STUDY PROTOCOL

Population Based Electronic Surveillance Tool to Identify Risk Factors for Developing Cervical Cancer- A Study Protocol

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A B S T R A C T

Background: Cervical cancer remains a significant global health concern, with well-established risk factors. Population-based electronic surveillance tools offer a promising avenue for identifying risk factors associated with cervical cancer development way before it becomes an actual concern for a woman. The objective of this study is to understand and to support the app- based decision-making tool for identifying risk factors of cervical cancer for the women between 30-60 years of age.

Method: The study will be conducted in the selected Sampoorna Non-Communicable Diseases (NCD) clinics at Lucknow, Uttar Pradesh (UP). A rigorous review of database was conducted to summarize the evidence on informatics available for early identification of cervical cancer app. An app-based decision- making tool will be developed to identify and detect the high- risk population developing cervical cancer. The app then will be shared with health workers at Sampoorna clinics and will be capacitated for using it to collect realtime data.

Conclusion: The utilization of a population-based electronic surveillance tool will facilitate the identification of various risk factors contributing to cervical cancer development. The methodology process will help to comprehend the analysis providing the insights. This approach has the potential to enhance targeted interventions, public health policies, and personalized screening programs to mitigate the burden of cervical cancer. The objective of this paper is to understand and to support the design of dashboards for creating transparency and accountability.

Keywords: Cervical cancer, population-based study, surveillance tool, risk factors for cervical cancer, protocol, evaluation

INTRODUCTION

Cervical cancer is defined as – "a malignancy that affects the cells of the cervix, most commonly in the transformation zone where glandular cells of the endocervix transition to squamous cells of the exocervix".[1] Globally, 604000 new cervical cancer cases were reported, standing at is the fourth most cancer among women in 2020.[2] Approximately, 90% of the 342,000 deaths were reported by cervical cancer occurred in low-income and middle-income countries (LMIC).[2,3] The burden of this illness still exists despite improvements in screening and treatment, particularly in marginalized and resource- constrained regions.[4] A thorough understanding of the risk factors for cervical cancer is necessary to successfully battle the disease and create focused prevention efforts.[3,4] Traditional epidemiological research has provided important insights into risk factors such human papillomavirus (HPV) infection, early sexual initiation, and smoking.[5] Cervical cancer has a complicated etiology that is impacted by a dynamic interactionof biological, behavioral, and environmental variables.[5]

In India, population-based electronic monitoring techniques have become effective resources for locating and deciphering the complex risk variables linked to the emergence of cervical cancer.[6] Women should be screened for cervical cancer every 5–10 years starting at age 30.[2] However, harnessing the potential of large-scale data and advanced analytics is imperative to uncover novel risk factors and delineate intricate relationships between diverse variables.[5]

In India, about 45300 deaths were reported due to Cervical Cancer[7] which is 6-29 % of all cancers in women[8]. The age-adjusted incidence rate of cervical cancer varies widely among registries is highest 23.07/100,000 in Mizoram state and the lowest is 4.91/100,000 in Dibrugarh district. Human Papiloma Virus vaccination is the way to prevent incidence of Cervical Cancer. However, HPV vaccine is not included in the national vaccination schedule among girls by the year 2020.[7]

Electronic techniques for population-based surveillance provide a viable way to accomplish these goals. These methods make it possible to build sizable data sets that are representative of many populations by combining information from electronic health records, cancer registries, demographic databases, and other sources.[9] Such databases make it easier to explore correlations that might not be immediately obvious through traditional study approaches.[10] This prepares the ground for a discussion on the function of population- based electronic monitoring technologies in pinpointing cervical cancer risk factors.

Researchers and public health professionals can better comprehend the intricate web of factors affecting the prevalence of cervical cancer by utilizing the potential of these technologies. The subsequent sections will delve into the methods, results, implications, and limitations of employing such tools in the quest to mitigate the burden of cervical cancer on a global scale.

The goal of this study is to develop and support the population based electronic surveillance tool app-based decision-making tool for identifying risk factors of cervical cancer for the women between 30-60 years of age.

METHODOLOGY

The first objective is to design and develop a population-based surveillance tool to identify the risk factor for Cervical Cancer at Sampoorna Clinics based in Lucknow, U.P. The second objective is to evaluation of population based electronic surveillance tool to identify risk factors for developing cervical cancer. The null hypothesis is that there is no significant impact of population based electronic surveillance tool to identify risk factors for developing cervical cancer. Alternate hypothesis is that there is a significant impact of Population based electronic surveillance tool to identify risk factors for developing cervical cancer.

Study Description

Phase 1: In the Phase 1 the objective is to design and develop an app-based decision-making tool to identify and detect the high-risk population to develop the cervical cancer. To review the framework related to the objective of the study a comprehensive and interdisciplinary analysis of dashboards in public health settings, which is why the state of research in communication sciences, as well as psychology and computer sciences/informatics, will be covered. Searches will be conducted among PubMed, Web of Science, Scopus, ProQuest, Cochrane Central Register of Controlled trials (CENTRAL), Communication & Mass Media Complete, OPenGrey and Google Scholar databases using Medical Subject Headings (MeSH) and associated keywords on Cervical Cancer.

All study designs evaluating the digital intervention for identifying risk factor for Cervical Cancer will be eligible. The study will include the all the females who are screened for Cervical Cancer using digital intervention between 2005 and 2022. The study has utilize digital forum for cervical cancer patients along with intervention models developed using the digital data. Studies must be conducted in English.

Data will be synthesized using MS Excel sheets and summarized in categories for the formulation of the questionnaire by using A toolkit for cervical cancer prevention and control programmes by World Health Organization (WHO)11 and Sampoorna Card at Sampoorna Clinic by State Innovations at Family Planning Services Project Agency (SIFPSA)12. All included studies in this review will be critically appraised for the methodological quality based on their appropriate study design using JBI Critical Appraisal tool13.
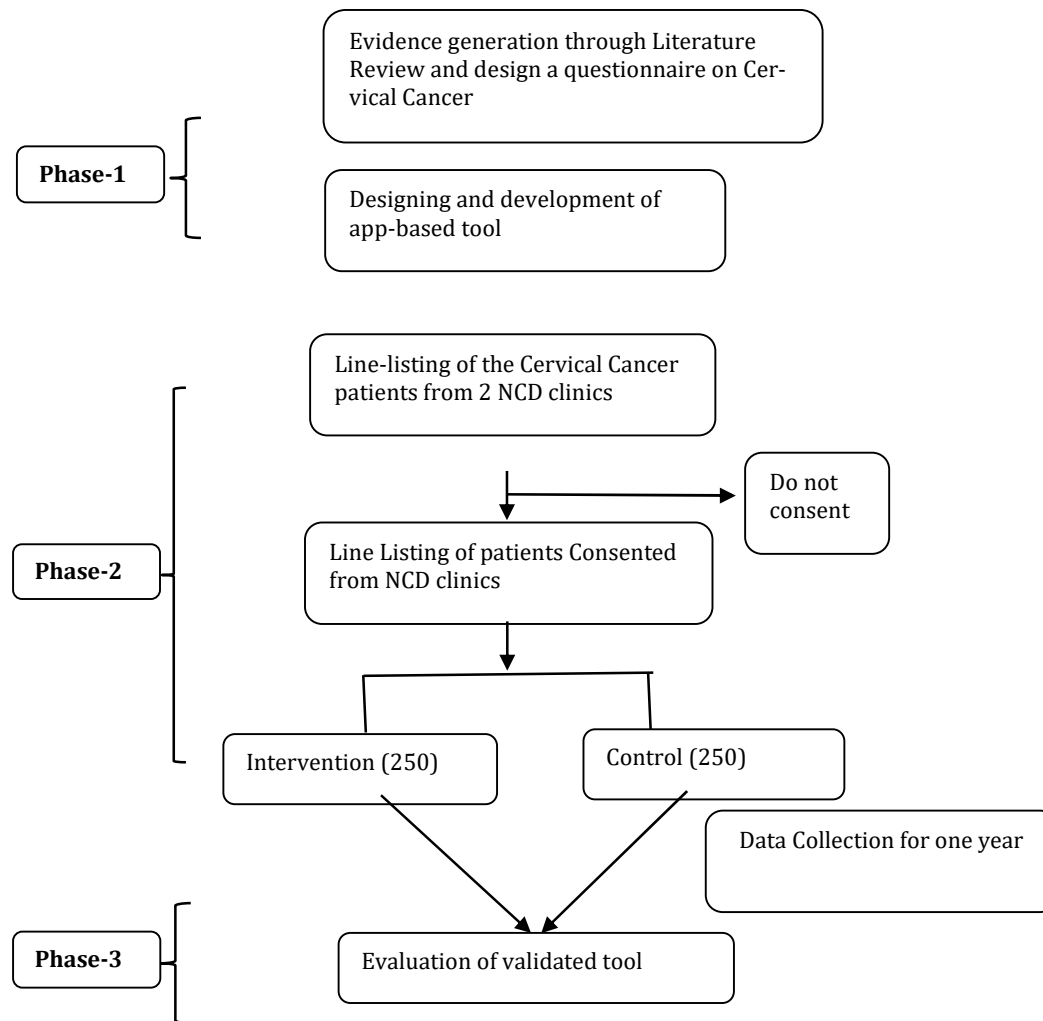
Figure 1: Phase wise description of the study

This literature review would assist in understanding the elements of available informatics tools or platform for Cervical Cancer which would help in the conceptualization and development of an evidence-based tool for identifying risk factors for Cervical Cancer patients, intervention characteristics, study methods, method of delivery, components of intervention, frequency and duration of intervention and outcomes measured in each study.

Phase 2: The objective of phase two is to implement the tool or platform for identifying the risk factors. A non-randomized study will be conducted where the information will be collected in App to identify early diagnosis of cervical cancer from the government based NCD clinic in the Lucknow, Uttar Pradesh. In Lucknow there are three NCD clinics, which earlier known as Sampoorna Clinics[11] were located in urban settings, as per the study design two NCD clinics will be selected one as intervention group and other as control group. The intervention and control group sites are similar type of facilities with parallel group ofpopulation. Two sites will be Maliabhag, NCD Clinic as control group and District Hospital NCD clinic as intervention group. The women who are visiting the NCD clinic for checkup from past one year of age between 30-60 years will be included in the study and willing to participate. The details will include personal information, demographics, socio-economic status, family history, life-style, menstrual history, HPV vaccination status, past & present medical history, Anthropometry Measurements, Clinical History, VIA Screening findings. The follow up will be done for one year.

The primary outcome to measure the risk factors will be measured in terms of will be identification of number of women who has risk of developing cervical cancer and associated risk factors.

Phase 3: The objective of phase three is to evaluate the app-based tool. A quasi-experimental study will be conducted to assess the impact of identifying risk factors of Cervical cancer by using app-based tool by the trained staff at NCD clinic.

The tool will be shared with health care workers at NCD clinic (LMO & Staff Nurses) and capacitated on using the app and collect the real time data from women aged 30 to 60 years clients who comes to clinic. Orientation and capacity building sessions on app is conducted to stake holders for data collection. Regular mentoring and follow up visits for one year will be conducted on weekly basis at intervention site for ensuring the data quality issues and data vali-

dation & feedback will be shared with staff regarding the punching in real time.

The outcome will determine the implementation issues in respect of tool, manpower capacity building, feasibility of the implementation of intervention, use ability of theinformatics platform.

Target Population and Sample Size:

$$n = \frac{2P(1-P)[Z_{1-\alpha} + Z_{1-\beta}]^2}{(d)^2}$$

Sample size calculation was done as per the formula in the Journal of Clinical and Preventive Cardiology[14,15]:

where P is proportion of Cervical Cancer detected (which is 23.7/1,00,000 population in Mizoram), d is 10% difference in early detection of cervical cancer (20% vs 30%) with 80% power and 95% confidence level. Therefore, the Sample size for each group is 221. With an anticipated dropout rate of 10%, total, 250 patients are recruited in each group. A convenientmethod of sampling is used in the study.

Ethical clearance: The present study includes human subjects; therefore, DIT University's, University Research Ethical Committee has approved this study on 12/5/2022;

Protocol No: UREC No. DITU/UREC/2022/04/12.

Data analysis: Data will be analysed using statistical software like SPSS 21 version. Descriptive statistics will be used to describe various participant's socio demographic characteristics and scoring of relevant questionnaires or scales used. Independent or student t-test will be used to analyse the mean difference between intervention and control groups. Chi square test will be done to find out the association between categorical variables. Logistic regression and linear regression will be used to assess the impact of the intervention.[16]

Outcomes: Presenting program results to local community groups and other local stakeholders. Will also share the recommendations to the UP government on the basis of findings.

Data Confidentiality and Privacy: Data confidentiality and privacy will be upheld throughout the study in accordance with the Government of India's data protection policy. Patient information collected during the study will only be accessible to the researcher, treating physician, and clinical staff, and will be stored in password-protected files. Under no circumstances will this information be shared with individuals not involved in the study. The collected data will be securely stored in an access-restricted area, accessible only to authorized researchers.

Additionally, the laptops or computers used for data storage will be password-protected to ensure further security measures.

DISCUSSION

A key development in public health research is the use of population-based electronic monitoring technologies to detect risk factors for acquiring cervical cancer. These tools provide a thorough and data-driven method for comprehending the intricate interaction of variables affecting the incidence of cervical cancer. The visual based techniques[17] offer a comprehensive perspective of the population being studied by combining several data sources such as demographic databases, cancer registries, and electronic health records. This enables the detection of risk variables[8] that conventional study designs could have missed.

Additionally, the use of data mining and machine learning techniques improves the capacity to spot subtle patterns and relationships in the data. When risk variables are discovered using population-based electronic monitoring methods, both predicted and unexpected connections are frequently found. The impact of known risk factors like HPV infection and smoking may be confirmed and measured in bigger, more varied populations. Additionally, these technologies can reveal previously unidentified risk factors for cervical cancer development, such as socio-economic inequalities, restricted access to healthcare, and behavioural issues.

Although these technologies have a lot of potential, there are several drawbacks that should be recognized. The accuracy and representativeness of the results may be impacted by data quality, privacy issues, and possible biases in electronic health records. Large dataset analysisis challenging, requiring strong methodology and knowledge of both epidemiology and data science. The results highlight the significance of having a multifaceted understanding of the risk factors that contribute to the development of cervical cancer. Public health professionalsand policymakers may more effectively design plans for early diagnosis, prevention, and education by utilizing electronic monitoring systems. The accuracy and applicability of discovered risk variables will need to be maintained, which will require continual data collecting and tool improvement. This will ultimately enhance population-level cervical cancer outcomes.

Most of the major registries have shown a decreasing trend of cervical cancer, however, the decrease was very small.[8] It was noted that in India most of the cervical cancer cases are detected with regional spread of the disease, and a very small proportion are diagnosed at a localized stage. This can be attributed to the absence of a nationwide screening program as survival is determined by age and the extent of disease, with younger women having longer survival. This could be because Indian registries suffer with the problem of under-reporting of death, which is more pronounced in the rural area.

In one of studies, it was stated that' there is no single portal where a cumulative data can be received along

with the detailed information, they have to be managed by the medical records department and to pathology to get complete information. The government medical colleges do not have online system, where report is required to identify whether it is malignant or not.

The mobile usage in India has increased to more than 1 billion which provides the opportunity for the implementation of app-based tool to identify the risk factors as an intervention for wider population.[18]

LIMITATIONS

The app is developed in context of Lucknow, Uttar Pradesh Population therefore it might need modification for application in other states and national level. The data is collected from NCD clinics which might not be a full representation of Uttar Pradesh women population.

CONCLUSION

In conclusion, population-based electronic surveillance tools provide a valuable means to explore risk factors for cervical cancer development on a broader scale. Their ability to integrate and analyze vast amounts of data enables the identification of both established and emerging risk factors, contributing to more informed and targeted public health interventions.

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