed malignant diagnosis. This means that 41.2% of all
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3 colon, rectal, and anal procedures were ultimately performed for malignant disease. The
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7 majority of these cancers were determined to be colon adenocarcinoma (29/49), 15/49
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10 were for adenocarcinoma located in the rectum, 3/49 were performed for squamous cell
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13 carcinoma of the anus, and 2/49 were indeterminate recto-anal malignancy. Colorectal
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16 cancers were evenly distributed between males and females with a slight female
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19 predominance (42.9% and 55.1% respectively). Those who were diagnosed with
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22 colorectal malignancy were on average older with a mean age of 55.1 years (SD 16.4)
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25 compared to the mean age of 43.5 years (SD 18.23) of all those undergoing colon and
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rectal surgical procedures.

Another surgical procedure found to have high rates of final malignant diagnosis
were gastric procedures, with 30.4% (17/56) of all gastric procedures performed during
this time period resulting in malignant diagnosis. Of the 17 patients with pathologic
evidence of gastric malignancy, there was similar incidence in male and female
patients. The mean age of patients diagnosed with gastric malignancy was 58.3 (SD
19.77) compared to 51.4 (SD 20.37) in those undergoing all gastric surgical procedures.

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4 The remaining types of procedures had malignancy rates of 10.3% (14/136) for
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7 all thyroid procedures, 8.8% (5/57) of all biliary procedures, 8.3% (21/253) of all soft
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10 tissue procedures, and less than 1% (12/1,239) of all other procedures resulting in a
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12
13 malignant diagnosis. Demographic information regarding age and gender can be seen
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17 in **Table 2**.
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21 Further investigation into patients with an admitting diagnosis of breast disease,
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24 including individuals with breast cancer, breast abscess, breast cyst, and breast lumps,
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28 is presented in **Table 3**. There were 145 patients admitted with a diagnosis related to
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31 breast disease with 57.2% (83/145) known to have breast cancer or suspected to have
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34 breast cancer based on physical exam resulting in an admitting diagnosis of “breast
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37 cancer”. Of the 83 patients with an admitting diagnosis of breast cancer, 81.0% (68/83)
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40 had surgical treatment with mastectomy. No documented surgical procedure was
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44 performed in 13.1% (11/84) of those admitted with a diagnosis of breast cancer.
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56 Discussion:
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4 The findings from this study represent important data that can be used locally,
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7 regionally, and nationally to better identify and treat patients with oncologic disease and
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10 allocate limited medical resources. Specifically, at ERH the results from this study can
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13 be used by physicians treating individual patients as well as by administration for
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16 resource planning. Given that a majority of patients with final malignant disease were
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19 suspected to have benign disease preoperatively based upon admitting diagnosis, the
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22 knowledge of incidence of malignancy and demographic information presented in this
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25 study could be used to guide surgeon decision making about operative intervention on
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28 possible malignant disease. For example, awareness that currently greater than 30% of
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31 all gastric procedures that are performed at ERH are for malignancy and that malignant
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34 diagnosis was found more often in older patients allows for consideration of further
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36
37 diagnostic work-up or referral to oncology prior to surgical intervention. On a larger
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40 health system scale, given the high burden of cancer at ERH demonstrated by this
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43 study, future development of local chemotherapy and radiation therapy programs should
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46 be considered a priority.
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4 Without an existing uniform population-based cancer registry system in Ghana
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7 (11), distribution of resources and development of medical infrastructure to enhance
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10 access to treatment of cancer is challenging. Unfortunately, formal population-based
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13 cancer registries are associated with significant cost and time to develop. Because of
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16 this, LMIC countries such as Ghana must often rely on basic estimates of cancer
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19 burden when developing plans for the distribution and development of systems focused
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22 on cancer treatment (18). While there have been significant advancements regarding
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25 planned development of cancer registries in primarily large, urban hospitals (9) such as
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28 those in Kumasi (10) and Accra (19), the burden of malignancy faced by smaller
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31 suburban and rural hospitals, with extremely limited resources, is unknown and is
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34 unlikely to be captured by formal cancer registries for the foreseeable future. With this
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37 in mind, this study demonstrates the current need for cancer resources in the Eastern
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40 Region of Ghana. Today patients who require specialized oncologic care must travel to
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43 another region for care, with a majority of patients from ERH referred to Korle Bu for
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46 treatment. These facilities are hours away from the patient's home and treatment is
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49 often delayed due to the high volume of patients that are referred to these limited
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3 specialized centers. With no regional access to oncology care, many patients are
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7 treated with systemic chemotherapy prescribed and managed by the operating surgeon
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10 at ERH, which likely accounts for the patients admitted to the surgical service with a
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13 diagnosis of breast cancer who then did not undergo any surgical procedure observed
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16 in this study. This study demonstrates that small, regional hospitals have a substantial
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19 and diverse oncologic burden, and are in dire need of infrastructure, resources, and
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22 specialized personnel to treat patients diagnosed with cancer.
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28 While this study contains important data regarding the burden of malignancy in
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31 this geographic area, there are limitations that must be considered when interpreting
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34 this data. As there is currently no existing cancer registry capturing malignancies
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37 treated in this region, we do not have access to many demographic, oncologic,
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40 treatment, and overall survival data. This additional information would be helpful for
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43 further planning and resource utilization. Additionally, while a majority of patients
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46 presenting with malignancy are admitted to and treated by the surgical service, this
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49 study does not capture cancer patients treated by other specialties, most notably
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60 gynecological cancers. Also, patients admitted to the surgical service with obvious

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3 advanced or metastatic disease are not considered surgical candidates, and are not
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7 accounted for in these data. Lastly, because patients must transport and pay additional
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10 fees in order to obtain pathology results, there are pathologic specimens that are never
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13 examined and recorded. Currently, it is estimated that about 20% of all specimens that
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16 surgeons request pathologic evaluation do not undergo pathologic evaluation due to
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19 patient noncompliance or inability to afford the extra associated fee. Missing pathologic
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22 results could lead to underestimation of the true incidence of malignancy treated
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25 surgically at ERH.
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35 Conclusion:

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38 This is the first study to investigate the cancer burden in Ghana's Eastern Region. This
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41 study reveals that over 13% of all surgical interventions were performed in patients with
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44 malignant disease. Rates of malignant diagnosis vary by type of procedure performed,
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47 but are very high in patients undergoing breast, colorectal, and gastric procedures. This
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50 study is a preliminary evaluation demonstrating the substantial cancer burden in the
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53 Eastern Region of Ghana and the burden of oncologic disease on general surgeons.
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3 Information from this study can be used to improve access to oncologic directed
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7 treatments in this region and plan future studies to further evaluate the burden of cancer
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10 and cancer related diseases at local and regional healthcare facilities in Sub-Saharan
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14 Africa.

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20 List of Abbreviations:

21
22 LMIC-low-and-middle income countries

23
24 IARC-International Agency for Cancer Research

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26 ERH-Eastern Regional Hospital

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28 SD- Standard Deviation

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36 • Authors' contributions

37
38
39 EO was involved in study design, data collection, data analysis, interpretation of
40 data, majority of manuscript authorship, and critical review and editing of
41 manuscript

42
43
44 PS was involved in study design, data collection, data analysis, interpretation of
45 data, and critical review and editing of manuscript

46
47
48 JD was involved in study design, data collection, data analysis, critical review
49 and editing of manuscript

50
51
52 WW was involved in study design, data collection, data analysis, critical review
53 and editing of manuscript

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3
4 KS was involved in study design, data collection, data analysis, critical review
5 and editing of manuscript

6
7 RO was involved in interpretation of data, critical review and editing of
8 manuscript.
9

10 FA was involved in study design, interpretation of data, critical review and editing
11 of manuscript, and supervised the entirety of the project.

12
13 CP was involved in study design, interpretation of data, critical review and editing
14 of manuscript, and supervised the entirety of the project.
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19 All authors read and approved the final manuscript
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25 • Acknowledgements

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28 Not Applicable
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Figure 1. Flow Chart of patients included in study.

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For peer

Table 1. Demographic Features of Patients Undergoing Any Surgical Procedures

	Gastric Procedure (N=56)	Soft Tissue Procedure (N=253)	Biliary/Hepatic Procedure (N=57)	Colon/Rectal Procedure (N=119)	Breast Procedure (N=83)	Thyroid Procedure (N=136)	Other Procedure (N=1,239)
Gender							
FEMALE	19 (33.9%)	94 (37.2%)	37 (64.9%)	24 (20.2%)	80 (96.4%)	126 (92.6%)	433 (34.9%)
MALE	37 (66.1%)	159 (62.8%)	20 (35.1%)	95 (79.8%)	3 (3.6%)	10 (7.4%)	806 (65.1%)
Age							
Mean (SD)	51.4 (20.37)	47.3 (21.73)	52.6 (20.24)	43.5 (18.23)	54.0 (13.44)	47.0 (13.10)	40.6 (20.40)
Median	58.0	45.0	51.0	42.0	54.0	47.0	38.0
Interquartile range	35.5, 65.5	31.0, 66.0	40.0, 68.0	30.0, 52.0	46.0, 61.0	38.0, 57.5	25.0, 55.0
Range	(0.0-88.0)	(1.0-94.0)	(7.0-96.0)	(5.0-97.0)	(15.0-94.0)	(16.0-83.0)	(0.0-140.0)
Insurance Status							
No	15 (26.8%)	45 (17.8%)	9 (15.8%)	41 (34.5%)	15 (18.1%)	7 (5.1%)	504 (40.7%)
Yes	41 (73.2%)	208 (82.2%)	48 (84.2%)	78 (65.5%)	68 (81.9%)	129 (94.9%)	735 (59.3%)

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Table 2. Demographic Features of All Patients with Malignant Diagnosis

	Gastric	Soft Tissue	Biliary/Hepatic	Colon/Rectal	Breast	Thyroid	Other	Total
Number	17	21	5	49	79	14	12	261
Gender								
Female	9 (52.9%)	11 (52.4%)	2 (40%)	27 (55.1%)	77 (97.5%)	13 (92.9%)	7 (58.3%)	
Male	8 (47%)	10 (47.6%)	3 (60%)	21 (42.9%)	2 (2.5%)	1 (7.1%)	5 (41.7%)	
Age								
Mean (SD)	58.3 (19.77)	49.2 (16.3)	56.6 (6.4)	55.1 (16.4)	50.0 (14.7)	44.7 (14.8)	54.3 (21.6)	
Median	59.5	48.0	57	58	48	44	53	
Range	(28-97)	(29-80)	(45-63)	(15-85)	(4-79)	(13-68)	(20-94)	

Table 3. Details of those with admitting diagnosis related to breast disease

Admitting Diagnosis	145
Breast Abscess	29
Breast Cyst	5
Breast Lump	28
Breast Cancer	83

Table 3. Details of those with admitting diagnosis related to breast disease

Surgical Procedure Performed for those with Breast Cancer	83
Mastectomy	68 (81.0%)
Chest Tube Placement	1 (1.2%)
Emergency Tracheostomy	1 (1.2%)
Palliative Excisional Procedure	3 (3.8%)
No Surgical Procedure	11 (13.1%)

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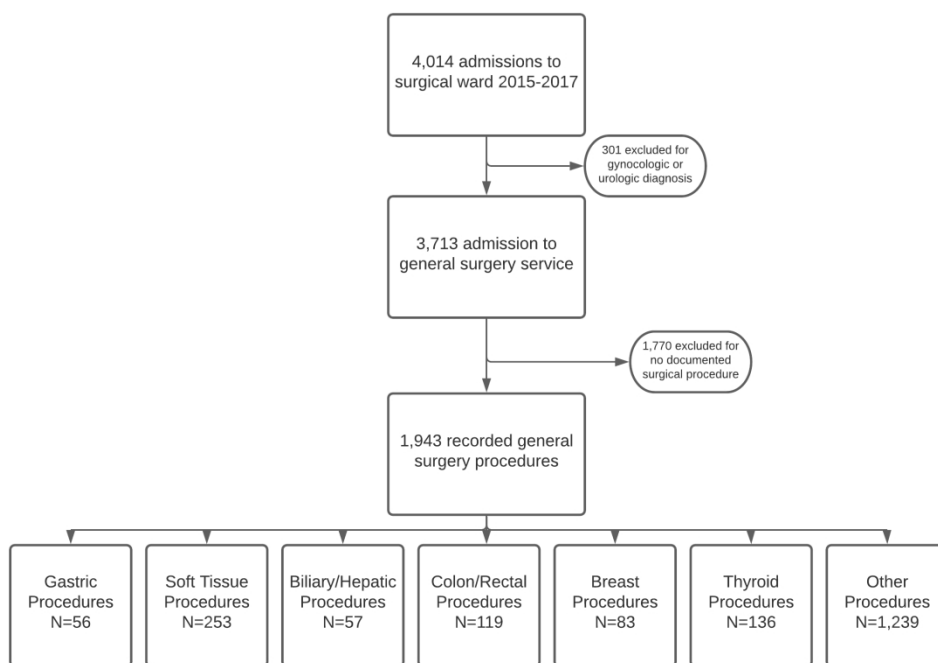


Figure 1. Flow Chart of patients included in study.

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectional reporting guidelines, and cite them as:

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		Page
	Reporting Item	Number
Title and abstract		
Title	#1a Indicate the study's design with a commonly used term in the title or the abstract	1

1	Abstract	#1b	Provide in the abstract an informative and balanced summary	2
2			of what was done and what was found	
3				
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6	Introduction			
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9	Background /	#2	Explain the scientific background and rationale for the	4
10	rationale		investigation being reported	
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14	Objectives	#3	State specific objectives, including any prespecified	5
15			hypotheses	
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19	Methods			
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23	Study design	#4	Present key elements of study design early in the paper	6
24				
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26	Setting	#5	Describe the setting, locations, and relevant dates, including	6
27			periods of recruitment, exposure, follow-up, and data	
28			collection	
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31	Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of	6
32			selection of participants.	
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39		#7	Clearly define all outcomes, exposures, predictors, potential	6
40			confounders, and effect modifiers. Give diagnostic criteria, if	
41			applicable	
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47	Data sources /	#8	For each variable of interest give sources of data and details	6
48	measurement		of methods of assessment (measurement). Describe	
49			comparability of assessment methods if there is more than	
50			one group. Give information separately for for exposed and	
51			unexposed groups if applicable.	
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1	Bias	#9	Describe any efforts to address potential sources of bias	11
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3				
4	Study size	#10	Explain how the study size was arrived at	7
5				
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7	Quantitative	#11	Explain how quantitative variables were handled in the	6
8	variables		analyses. If applicable, describe which groupings were	
9			chosen, and why	
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15	Statistical	#12a	Describe all statistical methods, including those used to	6
16	methods		control for confounding	
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20	Statistical	#12b	Describe any methods used to examine subgroups and	6
21	methods		interactions	
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26	Statistical	#12c	Explain how missing data were addressed	6
27	methods			
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31	Statistical	#12d	If applicable, describe analytical methods taking account of	6
32	methods		sampling strategy	
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35				
36	Statistical	#12e	Describe any sensitivity analyses	6
37	methods			
38				
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42	Results			
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45	Participants	#13a	Report numbers of individuals at each stage of study—eg	7
46			numbers potentially eligible, examined for eligibility,	
47			confirmed eligible, included in the study, completing follow-	
48			up, and analysed. Give information separately for for	
49			exposed and unexposed groups if applicable.	
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57	Participants	#13b	Give reasons for non-participation at each stage	7
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1	Participants	#13c	Consider use of a flow diagram	7
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4	Descriptive data	#14a	Give characteristics of study participants (eg demographic,	7
5			clinical, social) and information on exposures and potential	
6			confounders. Give information separately for exposed and	
7			unexposed groups if applicable.	
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14	Descriptive data	#14b	Indicate number of participants with missing data for each	7
15			variable of interest	
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19	Outcome data	#15	Report numbers of outcome events or summary measures.	7
20			Give information separately for exposed and unexposed	
21			groups if applicable.	
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27	Main results	#16a	Give unadjusted estimates and, if applicable, confounder-	7
28			adjusted estimates and their precision (eg, 95% confidence	
29			interval). Make clear which confounders were adjusted for	
30			and why they were included	
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37	Main results	#16b	Report category boundaries when continuous variables were	8
38			categorized	
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42	Main results	#16c	If relevant, consider translating estimates of relative risk into	8
43			absolute risk for a meaningful time period	
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48	Other analyses	#17	Report other analyses done—e.g., analyses of subgroups	8
49			and interactions, and sensitivity analyses	
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53	Discussion			
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56	Key results	#18	Summarise key results with reference to study objectives	10
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1	Limitations	#19	Discuss limitations of the study, taking into account sources	11
2			of potential bias or imprecision. Discuss both direction and	
3			magnitude of any potential bias.	
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9	Interpretation	#20	Give a cautious overall interpretation considering objectives,	11
10			limitations, multiplicity of analyses, results from similar	
11			studies, and other relevant evidence.	
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16	Generalisability	#21	Discuss the generalisability (external validity) of the study	11
17			results.	
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22	Other Information			
23				
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25	Funding	#22	Give the source of funding and the role of the funders for the	3
26			present study and, if applicable, for the original study on	
27			which the present article is based	
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35 made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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The Burden of Cancer in the General Surgical Population in the Eastern Region of Ghana

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The Burden of Cancer in the General Surgical Population in the Eastern Region of Ghana

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25 Abstract

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30 Objective: To estimate the surgical burden of malignant disease in the Eastern Region
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33 of Ghana
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37 Design: Descriptive cross-sectional study
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41 Setting: Regional hospital in the Eastern Region of Ghana
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44 Participants: Patients treated by the surgery department at Eastern Regional Hospital in
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47 Koforidua, Ghana
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51 Interventions: None
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4 Primary and Secondary Outcome Measures: Primary outcome was incidence of
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6 malignancy and secondary outcomes descriptive differences between patients who had
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8 a benign indication for surgery compared to those with a malignant indication for
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14 surgery.

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17 Results: A total of 1,943 inpatient surgical procedures were performed from 2015-2017
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20 with 13.4% (261) of all procedures ultimately performed for malignancy. Of all breast
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Results: A total of 1,943 inpatient surgical procedures were performed from 2015-2017 with 13.4% (261) of all procedures ultimately performed for malignancy. Of all breast procedures performed, 95.2% of procedures resulted in a malignant diagnosis. The remaining subtypes of procedures had rates ranging from <1% to 41.2% of procedures performed for malignant disease. Additionally, this study found over 13% of patients admitted to the surgical service for breast cancer ultimately did not undergo a surgical procedure.

Conclusion: This is the first study investigating the burden of malignant disease in the Eastern Region of Ghana. We found a substantial prevalence of malignant disease in the surgical population in this region. This information can be used to aid in future medical resource planning in this region.

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4 Trial Registration: Not Applicable
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7 Article Summary:
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- 10 • Strengths:
 - 11 ○ The burden of malignant disease in the Eastern Region of Ghana is
 - 12 currently unknown and this study represents the first study to characterize
 - 13 the incidence, distribution, and demographics of patients with malignant
 - 14 disease in this region.
 - 15
 - 16 ○ This study represents a novel method to estimate cancer burden in low-
 - 17 resource communities without comprehensive cancer registries using
 - 18 surgical log books and pathology records
 - 19
 - 20 ○ This study contains important results that can be used for resource
 - 21 allocation and capacity building of oncologic care programs.
 - 22
 - 23 • Limitations
 - 24 ○ Given the lack of cancer registries there is no way to characterize detailed
 - 25 oncologic, treatment, and overall survival data in this population.
 - 26
 - 27 ○ This study includes only patients treated by general surgery given limited
 - 28 records of other specialties and does not include patients with obvious
 - 29 advanced or metastatic disease who are not considered surgical
 - 30 candidates.
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7 Keywords:

8 Cancer, Ghana, Sub-Saharan Africa, Eastern Regional Hospital, Surgery
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14 Funding Statement:

15 This research received no specific grant from any funding agency in the public,
16 commercial or not-for profit sectors.
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21 Competing Interests:

22 None Declared
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31 Background

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35 Cancer is a major cause of morbidity and mortality worldwide with low-and-middle
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38 income countries (LMIC) such as those in Sub-Saharan Africa shouldering a majority of
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41 the burden of cancer related mortality (1). In 2016, out of 9 million cancer related
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44 deaths, 70% occurred in LMIC (2). Historically, the burden of cancer has been
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48 overshadowed in LMICs countries by infectious and neonatal mortalities. However, as
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51 life expectancy has been progressively increasing in countries such as Ghana, attention
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55 has been shifted toward preventing cancer-related deaths (3, 4). In Ghana, cancer-
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3 related disease is currently the fifth leading cause of death at 58 deaths per 100,000
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7 population annually (5) . While the current burden of cancer in Ghana is significant, the
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10 International Agency for Cancer Research (IARC) estimates that cancer incidence and
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13 mortality to double by 2040 (6), reinforcing the importance of understanding and
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17 addressing burden of cancer related mortality in this region.
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21 Contributing to this disproportionate burden of cancer in Ghana and other parts of
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24 Sub-Saharan Africa is inadequate data and lack of centralized cancer registries. Cancer
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27 registries are a basic but essential tool for understanding patterns of cancer and
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30 developing effective programs regarding resource utilization (7). High quality cancer
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33 registries such as the Cancer Incidence in Five Continents have provided valuable
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36 information for high income continents such as North America, where over 95% of the
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38
39 population is included in existing cancer databases. Data is inadequate for continents
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42 such as Africa, where the proportion of population covered is less than 2% (8). While
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45 attempts have been made to develop sustainable population based cancer registries
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49 (PBCR) in Ghana, inadequate funding, lack of personnel, insufficient coordination of
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52 reporting sources and the lack of available census data have made it difficult to
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4 implement (9, 10). Currently the only existing PBCR in Ghana is the Kumasi Cancer
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7 Registry, which was established in 2012 and collects cancer data from Komfo Anokye
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10 Teaching Hospital and Kumasi South Regional Hospital (11). In the absence of PBCRs,
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12
13 the majority of cancer incidence estimates for Ghana are based on mathematical
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16 modelling which includes prevalence of risk factors and the use of data from other
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19 countries in Sub-Saharan Africa (12).
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25 Despite the known growing burden of cancer in Sub-Saharan Africa, the lack of
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28 cancer registries along with limited understanding of the incidence and distribution of
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31 different tumor types makes it difficult to allocate resources for early detection and
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34 treatment (10, 13). Limited existing research has shown that a majority of patients with
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37 cancer in Ghana present with advanced disease (14-16), and often require surgical
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40 intervention. In fact, an existing cancer registry found that over 50% of cancers treated
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43 at Komfo Anokye Teaching Hospital in Kumasi were treated by surgical resection only
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46 and never received medical or radiation oncology treatments (10, 17). This is
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49 concerning as the cancer registry initially collected information only from the medical
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3 oncology department, resulting in a majority of the cancer cases inadvertently being left
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7 out of the registry.
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10 Given both the unknown burden of cancer outside of large cities in Ghana, as well
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12 as the likely significant surgical burden of cancer related disease, the aim of this study
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14 was to investigate the surgical cancer burden in the suburban/rural setting of Ghana's
15
16 Eastern Region. We hypothesized that there is a high burden of cancer related disease
17
18 affecting the population of Ghana's Eastern Region, and that a substantial proportion of
19
20 general surgery resources are currently being utilized to treat malignant disease. By
21
22 using data obtained from the inpatient general surgical service at Eastern Regional
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24 Hospital (ERH), a large referral center for the Eastern Region of Ghana, our study aims
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26 to estimate the incidence and burden of cancer related surgeries from 2015-2017 at this
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28 institution.
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49 **Methods:**

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52 **Data Source:**
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4 Surgical logbooks and the electronic medical record at Eastern Regional Hospital
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6
7 (ERH) in Koforidua, Ghana were reviewed for all surgical admissions from 2015-2017 to
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9
10 create a database of surgical patients. Demographic information including age, sex,
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12
13 admitting diagnosis and surgical procedure performed were available within the
14
15
16 database. Primary surgical procedures for potentially malignant disease were grouped
17
18
19 into one of seven categories including gastric, soft tissue, biliary/hepatic, colon/rectal,
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21
22 breast, thyroid, or other. Any patient admitted to the inpatient surgical service at ERH
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24
25 between 2015-2017 and who had a procedure with general surgery was included in the
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27
28 database. Men, women and children were included in this study. Patients having
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30
31 gynecological or urologic surgery were excluded. Patients who did not have surgery or if
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34 the procedure was not recorded were excluded (**Figure 1**).

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42 Data regarding pathologic information was obtained directly from pathology
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45 records. All pathology for ERH is performed at the neighboring hospital, St. Joseph
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48 Orthopaedic Hospital. After any surgical procedure that results in a specimen that is
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51 appropriate for pathologic evaluation, patients are asked to transport the specimen and
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54 must pay an additional fee to St. Joseph Orthopaedic Hospital. Pathologic results are
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3 then given directly to the patient or family member and must be physically brought to
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7 their subsequent follow-up appointment with the operating surgeon at ERH. There is
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10 inconsistent inclusion of pathology reports in medical records, thus all pathology reports
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13 recorded at St. Joseph Orthopaedic hospital for procedures performed at ERH were
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16 examined from 2015-2017. Any pathologic reports of malignancy were obtained and
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19 included in this study except for gynecological and urologic tumors. Only patients
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22 admitted to the surgical ward were included in this study, with all outpatient procedures
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24
25 and patients admitted to medical, gynecological, and pediatric wards excluded from this
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28 study. Approval for use of the data was given by the institutional review board at The
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31 Pennsylvania State University College of Medicine (STUDY00011242) as well as by
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34 ERH ethical review board.
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45 Patient and Public Involvement:

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48 It was not appropriate or possible to involve patients or the public in the design, or
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Statistics:

Descriptive statistics including mean and standard deviation or median and interquartile range for normally distributed and skewed continuous data were reported. Categorical variables were expressed as frequencies and percentages. The incidence of cancer diagnosis by type of procedure was calculated by determining the number of malignancies identified by pathology report divided by the overall number of surgical procedures performed during the same time period.

Results:

There were 4,014 admissions to the surgical service from 2015-2017. After excluding gynecological and urological procedures, a total of 3,713 admissions for the general surgical service occurred during this time period, with 1,943 having recorded surgical procedures. The 1,943 patients with recorded surgical procedures included 56 gastric procedures, 253 soft tissue procedures, 57 biliary/hepatic procedures, 119 colon/rectal procedures, 83 breast procedures, 136 thyroid procedures, and 1,239

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3 classified as other, most commonly hernia repair or appendectomy. The mean age,
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7 gender, and insurance status distribution can be seen in **Table 1**.
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10 Information obtained from pathology reports is presented in **Table 2**. A total of
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14 261 pathology reports during 2015-2017 revealed a definitive malignant diagnosis. This
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16
17 indicates that 134 per 1000 surgeries performed at EHR during this time period were
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20 performed due to a malignant diagnosis with confirmed pathologic evaluation. When
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22
23 including all patients admitted to and treated by the surgical service, with or without
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25
26 documented surgical intervention, this study found that 70 per 1000 surgical admissions
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28
29 had a diagnosis of malignancy that was pathologically confirmed.
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35 When further investigating categories of surgical procedure, the highest
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38 incidence of malignancy was found to be in those undergoing inpatient breast
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40
41 procedures. 95.2% (79/83) of all breast procedures resulted in a diagnosis of breast
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44 cancer. Of those with a diagnosis of breast cancer, 97.5% were female with an average
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46
47 age of 54 years old (SD 13.44).
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52 A total of 119 colon, rectal, and anal procedures were performed from 2015-2017
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56 resulting in 49 with a confirmed malignant diagnosis. This means that 41.2% of all
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3 colon, rectal, and anal procedures were ultimately performed for malignant disease. The
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7 majority of these cancers were determined to be colon adenocarcinoma (29/49), 15/49
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10 were for adenocarcinoma located in the rectum, 3/49 were performed for squamous cell
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13 carcinoma of the anus, and 2/49 were indeterminate recto-anal malignancy. Colorectal
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16 cancers were evenly distributed between males and females with a slight female
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19 predominance (42.9% and 55.1% respectively). Those who were diagnosed with
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22 colorectal malignancy were on average older with a mean age of 55.1 years (SD 16.4)
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25 compared to the mean age of 43.5 years (SD 18.23) of all those undergoing colon and
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rectal surgical procedures.

Another surgical procedure found to have high rates of final malignant diagnosis
were gastric procedures, with 30.4% (17/56) of all gastric procedures performed during
this time period resulting in malignant diagnosis. Of the 17 patients with pathologic
evidence of gastric malignancy, there was similar incidence in male and female
patients. The mean age of patients diagnosed with gastric malignancy was 58.3 (SD
19.77) compared to 51.4 (SD 20.37) in those undergoing all gastric surgical procedures.

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4 The remaining types of procedures had malignancy rates of 10.3% (14/136) for
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7 all thyroid procedures, 8.8% (5/57) of all biliary procedures, 8.3% (21/253) of all soft
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10 tissue procedures, and less than 1% (12/1,239) of all other procedures resulting in a
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13 malignant diagnosis. Demographic information regarding age and gender can be seen
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17 in **Table 2**.
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21 Further investigation into patients with an admitting diagnosis of breast disease,
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24 including individuals with breast cancer, breast abscess, breast cyst, and breast lumps,
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28 is presented in **Table 3**. There were 145 patients admitted with a diagnosis related to
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31 breast disease with 57.2% (83/145) known to have breast cancer or suspected to have
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34 breast cancer based on physical exam resulting in an admitting diagnosis of “breast
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37 cancer”. Of the 83 patients with an admitting diagnosis of breast cancer, 81.0% (68/83)
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40 had surgical treatment with mastectomy. No documented surgical procedure was
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44 performed in 13.1% (11/84) of those admitted with a diagnosis of breast cancer.
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56 Discussion:
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4 The findings from this study represent important data that can be used locally,
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7 regionally, and nationally to better identify and treat patients with oncologic disease and
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10 allocate limited medical resources. Specifically, at ERH the results from this study can
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12
13 be used by physicians treating individual patients as well as by administration for
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16 resource planning. Given that a majority of patients with final malignant disease were
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19 suspected to have benign disease preoperatively based upon admitting diagnosis, the
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21
22 knowledge of incidence of malignancy and demographic information presented in this
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24
25 study could be used to guide surgeon decision making about operative intervention on
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28 possible malignant disease. For example, awareness that currently greater than 30% of
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31 all gastric procedures that are performed at ERH are for malignancy and that malignant
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34 diagnosis was found more often in older patients allows for consideration of further
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37 diagnostic work-up or referral to oncology prior to surgical intervention. On a larger
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40 health system scale, given the high burden of cancer at ERH demonstrated by this
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43 study, future development of local chemotherapy and radiation therapy programs should
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46 be considered a priority.
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4 Without an existing uniform population-based cancer registry system in Ghana
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7 (11), distribution of resources and development of medical infrastructure to enhance
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10 access to treatment of cancer is challenging. Unfortunately, formal population-based
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13 cancer registries are associated with significant cost and time to develop. Because of
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16 this, LMIC countries such as Ghana must often rely on basic estimates of cancer
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19 burden when developing plans for the distribution and development of systems focused
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22 on cancer treatment (18). While there have been significant advancements regarding
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25 planned development of cancer registries in primarily large, urban hospitals (9) such as
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28 those in Kumasi (10) and Accra (19), the burden of malignancy faced by smaller
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31 suburban and rural hospitals, with extremely limited resources, is unknown and is
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34 unlikely to be captured by formal cancer registries for the foreseeable future. With this
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37 in mind, this study demonstrates the current need for cancer resources in the Eastern
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40 Region of Ghana. Today patients who require specialized oncologic care must travel to
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42
43 another region for care, with a majority of patients from ERH referred to Korle Bu for
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46 treatment. These facilities are hours away from the patient's home and treatment is
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49 often delayed due to the high volume of patients that are referred to these limited
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3 specialized centers. With no regional access to oncology care, many patients are
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7 treated with systemic chemotherapy prescribed and managed by the operating surgeon
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10 at ERH, which likely accounts for the patients admitted to the surgical service with a
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13 diagnosis of breast cancer who then did not undergo any surgical procedure observed
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16 in this study. This study demonstrates that small, regional hospitals have a substantial
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19 and diverse oncologic burden, and are in dire need of infrastructure, resources, and
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22 specialized personnel to treat patients diagnosed with cancer.
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28 While this study contains important data regarding the burden of malignancy in
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30 this geographic area, there are limitations that must be considered when interpreting
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33 this data. As there is currently no existing cancer registry capturing malignancies
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36 treated in this region, we do not have access to many demographic, oncologic,
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39 treatment, and overall survival data. This additional information would be helpful for
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42 further planning and resource utilization. Additionally, while a majority of patients
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45 presenting with malignancy are admitted to and treated by the surgical service, this
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48 study does not capture cancer patients treated by other specialties, most notably
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gynecological cancers. Because this is a hospital-based study and not a population

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3 study, this study cannot account for patients in the region who did not seek care at ERH
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7 for their malignancy. This has the potential to bias our results in unpredictable ways,
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10 especially if the decision to not seek medical care was different among different groups.
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14 For example, if elderly patients were less likely to seek care compared to younger
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17 patients or if uninsured patients were less likely to seek care compared to patients with
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20 health insurance this could lead to lower estimation of median age or under estimation
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23 of incidence of cancer diagnoses. In addition, patients admitted to the surgical service
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26 with obvious advanced or metastatic disease are not considered surgical candidates,
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29 and are not accounted for in these data. Lastly, because patients must transport and
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32 pay additional fees in order to obtain pathology results, there are pathologic specimens
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35 that are never examined and recorded. Currently, it is estimated that about 20% of all
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38 specimens that surgeons request pathologic evaluation do not undergo pathologic
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41 evaluation due to patient noncompliance or inability to afford the extra associated fee.
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45 Missing pathologic results could lead to underestimation of the true incidence of
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49 malignancy treated surgically at ERH.
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Conclusion:

This is the first study to investigate the cancer burden in Ghana's Eastern Region. This study reveals that over 13% of all surgical interventions were performed in patients with malignant disease. Rates of malignant diagnosis vary by type of procedure performed, but are very high in patients undergoing breast, colorectal, and gastric procedures. This study is a preliminary evaluation demonstrating the substantial cancer burden in the Eastern Region of Ghana and the burden of oncologic disease on general surgeons. Information from this study can be used to improve access to oncologic directed treatments in this region and plan future studies to further evaluate the burden of cancer and cancer related diseases at local and regional healthcare facilities in Sub-Saharan Africa.

List of Abbreviations:

LMIC-low-and-middle income countries

IARC-International Agency for Cancer Research

ERH-Eastern Regional Hospital

SD- Standard Deviation

- Authors' contributions

EO was involved in study design, data collection, data analysis, interpretation of data, majority of manuscript authorship, and critical review and editing of manuscript

PS was involved in study design, data collection, data analysis, interpretation of data, and critical review and editing of manuscript

JD was involved in study design, data collection, data analysis, critical review and editing of manuscript

WW was involved in study design, data collection, data analysis, critical review and editing of manuscript

KS was involved in study design, data collection, data analysis, critical review and editing of manuscript

RO was involved in interpretation of data, critical review and editing of manuscript.

FA was involved in study design, interpretation of data, critical review and editing of manuscript, and supervised the entirety of the project.

CP was involved in study design, interpretation of data, critical review and editing of manuscript, and supervised the entirety of the project.

All authors read and approved the final manuscript

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Not Applicable

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Figure 1. Flow Chart of patients included in study.

For peer review only

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40**Table 1. Demographic Features of Patients Undergoing Any Surgical Procedures**

	Gastric Procedure (N=56)	Soft Tissue Procedure (N=253)	Biliary/Hepatic Procedure (N=57)	Colon/Rectal Procedure (N=119)	Breast Procedure (N=83)	Thyroid Procedure (N=136)	Other Procedure (N=1,239)
Gender							
FEMALE	19 (33.9%)	94 (37.2%)	37 (64.9%)	24 (20.2%)	80 (96.4%)	126 (92.6%)	433 (34.9%)
MALE	37 (66.1%)	159 (62.8%)	20 (35.1%)	95 (79.8%)	3 (3.6%)	10 (7.4%)	806 (65.1%)
Age							
Mean (SD)	51.4 (20.37)	47.3 (21.73)	52.6 (20.24)	43.5 (18.23)	54.0 (13.44)	47.0 (13.10)	40.6 (20.40)
Median	58.0	45.0	51.0	42.0	54.0	47.0	38.0
Interquartile range	35.5, 65.5	31.0, 66.0	40.0, 68.0	30.0, 52.0	46.0, 61.0	38.0, 57.5	25.0, 55.0

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60BMJ Open: first published as 10.1136/bmjopen-2021-051741 on 29 March 2022. Downloaded from <http://bmjopen.bmj.com/> on April 18, 2024 by guest. Protected by copyright.**Table 1. Demographic Features of Patients Undergoing Any Surgical Procedures**

	Gastric Procedure (N=56)	Soft Tissue Procedure (N=253)	Biliary/Hepatic Procedure (N=57)	Colon/Rectal Procedure (N=119)	Breast Procedure (N=83)	Thyroid Procedure (N=136)	Other Procedure (N=1,239)
Range	(0.0-88.0)	(1.0-94.0)	(7.0-96.0)	(5.0-97.0)	(15.0-94.0)	(16.0-83.0)	(0.0-140.0)
Insurance Status							
No	15 (26.8%)	45 (17.8%)	9 (15.8%)	41 (34.5%)	15 (18.1%)	7 (5.1%)	504 (40.7%)
Yes	41 (73.2%)	208 (82.2%)	48 (84.2%)	78 (65.5%)	68 (81.9%)	129 (94.9%)	735 (59.3%)

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Table 2. Demographic Features of All Patients with Malignant Diagnosis

	Gastric	Soft Tissue	Biliary/Hepatic	Colon/Rectal	Breast	Thyroid	Other	Total
Number	17	21	5	49	79	14	12	261
Gender								
Female	9 (52.9%)	11 (52.4%)	2 (40%)	27 (55.1%)	77 (97.5%)	13 (92.9%)	7 (58.3%)	
Male	8 (47%)	10 (47.6%)	3 (60%)	21 (42.9%)	2 (2.5%)	1 (7.1%)	5 (41.7%)	
Age								
Mean (SD)	58.3 (19.77)	49.2 (16.3)	56.6 (6.4)	55.1 (16.4)	50.0 (14.7)	44.7 (14.8)	54.3 (21.6)	

Table 2. Demographic Features of All Patients with Malignant Diagnosis

	Gastric	Soft Tissue	Biliary/Hepatic	Colon/Rectal	Breast	Thyroid	Other	Total
Median	59.5	48.0	57	58	48	44	53	
Range	(28-97)	(29-80)	(45-63)	(15-85)	(4-79)	(13-68)	(20-94)	

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Table 3. Details of those with admitting diagnosis related to breast disease

Admitting Diagnosis	145
Breast Abscess	29
Breast Cyst	5
Breast Lump	28
Breast Cancer	83

Table 3. Details of those with admitting diagnosis related to breast disease

Surgical Procedure Performed for those with Breast Cancer	83
Mastectomy	68 (81.0%)
Chest Tube Placement	1 (1.2%)
Emergency Tracheostomy	1 (1.2%)
Palliative Excisional Procedure	3 (3.8%)
No Surgical Procedure	11 (13.1%)

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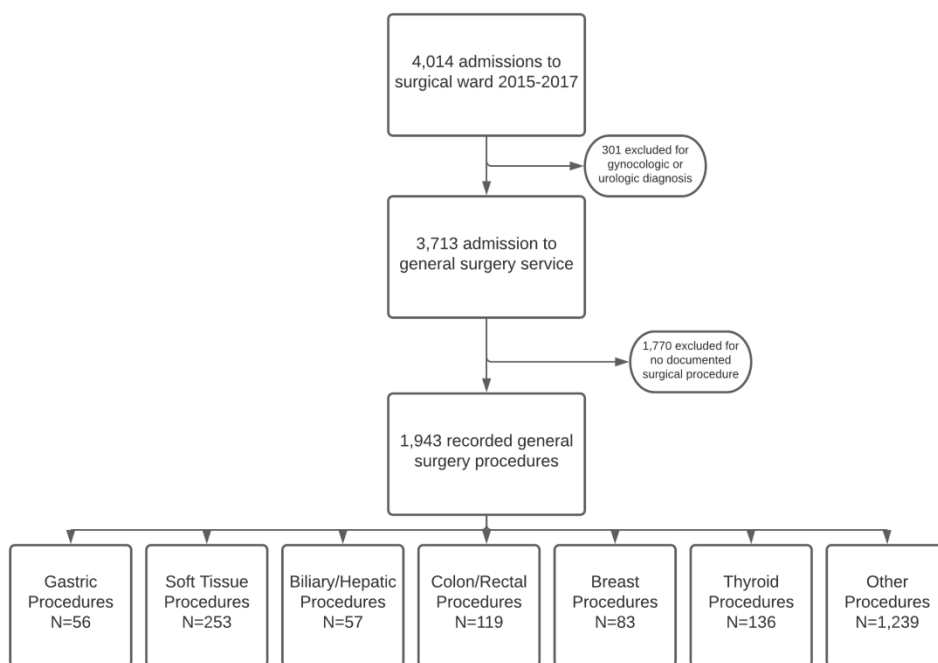


Figure 1. Flow Chart of patients included in study.

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectional reporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Page
	Reporting Item	Number
Title and abstract		
Title	#1a Indicate the study's design with a commonly used term in the title or the abstract	1

1	Abstract	#1b	Provide in the abstract an informative and balanced summary	2
2			of what was done and what was found	
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6	Introduction			
7				
8				
9	Background /	#2	Explain the scientific background and rationale for the	4
10	rationale		investigation being reported	
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14	Objectives	#3	State specific objectives, including any prespecified	5
15			hypotheses	
16				
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18				
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20	Methods			
21				
22				
23	Study design	#4	Present key elements of study design early in the paper	6
24				
25				
26	Setting	#5	Describe the setting, locations, and relevant dates, including	6
27			periods of recruitment, exposure, follow-up, and data	
28			collection	
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34	Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of	6
35			selection of participants.	
36				
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39		#7	Clearly define all outcomes, exposures, predictors, potential	6
40			confounders, and effect modifiers. Give diagnostic criteria, if	
41			applicable	
42				
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46				
47	Data sources /	#8	For each variable of interest give sources of data and details	6
48	measurement		of methods of assessment (measurement). Describe	
49			comparability of assessment methods if there is more than	
50			one group. Give information separately for for exposed and	
51			unexposed groups if applicable.	
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1	Bias	#9	Describe any efforts to address potential sources of bias	11
2				
3				
4	Study size	#10	Explain how the study size was arrived at	7
5				
6				
7	Quantitative	#11	Explain how quantitative variables were handled in the	6
8	variables		analyses. If applicable, describe which groupings were	
9			chosen, and why	
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15	Statistical	#12a	Describe all statistical methods, including those used to	6
16	methods		control for confounding	
17				
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19				
20	Statistical	#12b	Describe any methods used to examine subgroups and	6
21	methods		interactions	
22				
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24				
25				
26	Statistical	#12c	Explain how missing data were addressed	6
27	methods			
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31	Statistical	#12d	If applicable, describe analytical methods taking account of	6
32	methods		sampling strategy	
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36	Statistical	#12e	Describe any sensitivity analyses	6
37	methods			
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42	Results			
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45	Participants	#13a	Report numbers of individuals at each stage of study—eg	7
46			numbers potentially eligible, examined for eligibility,	
47			confirmed eligible, included in the study, completing follow-	
48			up, and analysed. Give information separately for for	
49			exposed and unexposed groups if applicable.	
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57	Participants	#13b	Give reasons for non-participation at each stage	7
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1	Participants	#13c	Consider use of a flow diagram	7
2				
3				
4	Descriptive data	#14a	Give characteristics of study participants (eg demographic,	7
5			clinical, social) and information on exposures and potential	
6			confounders. Give information separately for exposed and	
7			unexposed groups if applicable.	
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14	Descriptive data	#14b	Indicate number of participants with missing data for each	7
15			variable of interest	
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19	Outcome data	#15	Report numbers of outcome events or summary measures.	7
20			Give information separately for exposed and unexposed	
21			groups if applicable.	
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27	Main results	#16a	Give unadjusted estimates and, if applicable, confounder-	7
28			adjusted estimates and their precision (eg, 95% confidence	
29			interval). Make clear which confounders were adjusted for	
30			and why they were included	
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37	Main results	#16b	Report category boundaries when continuous variables were	8
38			categorized	
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42	Main results	#16c	If relevant, consider translating estimates of relative risk into	8
43			absolute risk for a meaningful time period	
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48	Other analyses	#17	Report other analyses done—e.g., analyses of subgroups	8
49			and interactions, and sensitivity analyses	
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53	Discussion			
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56	Key results	#18	Summarise key results with reference to study objectives	10
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1	Limitations	#19	Discuss limitations of the study, taking into account sources	11
2			of potential bias or imprecision. Discuss both direction and	
3			magnitude of any potential bias.	
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7				
8	Interpretation	#20	Give a cautious overall interpretation considering objectives,	11
9			limitations, multiplicity of analyses, results from similar	
10			studies, and other relevant evidence.	
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16	Generalisability	#21	Discuss the generalisability (external validity) of the study	11
17			results.	
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22	Other Information			
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25	Funding	#22	Give the source of funding and the role of the funders for the	3
26			present study and, if applicable, for the original study on	
27			which the present article is based	
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 34 made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)