"DATA QUALITY AUDIT OF CANCER SCREENING DATA"

Indian Cancer Society, New Delhi

A dissertation submitted in partial fulfilment of the requirements for the award of Post - Graduate Diploma in Health and Hospital Management

By Johini

Dr. Mohini Sardana

PG/13/037



International Institute of Health Management Research

New Delhi - 110075

May, 2015

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Under the Guidance of

Dr. Priya Dr. Anandhi Ramachandran

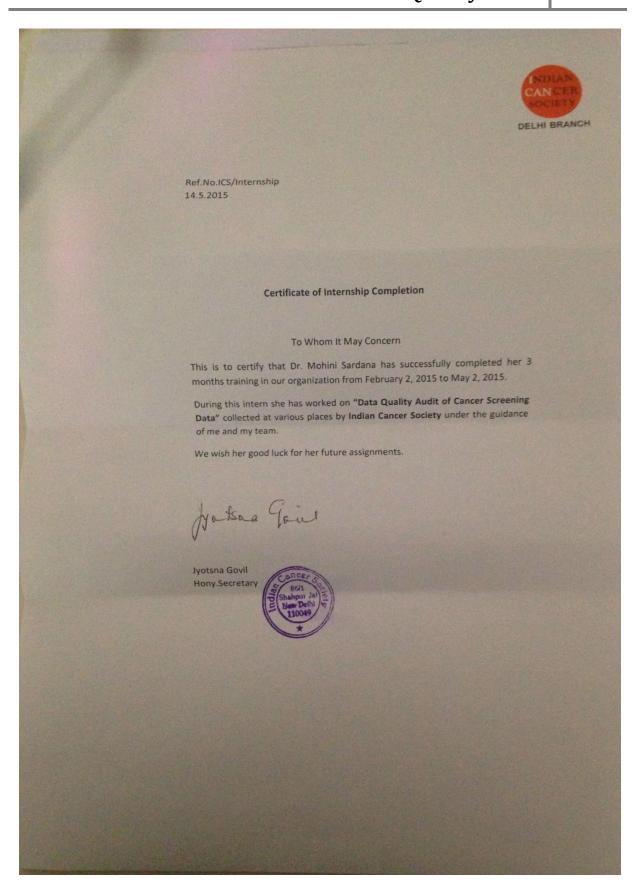
Director operations Associate Professor

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New Delhi New Delhi



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TO WHOMSOEVER IT MAY CONCERN

This is to certify that Dr. MohiniSardanastudent of Post Graduate Diploma in Hospital and Health Management (PGDHM) from International Institute of Health Management Research, New Delhi has undergone internship training at Indian Cancer Society, New Delhi from 2nd February, 2015 to 2nd May, 2015.

The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.

Dr. A.K. Agarwal Dean, Academics and Student Affairs

IIHMR, New Delhi

Dr. Anandhi Ramachandran Associate Professor IIHMR, New Delhi

Certificate of Approval

The following dissertation titled "Data Quality Audit of Cancer Screening Data" is hereby approved as a certified study in management carried out and presented in a manner satisfactory to warrant its acceptance as a prerequisite for the award of Post - Graduate Diploma in Health and Hospital Management for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation

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Certificate from Dissertation Advisory Committee

This is to certify that Dr. Mohini Sardana, a graduate student of the Post-Graduate Diploma in Health and Hospital Management Research has worked under our guidance and supervision. She is submitting this Dissertation titled "Data Quality Audit of Cancer Screening Data" in partial fulfilment of the requirements for the award of the Post- Graduate Diploma in Health and Hospital management.

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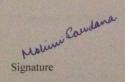
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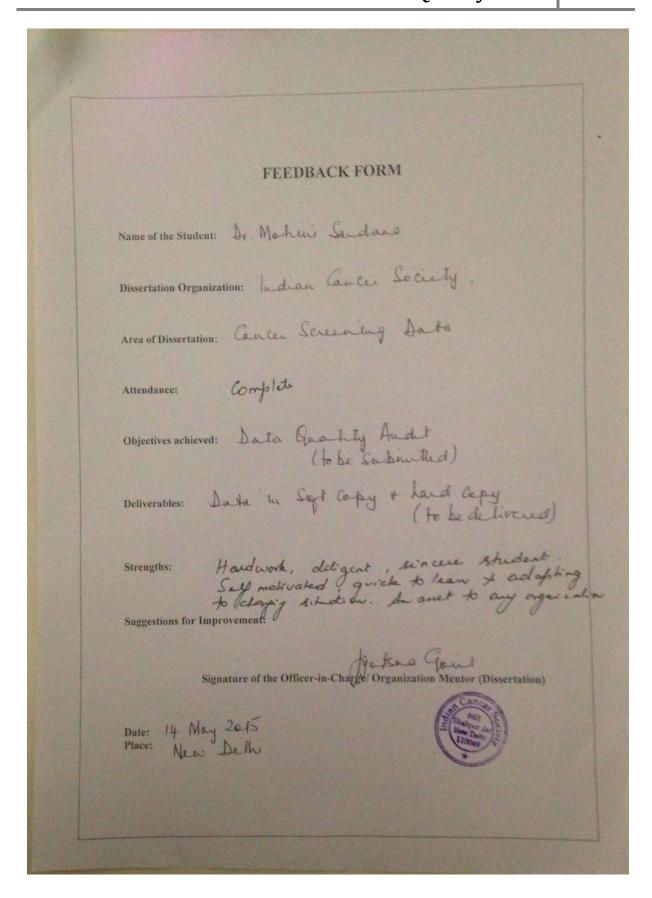
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CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled "Data Quality Audit of Cancer Screening Data" at Indian Cancer Society, New Delhi and submitted by Dr. MohiniSardana, Enrollment No. PG/13/037, under the supervision of Dr. Anandhi Ramachandran for award of Postgraduate Diploma in Hospital and Health Management of the Institute carried out during the period from 2nd February, 2015 to 2nd May, 2015 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.





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Dr. Mohini Sardana

PG/13/037

ABSTRACT

DATA QUALITY AUDIT OF CANCER SCREENING DATA.

Background: - Cancer screening can help find cancer at an early stage before symptoms appear. Cancer treatment is not just about proper interventions but also proper follow ups and counselling for the patients. For this reason different approaches are required in various areas to collect proper data, so, that there is an optimum response and outcome rate. Collecting proper data in a standardized way is a major concern for most of the research organizations. This is mainly taken into considerations to reduce errors at the time of data analysis. There are various issues that result in poor data quality. These issues mainly are missing values for an indicator or ambiguous values for an indicator. These problems result in a data which is poor in all the dimensions (accuracy, reliability, precision, completeness, integrity and timeliness) of data quality. A good data quality is important because no matter how quickly one can analyze and put the data in the proper context for the people who are consuming information, the value of data for decision making will be jeopardized if the data does not have good data quality dimensions. This study mainly focuses on the auditing of data for various dimensions of data quality. Objectives of the study: - To perform a data quality a data quality audit on cancer screening data collected by ICS during period 2014-2015.To verify the quality of the reported key indicators in terms of dimensions (accuracy, reliability, precision, completeness, timeliness, integrity and confidentiality). Research Design/Methodology:- This dissertation study is a mixture of both qualitative and quantitative data. It is descriptive study and retrospective in nature. a) Sample size: - 3,787 people were screened for different type of cancer. b) Sampling Technique used: - Purposive sample. c) Data source: - secondary data is used of three different cancer data sets (PSA, GRC data and IITF data). Results: - overall data quality was insufficient to carry out proper analysis of the data. Available records for PSA 89%, GRC 98% and IITF 100% but these were of not much significant because completeness of data was too less i.e. only 28.2% of the PSA data was complete whereas GRC and IITF data were entirely incomplete. Also data quality of key indicators and functional components was not that compliant with dimensions of the data quality. Conclusions: - The collection of appropriate high quality information before the programme starts is, important to measure the success of the screening programme.

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List of Abbreviations:-

- 1. DQA tool- Data Quality Audit
- 2. GRC- General resource centre
- 3. ICS- Indian Cancer Society
- 4. IITF- India International Trade Fair
- 5. PSA- Prostate specific antigen
- 6. RDQA tool- Routine Data Quality Assessment Tool
- 7. USAID- United States Agency for International Development
- 8. UICC- Union Internationale Contre Le Cancer
- 9. WACC- Women Against Cervical Cancer
- 10.WHO- World Health Organization

PART 1

INTERNSHIP REPORT

ORGANIZATION'S PROFILE:-1.1



Indian Cancer Society was founded in Mumbai in 1951 by the renowned oncologist Dr. DJ Jussawala, with the stated objective of providing cancer awareness and education, as well as offering high quality-low cost cancer screening facilities. Dr. Jussawala saw even in those early years that prevention through awareness and understanding was the only way to fight the scourge of cancer.

The **Delhi Branch** was set up in 1983 by a group of enlightened citizens, led by Mr. KK Mehta, who continued to guide the activities of ICS Delhi until 2011. These include:

- Cancer Jagriti. Our Awareness group of trained volunteers deliver cancer awareness talks at a wide variety of locations, ranging from schools and colleges, offices and factories, women's' groups, urban slums, villages, and with other socially committed organizations. We have trained workers of other NGO's working in the Basti areas, so that our message of Cancer Awareness gets a sustained follow-up. Speakers carry instructive video films, as well as information literature, which is given free of cost. This service is available completely free of cost, though a pick-up for speakers is much appreciated. The Schools programme carries cancer education to a receptive audience. The use of FM channels carries our message further afield. We find that our programmes are reaching a wider audience, when AIR airs them on other channels. A Cancer Helpline 99 105 16562 is very popular. Focus has shifted from requests for financial help to request for information.
- Cancer Screening. ICS offers Cancer Screening at the Cancer Detection Centre, 42 Babar Road, New Delhi 110 001. The Centre is open on all working days from 0900 to 1200 hours. The Centre is served by 3 specialist doctors of ENT, Gynecology and Surgery, supported by a team of technicians. In a package, which includes a blood analysis, chest Xray, and physical examination by these experienced doctors, you can avail a screening for cancer at minimal, heavily subsidized cost. No prior appointment

required, and the entire process takes only 35 minutes of your time. In order to detect cancer early, and even at a pre-cancer stage, ICS urges that every person over the age of 30 years should have an annual check-up. Thanks to the generosity of a local Trust, we now have a Mammography & Bone Densitometry facility operating out of Prashanti. Both services are offered at highly subsidized rates. Since November 2010 we offer HPV/DNA tests at the Cancer Detection Centre, Babar Road, with help from Gentech & the Max Foundation.

- Mobile Cancer Screening. Cancer Screening at your doorstep! This service is ideal for offices, factories, and other clusters of people who cannot take time off to come to the Babar Road Centre. 40 persons are screened in a 3-hour period by our specialist staff. This service is available on weekends, and on weekday afternoons. Bookings can be made through our office, and a payment is required to be made in advance to confirm the booking. Philanthropic individuals and organizations often sponsor camps for people living in the slums of Delhi. Please check with us about the availability of free camps. The Mobile Service is an essential part of the Community Projects, which ICS undertakes in the basti's (slums) around Delhi.
- Projects. ICS undertakes Community Screening Projects supported by corporate houses as part of their CSR Projects. Over 2000 women from disadvantaged areas were screened for Cervical Cancer in 2009-10. In addition, Awareness Talks and intensive training for chosen leaders among local women as Basti Sevika's are organized, with the doctors from IRCH/AIIMS. A series of talks and screening Camps were organized for the elderly with HelpAge. This was part of a Project, giving the elderly financial assistance with treatment costs. Assistance is also available to the elderly for treatment of chronic disease in an on-going programme. A special booklet on Cancer in the Elderly was produced.
- Cancer Sahyog: Since 1991, this Support group for people living with cancer has been working under the umbrella of ICS Delhi. Founded by a cancer survivor, all members of Cancer Sahyog have a personal experience with cancer. Besides offering a listening ear and a shared experience, volunteers provide literature, helpful suggestions and tips regarding the side effects of treatment. Most of all, volunteers in hospitals, all of whom are survivors, offer hope. Cancer Sahyog offers a measure of financial assistance to deserving cases. Sahyog's annual seminar addresses issues of importance to cancer survivors. The Seminar in 2011 addressed Familial Cancer.

Financial assistance of over Rs 20 lakhs is disbursed to needy patients. All of this money is collected through Donations from public spirited persons.

- The annual Walk for Cancer Awareness is a popular fixture on the Delhi calendar, as is Cancer Survivors Day. Many Hospitals are bringing their patients. Inspirational leaders flag off the Walk. We have invited Sports Icons to inspire the children. Both the Walk & Survivors Day seek to draw the general public into aspects of living with cancer. Survivors Day is a celebration of Life after Cancer. It will be celebrated as always on the second Saturday in February at Delhi's fun hot-spot Dilli Haat.
- Breast Cancer Care. This group of Breast Cancer Survivors has joined the ICS family. They provide badly needed advice on prosthesis and bra's; as well as living life under altered circumstances. They also join Volunteers from Jagriti & Sahyog in spreading awareness about Breast Cancer. This group has helped set up a Comprehensive Breast Cancer Care Centre at the Rajiv Gandhi Cancer Institute, with support from Doctors & Nurses, recognizing the needs of women beyond mere medical intervention.
- **Prashanti** is the addition to the family, encouraging a serene return to normal living after cancer. Working under the aegis of ICS, this is a Centre for Healing therapies. Patients and Survivors are encouraged to explore the various therapies on offer, and use the one of their choice to better their quality of life. Prashanti has recently added a Diagnostic facility offering Mammography & Bone Densitometry. Both services are offered at no profit – no loss basis. There are plans to restructure this Unit on the lines of the Breast Cancer Haven (UK)
- ICS Newsletter "Nargis" offers information and has a small but loyal readership of 3000 persons. Nargis covers the activity of all ICS units, and gives useful information about cancer. It is distributed free of cost in Hospital clinics.
- Website. Our revamped website is popular with Internet users. We get calls from all across the country. We attempt to reach out to people with information and latest news.
- **Pressure Group.** ICS Delhi has worked as a watch dog for cancer information being delivered in sensitive manner. ICS works with tobacco regulation lobbies working to stem the easy availability of tobacco, especially to vulnerable youth. ICS has made presentations to the Parliamentary Sub Committee on Tobacco Regulation, putting

forward its views on the tobacco-cancer connection. ICS successfully lobbied the Defence Forces to include cancer screening as part of the Annual Medical examination of all service personnel. We continue to keep an eye on cost of new generation cancer drugs, whose prices are beyond the reach of ordinary people. ICS has worked to get warning signs put onto bidi & gutka packets. Special programmes during the year highlight different cancers – Prostate Cancer (April), Tobacco/Oral cancers (May), Breast (October), Cervix (November)

- ICS works with International bodies such as UICC, WHO, American Cancer Society, WACC and Livestrong, in learning experience and interaction for Volunteers & Management alike. We also work closely with the Government of India's Ministry of Health & Family Welfare & the Delhi Administration.
- **Internship/NSS.** ICS has welcomed young people/Interns to study our working, and to work with different Units. We hope this will sensitize them to the trauma of cancer. We are encouraged by calls from Management students from as far afield as Bangalore. Young college students are encouraged to undertake Social Audit of lifestyle leading to cancer. It helps them to understand their role in helping cancer to enter their lives.
- Cancer Insurance. Recognizing the fact that cancer treatment is long and expensive, ICS was the first to offer Cancer Insurance in collaboration with New India Assurance Company. Presently, there are two slabs of cover available. Details can be obtained from our office. At a time when one in eight Indians is likely to get cancer, insurance to offset the high cost of treatment has become a necessity

VISION:-

"The Conquest of Cancer by Choice; not Chance. There is compelling evidence available to suggest that a majority of cancers are related to life style choices. In India where over half the cancers are in the head and neck region, it is important for people to recognise the connection between tobacco (including chewed tobacco such as gutka, khaini, paan masala) and cancer. Most cancers of the mouth, throat and lung are avoidable. The importance of diet in cancers is increasingly evident with new research. The connection of faulty diet is more clearly known. Diet is implicated in cancers such as those of the breast, stomach, gall bladder, colon and rectum, which are rising as life styles include richer diets, and people

become more sedentary in their habits. Breast cancer, often referred to as the "empowered woman's cancer", is overtaking cervical cancer as the number one cancer in women in urban areas. Most cancers are curable if detected early. Many cancers are avoidable with an awareness of the way life styles help create these monsters."

1.2Area of Engagement:-

The area of engagement in the organization was the data quality audit project of the three data sets collected in different locations in the year 2014-2015 by ICS. The internship period consisted of both on site and off site data analysis. On site visits included visit to the ICS office which is located in Shahpur Jat, Siri Fort, New Delhi. In this office orientation of the functioning of the organization was given. Another on site frequent visits was made to the cancer detection centre located at Babar Road. In the cancer detection centre entire process of cancer screening was explained. This process consisted of various phases, right from the beginning of patient registration, to screening, sample collection, taking X rays, sending of the sample and X ray reports to various hospitals for examination and then integration of the reports with other details of the patient and maintaining of the records manually and electronically in registers and excel sheets respectively. Off site analysis of data for quality was done in IIHMR, New Delhi.

1.3 Reflective Learning:-

During entire duration of internship, there has been a lot of individual's learning. Some of the learning's during internship are as follows:-

- 1) Issues followed during screening of the patients for cancer.
- 2) Though the form filled at the time of registration and screening is structured and is a mix of close ended and open ended questions still the data which was given for analysis was not in a standardized form.
- 3) Due to non standard form of the data, the quality of the data was poor.
- 4) There was a change in the workflow after implementing ICT. However it was still under test so, much conclusions could not be drawn.

PART 2

DISSERTATION

REPORT

CHAPTER 1

Dissertation

Overview

Dissertation overview: - This study was conducted in time duration of three months by using the data provided by Indian Cancer Society. The cancer society uses structured, mix of close and open ended form to collect the epidemiological, economic, education, profession, habits, diet and clinical indicators manually. This data is then ported into the excel sheet. This dissertation report focuses on the issues due to poor data quality at the time of data collection and porting of the data and also to provide recommendations to improve the data quality.

1.1 Problem Statement: -

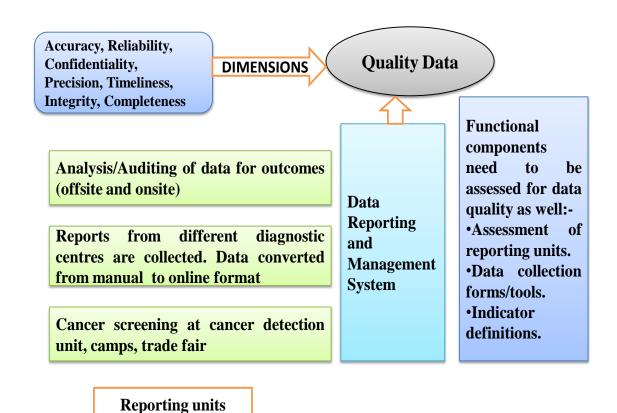
ICS maintain records for the patients they screen for cancer but so far no data quality audit has been conducted on the collected data. This needs to be done because poor data quality is a common issue and requires addressing. The impact of poor data quality has several pernicious effects like improper analysis, with resulting weak response rates, inability to match and integrate data from other data sources, inability to report and draw accurate conclusions from the data and inability to draw comparisons across national and international boundaries. Thus problem is becoming both epidemic and pandemic. In particular it is impacting the quality care, increasing costs and inefficiencies and undermining the reliability and benefits of information technology investments, including the potential to streamline the system. Despite the severity of the problem, the risk caused by poor data is going unrecognized and in many ways, the problem of inaccurate data remains low priority for the organization. It is critical to understand the problem and to develop strategies for minimizing data inaccuracies and potential harm they cause.

1.2 Objectives of the study:-

The main objectives of this report were:

- To perform a data quality a data quality audit on cancer screening data collected by ICS during period 2014-2015.
- To verify the quality of the reported key indicators in terms of dimensions (accuracy, reliability, precision, completeness, timeliness, integrity and confidentiality).
- 1.2 **Scope of the study:** - This study includes assessing the quality of screening data to get accurate results and interpretations. It will also focus on the comparisons between actual and expected number and percentage of available and complete reports. Values of the key indicators will be examined which is resulting ambiguity of data.
- 1.3 **Need of the study:** - ICS has a big database of cancer records. However till today no data quality audit has been performed. There has been no documentation or check on the data being collected during screening, their relevance, accuracy and completeness. Also ICS has recently started computerization of screening process. As a first step all the manual data is proposed to be converted into online entry. All the data collected so far using manual forms are being uploaded in the database without any data verification and validation checks. So this study is required to evaluate the quality of the manual data before porting it into the database. It is also hoped that this would help to standardise the data collection process.

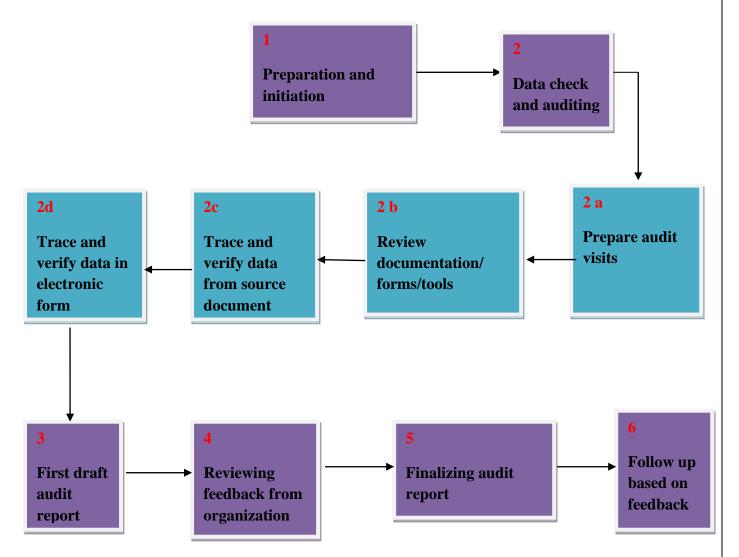
1.5 framework **Conceptual** of the study



#Figure 1Conceptual framework

1.6 <u>Implementation of the study</u>:-

The Data Quality Audit will be implemented chronologically in six phases:-



#Figure 2 Implementation Phases

1) Preparation and initiation:-

First and foremost is the data that needed to be audited was selected. There is no single formula for selecting it. Then key indicators (socio demographic and clinical) were selected that needed to be checked for various dimensions of data quality.

The criteria of selecting the indicators:-

- a) "Must Review" the indicators- Based on the literature survey, dependent and independent indicators were identified. With the help of this only it could be made clear that what all factors can affect an outcome. Independent variables were age and socio demographic indicators like (education, profession, income) and dependent variables were the clinical indicators like PSA value in prostate cancer screening
- b) Relative magnitude of an indicator or Reported number for an indicator- this is mainly important when we are considering indicators which come under Missing Not at Random. It means missing data mechanism is said to be non ignorable, if failure to observe a value depends on the value that would have been observed or other missing values in the data set.

2) Data check and auditing

This was conducted in further four steps. Firstly audit visits were made. These audit visits were both onsite and offsite. The onsite audit was to conduct a desk review of the documentation. In this desk review forms were reviewed for their format and the data was cross checked from the source document. Off site review was done for the data in the electronic form. The reason behind both the audits was mainly to check the key indicators for their missing values, ambiguity and how compliance was they with the dimensions of the data quality.

3) First draft audit report

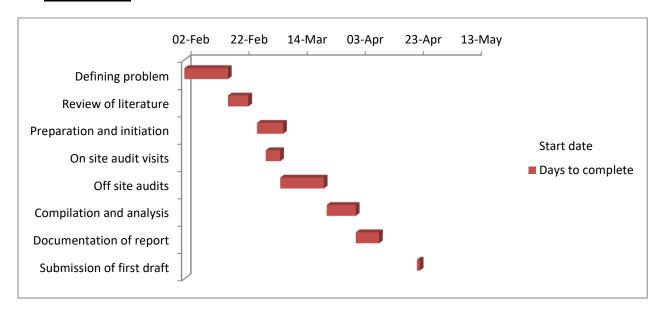
After we traced and verified the reporting units and other functional components as mentioned in the Fig. 1 of conceptual framework and the selected indicators from source documents a draft was made for the audit report and feedback was asked by stakeholders.

4) Review the feedback form and Final Audit Report

Based on the feedback provided the Final Audit Report was made and communicated it to the in-charge in ICS.

5) Follow up- Based on the recommendations follow up for the data quality maintenance was done.

1.7 **Work plan:**-



#Figure 3 Gantt chart representing implementation of dissertation project plan

Activity	Estimated Time Taken	Expected outcome
Defining problem	15 days	Problem define and proposal
		made
Review of literature	07 days	Draft of proposal
Preparation and initiation	09 days	Data and key indicators were
		selected.
On site audit visits	05 days	Understanding workflow and
		review source documents and
		forms.
Off site audit visits	15 days	Key indicators were viewed
		and their values were
		identified
Compilation and analysis	10 days	Percentage of available and
		complete reports was
		calculated. Dimensions of
		good quality data were also
		examined.
Documentation of report	08 days	First draft made
Submission of the first draft	01 day	
to the advisor		

Table 1 Activity Table for dissertation project.

CHAPTER 2

PROJECT

OVERVIEW

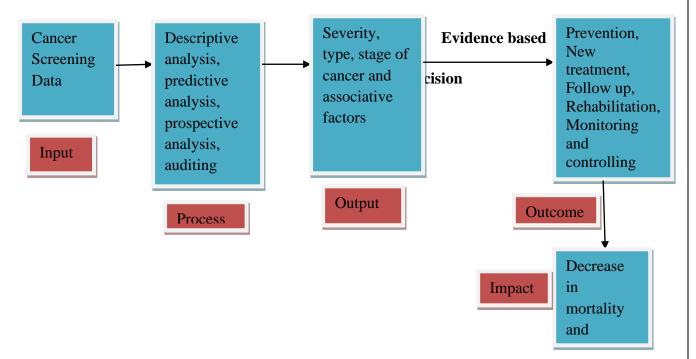
2.1 Introduction:-

Cancer, though a non communicable disease has a high incidence of morbidity and mortality worldwide. It is second most common cause of mortality followed by cardiovascular disorders in the world [Ali I et al, 2012; Jemal et al 2007]. In 2012 there were approximately 14 million new cases and 8.2 million cancer related deaths [World Cancer Report, 2014]. The cancer cases are expected to increase to 70% over next two decades [World Cancer Report, 2014]. The five most common areas of cancer diagnosed in men in 2012 were lung, prostate, colorectum, stomach and liver and in women were breast, colorectum, lung, cervix and stomach [World Cancer Report, 2014]. 70% of cancer deaths occur in Africa, Asia, Central and South America. There were 13.3 % new cases of prostate cancer in India in 2015 and 4.7% deaths due to prostate cancer and 14% new cases of breast cancer 6.8% deaths due to breast cancer in India in 2015 [National Cancer Institute]. One- third of cancer deaths are due to improper behavioural and dietary habits like high body mass index, low fruit and vegetable intake, lack of physical activity, tobacco use and alcohol use [World Cancer Report, 2014]. It has been observed that cancer cases are increasing even though there is advancement in diagnostic and treatment procedures. It may be due to reasons like late screening or no screening of the cases because people don't want to hear a positive test report related to deadly disease like cancer [Kleier, 2010]. However if proper screening is done survival rate can be increased. Percent surviving five years (2005-2011) for breast cancer was 89.4% and prostate cancer 98.9% [National cancer Institute].

Cancer screening can help find cancer at an early stage before symptoms appear. Cancer treatment is not just about proper interventions but also proper follow ups and counselling for the patient. Indian Cancer Society provides low price high quality screening, counselling, interventions and follow up for the cancer patients. Various approaches are required in these areas to formulate a proper study design and analysis of data [Jake Olivier, 2012]. Missing values of the variables is common error occurring in data analysis [Joseph G, 2012]. For a proper epidemiological researches including planning and monitoring a good quality data is important [Kurt G, 2014; Evans, 2011]. So, it is important to know the consistency of the data. Data can be either missing or incorrect. Causes of errors in these data sets can be due to any of the following reasons- errors in the initial documents that were copied into database, errors in the interpretation of the data in initial documents or errors while entering the data in the database [Saveli I. Goldberg 2008, Day S, 1998]. They can vary for the individual data set also like linguistic differences between research staff and respondents which results in improper collection of the demographic data and secondly challenges with reporting units submitting the data like lack of infrastructure and untrained research staff collecting the data which result difficulties in aggregation, warehousing and analysis of the data [Stefaan Verhulst, 2005].

Data should be mainly checked for severity of inconsistency, incompleteness, accuracy, precision and missing. So, that data quality can be improved.

2.2 <u>Logical Framework of Screening Process</u>:-



#Figure 4

2.3 Review of Literature:-

1. A report on Background Issues on Data Issues. This document is a part of The Health **Connecting** for Common Framework. At http://www.connectingforhealth.org/license.html. (Accessed on 24/42015). Document drafted by Stefaan Verhulst, 2005.

Background: - Dirty data can have several pernicious effects. In particular, it:-Impacts the quality of care; Introduces privacy and other civil liberty concerns; increases costs and inefficiencies; creates liability risks; and undermines the reliability and benefits of information technology (IT) investments, including the potential to streamline service delivery, accounting, and billing.

Conclusions: - comprehensive data quality program should include both automated and human strategies, such as:-Standardize data entry fields and processes for entering data. Institute real-time quality checking, including the use of validation and feedback loops. Design data element to avoid errors (for example, through the use of check digits and checking algorithms on numeric identifiers where human entry is involved and the use of well-designed user interfaces). Develop and adhere to guidelines for documenting the care that was provided to the patient. Review automated billing software. Build human capacity, including training, awareness-building, and organizational change.

2. Report on Data Quality Tool- Implementation Guidelines by USAID, September 2008

Background:- National programs and donor-funded projects are working towards achieving ambitious goals related to the fight against diseases such as Acquired Immunodeficiency Syndrome (AIDS), Tuberculosis (TB), and Malaria. Measuring the success and improving the management of these initiatives is predicated on strong monitoring and evaluation (M&E) systems that produce quality data related to program implementation. In the spirit of the "Three Ones," the "Stop TB Strategy," and the "RBM Global Strategic Plan," a number of multilateral and bilateral organizations have collaborated to jointly develop a Data Quality Assessment (DQA) Tool.

Methodology:- The DQA and RDQA are grounded in the components of data quality, namely, that programs and projects need accurate, reliable, precise, complete and timely data reports that managers can use to effectively direct available resources and to evaluate progress toward established goals. Furthermore, the data must have integrity to be considered credible and should be produced ensuring standards of confidentiality.

3. Nutritional and Socioeconomic Factors in Relation to Prostate Cancer Mortality:

a Cross-National Study. James R. Hebert et. al (1998), Journal of the National Cancer Institute, Vol. 90, 1637-47.

Background: - Large international variations in rates of prostate cancer incidence and mortality suggest that environmental factors have a strong influence on the development of this disease. The purpose of this study was to identify predictive variables for prostate cancer mortality in data from 59 countries.

Methods: - Data on prostate cancer mortality, food consumption, tobacco use, socioeconomic factors, reproductive factors and health indicators were obtained from United Nation sources. Linear regression models were fit to these data. The influence of each variable fit in regression models were assessed by multiplying the regression coefficient b by 75th and 25th percentile value of the variable. The difference, bX₇₅-bX₂₅, is estimated effect of variable across its interquartile range on mortality rates measured deaths per 100000 males aged 45-74 years.

Results: - Prostate cancer mortality was inversely proportional with estimated consumption of cereals (deaths; p= .001, bX_{75} - bX_{25} = -7.31), nuts and oilseeds (bX_{75} $bX_{25}=-1.72$ deaths; p= .003) and fish ($bX_{75}-bX_{25}=-1.47$ deaths; p= .001). Besides variables related to diet, association was observed b/w prostate cancer mortality rates and a composite of other health related, sanitation and economic variables (p=.003)

Conclusions: - The specific food related results from this study are consistent with previous information and support the current dietary guidelines and hypothesis that grains, cereals and nuts are protective against cancer.

CHAPTER 3 RESEARCH **METHODOLOGY**

3 Research Methodology:-

3.1 Study Design- The dissertation study involves analysis of secondary data. It is a mixture of both quantitative and qualitative data which is a cross sectional study and is retrospective.

Cross - Sectional Study: Also known as one – shot or status studies are the most commonly used designs in the social sciences. The design is best suited to studies aimed at finding out the prevalence of a phenomenon, situation, problem, attitude or issue, by taking a cross section of the population. They are useful in obtaining an "overall" picture as it stands at the time of the study.

Retrospective- It refers to the event which had already happened. Such studies help to understand what could all be the necessary causes of that event that occurred and likely association between them.

3.2 Type of data- Secondary data was used for the study. It is the type of data that has been already collected by someone else for different purpose. Here we have to extract the required data from available resources. Data was collected in the form of questionnaires. There are three sets of data- PSA data, GRC data and IITF data. Different key indicators or variables were observed for the data. The common indicators in all the three data sets were a) registration number b) socio- demographic indicators -name (first, middle and last), age, gender, address, education, profession, income, habits (smoke/ smokeless form of tobacco) and diet (vegetarian or non vegetarian), blood indicators i.e. Haemoglobin and White Blood Cell count, X- ray and surgeon indicators (enlarged prostate and abdomen, ENT). PSA values were collected only for PSA data. The other indicators i.e. Gynaecological (breast, cervix, Pap smear) were present in GRC data and IITF data.

3.3 Sample Size: - A total of 3,787 records screened for different type of cancer.

Data set	Records	Period
Prostate Screening Analysis (PSA)	500	April 2014
General Resource Centre (GRC)	1677	September & October 2014
India International Trade Fair (IITF)	1610	December 2014

- 3.4 Selection site: Initially random sampling method was used to check the quality of any randomly picked indicator. However due to excessive missing values of the indicators entire data was audited.
- **3.5 Tools** used for study were: SPSS v 16.0; Microsoft Office Excel 2007
- **3.6** Methodology: Analysis was started by retrospectively re abstracting the secondary data. All the key indicators were identified for their values w.r.t to data quality dimensions. These dimensions are:-

Dimensions of data	Operational definitions
quality	
Accuracy	Also known as validity. Accurate data are considered correct:
	the data measure what they are intended to measure. Accurate
	data minimize errors (e.g., recording or interviewer bias,
	transcription error, sampling error) to a point of being
	negligible.
Reliability	The data generated by a program's information system are based
	on protocols and procedures that do not change according to
	who is using them and when or how often they are used. The
	data are reliable because they are measured and collected
	consistently.
Precision	This means that the data have sufficient detail. For example, an
	indicator requires the number of individuals who received
	cancer screening and received their test results, by gender of the
	individual. An information system lacks precision if it is not
	designed to record the gender of the individual who received

	screening.
Completeness	Completeness means that an information system from which the
	results are derived is appropriately inclusive: it represents the
	complete list of eligible persons or units and not just a fraction
	of the list
Timeliness	Data are timely when they are up-to-date (current), and when
	the information is available on time. Timeliness is affected by:
	(1) the rate at which information is updated; (2) the rate of
	change of actual program activities; and (3) when the
	information is actually used or required
Integrity	Data have integrity when the system used to generate them is
	protected from deliberate bias or manipulation for political or
	personal reasons
Confidentiality	Confidentiality means that clients are assured that their data will
	be maintained according to national and/or international
	standards for data. This means that personal data are not
	disclosed inappropriately, and that data in hard copy and
	electronic form are treated with appropriate levels of security
	(e.g. kept in locked cabinets and in password protected files).

Table 2 Operational Definitions of Data Quality

Source: - Data Quality Audit Tool (USAID) Guidelines for Implementation

3.7 Data Quality Methods:-

Based on the dimensions of data quality, data quality auditing methods are of two types:-

(1) Assessment of reporting systems; and

(2) Verification of reported data for key indicators at selected site.

3.7.1 Assessment of reporting systems:-

- a) Off site review of data provided in excel sheets
- b) On site review requires observing functional components as mentioned in conceptual framework (Figure 1) as follows:-

Functional		Assessing criteria
components		
Reporting sites	1	Does clear documentation of collection and aggregation exist?
	2	Does proper entry of data in excel sheet occur?
	3	Are issues related to maintain data quality identified and resolved?
Data collection	1	Are there standard data-collection and reporting forms that are
forms/tools		systematically used?
	2	Is data recorded with sufficient precision/detail to measure relevant
		indicators?
Indicators	1	Are there operational indicator definitions meeting relevant
definitions and		standards that are systematically followed by all service points?
guidelines		
	2	How often these are checked at different reporting sites to maintain
		quality of data?

Table 3 Observational Questions to be checked for assessment of functional components

3.7.2 <u>Data Verification:</u>-

The purpose of this step is to assess the reported data for measuring audited indicators accurately and on time- and to cross check the reported results with other data sources. This will determine if a reporting site have accurately recorded the activity related to the selected indicators on source data. It will trace that whether recorded data has met all the data quality dimensions or it has been manipulated. It was done using tracking method and cross checks.

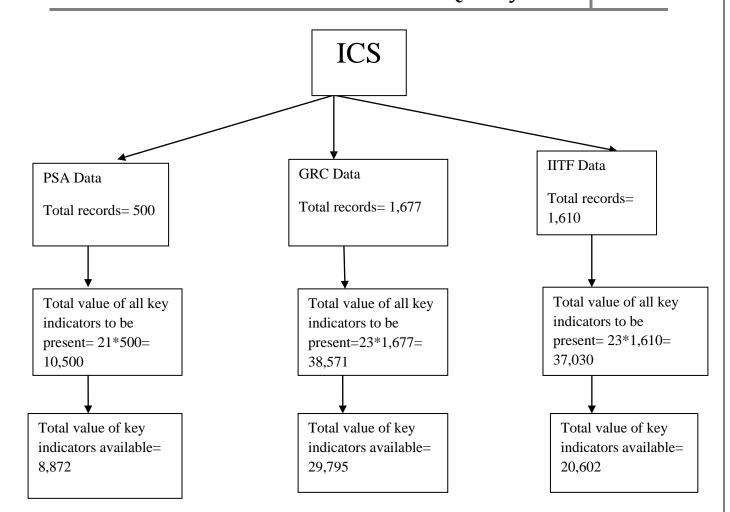


Figure 5Representing tracking of data

3.8 Ethical considerations:-

The data quality audits must be conducted with the utmost adherence to the ethical standards. While the audit teams may require access to personal information (e.g., medical records) for the purposes of recounting and cross-checking reported results, under no circumstances will any personal information be disclosed in relation to the conduct of the audit or the reporting of findings and recommendations. The Audit Team should neither photocopy nor remove documents from sites.

3.9Limitations of the study: - The only limitation of the study was that primary data and all the manual data were not available at the time of auditing.

CHAPTER 4

RESULTS

4 Results and Observations: - Most figures in this report are presented as simple counts or percentages (rounded to two decimal place).

Input data analysis:-

Data supplied:-

Socio demographic data and clinical data.

Missing values of the key indicators were observed in all the three data sets.

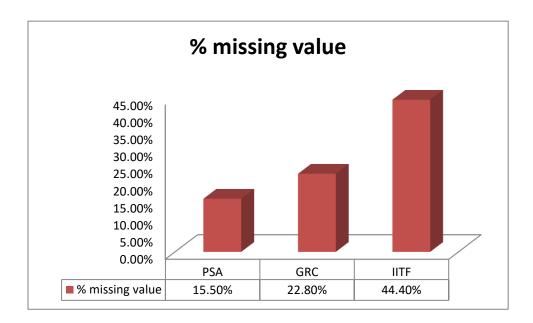


Figure 6 Graph showing missing values of the key indicators.

% Available Reports (Figure 6) in all three data sets is as follows and it was calculated as

Number of reports received/Number of reports expected

% Complete Reports (Figure 7). When it comes to complete reports, highly under reporting was found. This was because of excessive missing values of the key indicators. In case of GRC and IITF data set there was no complete report. It was calculated as follows

Number of complete reports/Number of total reports

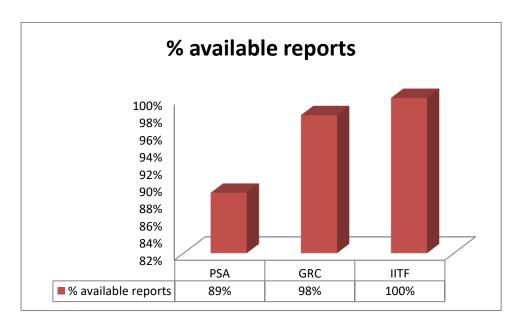
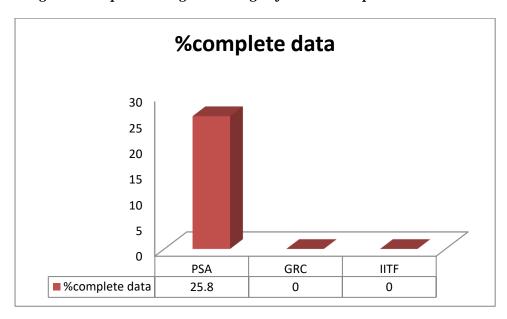


Figure 7 Graph showing Percentage of available reports



#Figure 8 Graph showingPercentage of complete reports

It was also observed that the key indicators were not in compliance with the dimensions of the data quality.

Dimensions	Compliance
Accuracy	The accuracy of the data was not 100%.
Reliability	Though the reliability could not be accessed due to retrospective nature of the
	work, since most of the variables collected
	were socio demographic in nature it can be
	safely assumed to be a reliable data.
Precision	Although at a broader prospective data was
	precise, it could not be verified as this is a
	retrospective study. For example variables
	like education, income and profession.
	Most of the records had various values and
	were difficult to be categorized accurately.
Completeness	None of the data was 100% complete. PSA
	data was 28.2% complete whereas no
	single complete record was found in GRC
	data and in IITF data values for clinical
	indicators were completely missing.
Timeliness	Manual records were in compliance with
	time but porting of the data in excel sheets
	was not done on time.
Integrity	Data showed complete compliance with
	this dimension. There was no deliberate
	manipulation of the data.
Confidentiality	There was no breach in the security of the
	records of the patients with respect to
	physical and electronic security.
Ambiguity	The data entered for open ended questions
	were highly ambiguous. The values entered
	had different formats for the same indicator
	and this increased the ambiguity of the
	data. For example, if the woman was a

housewife the values were "housewife",
"H/W", "h/w " etc

#Table 4 Compliance with dimensions

Matrix showing quality of functional components at time of data collection:-

Functional	Accuracy	Reliability	Completeness	Precision	Integrity	Timeliness
components						
Reporting						
units						
Data						
collection						
forms/tools						
(manual)						
Data						
collection						
forms/tools						
(electronic)						
Indicator						
definitions						
Very high (High 🔘 🛚	Moderate 🛑	Low			

Figure 9

Statistical analysis was done using SPSS (SPSS V. 16, IBM, USA) software on complete, validated and audited data out of 129 records out of 3,787. Data was analyzed using student t test; P<0.05 was considered significant. Mean, median, SEM, SD, Minimum and Maximum were also calculated.

Taking age, education and diet as independent variable and PSA as dependent value

Report

PSA

Age	Mean	N	Std. Deviation	Std. Error of Mean	Minimum	Maximum
50-54	.98	34	.73	.12	.22	3.12
55-59	1.17	21	1.19	.26	.17	4.08
60-64	1.42	24	1.34	.27	.15	5.67
65-69	1.28	22	1.16	.24	.23	4.51
70-74	1.64	15	1.75	.45	.28	6.58
75-79	2.04	7	2.82	1.06	.07	8.02
<50	.67	6	.68	.28	.19	2.05
Total	1.27	129	1.31	.11	.07	8.02

[#] Table 5 showing range of PSA value in different age group

Report

PSA

education	Mean	N	Std. Deviation	Std. Error of Mean	Minimum	Maximum
Less than						
secondary	1.08	9	.88	.29	.23	3.12
school						
Secondary						
school	.85	20	.69	.15	.17	2.77
completed						
Less than						
higher	.22	1			.22	.22
secondary						
Higher						
secondary	.59	7	.35	.13	.18	1.22
completed						
Graduation	1.58	58	1.42	.18	.24	6.58
Post	4.00	24	4.50	200	07	0.00
graduation	1.20	34	1.52	.26	.07	8.02
Total	1.27	129	1.31	.11	.07	8.02

[#] Table 6showing range of PSA value in different level of education

Report

PSA

Non veg	Mean	N	Std. Deviation	Std. Error of	Minimum	Maximum
Diet				Mean		
No	1.17	74	1.11	.13	.07	5.67
Yes	1.39	55	1.54	.20	.17	8.02
Total	1.27	129	1.31	.11	.07	8.02

[#] Table 7showing range of PSA value in males consuming non vegetarian diet

5 Discussions: -

The goal of any cancer screening program is not only to reduce mortality and morbidity but also create awareness among the masses for cancer. There is no conclusive evidence to determine what proportion of the decline in cancer mortality is due to screening versus improved treatment, or other factors; it is likely that screening does contribute and guidelines have been developed globally for effective screening. Such screening programs with indicators to monitor the effectiveness is the hour of need in India, where the disease burden due to cancers especially lung, cervical, prostate, breast, oral cancers etc is growing in an alarming rate.

The current data audit of the cancer screening data of ICS has highlighted lacunae of quality in the collected data. This was mainly due not using a standardized format for data collection. The forms which was used for data collection was open ended which lead to different values for the same key indicator because it made data too much qualitative. This indicates high inconsistency in data collection. There were problems due to inconsistency; ambiguity and missing values. All the three data sets available for auditing have violated the dimensions of data quality with respect to accuracy, precision, completeness, integrity and reliability. There were lots of issues while analyzing the available and complete data. Not much meaningful associations relating socio-demographic indicators to the probable cancer occurrence could be arrived at. This also indicates that proper training to end users collecting the data, monitoring of the data being collected and entered has not been carried out.

From the analysis of the data given it is very much that there is under reporting of data with poor data quality of the collected data. This lead to flawed information at the time of analysis. All the variables which were collected at the time of screening through the forms were not present in the excel sheet. Variables like weight of the patient, type of non vegetarian diet product consumption (eg. Egg, meat, fish) were missing which were present in the forms. Similarly a person consumes a vegetarian diet is still a very subjective term to be used. As reviewed from literature to find associations between two variables, their values should be clearly mentioned. Like if vegetarian diet, then type of product consumed (milk products, green vegetables) should have been mentioned [James R, 1998]. Poor data quality affects the overall cost and effectiveness of a programme [Stefaan Verhulst, 2005]. At the time of analyzing the key indicators for compliance with the dimensions of the data quality, deviations were observed. This could be due to unclear data collection guidelines, lack of insufficient data checks, incomplete data sources and typing errors. Also while analyzing the functional components as mentioned in Figure 1 it was seen at the screening sites that patients were not ready to response to the questions related to ethnicity and income. So, data collecting team needs to break these barriers and should tell the patients benefit of complete information [Karolyn Kerr, 2007].

To show the importance of good quality data, statistical analysis was done on complete, validated and audited 129 records out of 3,787 records. Data was analyzed using student t test; P<0.05 was considered significant. Mean, median, SEM, SD, Minimum and Maximum were also calculated. Results shown in Table 5 are inconsistent with other studies conducted showing that PSA value is less in younger people and it increases with age [Aditi Gupta, 2014] and in Table 7 are in consistent with studies conducted earlier that males consuming non vegetarian diet have higher range of PSA [James R. Hebert, 1998]. So, by removing the missing values and putting the data into standard form optimum outcome has been observed.

Thus from the report it is clear that data is an organization's greatest asset and the importance of having quality data can no longer be underestimated and it is important to realize the consequences of not addressing the issue of poor data quality. So a better understanding of misreported data will surely help to design better cancer screening programmes.

6 Way Forward:-

When a screening programme is started, it is vital that forward planning is undertaken to ensure that the indicators to be measured is already decided before the start of the programme. The collection of appropriate high quality information is critical to measuring the success of the programme. Also the data if meaningful with relevant indicators they can be an effective research tool, help for providing timely follow up and create increased cancer awareness. Hence the data should be collected in a systematic way that will generate indicators for monitoring the screening programs. Based on our studies we have put forth the following recommendations to make the screening programs effective. Cancer registration centres and staff within the screening programme need to be ready to collect appropriate data before the introduction of a screening programme. The report undertaken therefore has important implications where new screening programmes are being considered. So, for that following recommendations are suggested:-

- Create, maintain, and use a data dictionary so that proper guidelines and operational definitions can be followed and thus standardize data entry fields and processes for entering data.
- Be vigilant with missing values.
- Regular cross checks of the data should be done to prevent accumulations of the dirty/ poor quality data.
- Build human capacity, including training, awareness-building, and organizational change
- Monitor program indicators like participation rate (relates proportion of people invited to those who took screening at camps), retention rate (detected as cancer & subsequent follow up), abnormal call rate (proportion of cases identified as probable abnormal to those screened), degree to which those who were screened were accurately informed of the risks and benefits of screening (ideally using an evidencebased decision aid), and rate of potential cancer targets to all those who were screened (many instances children were screened for lump in breast).
- Update/ include the indicators being collected for providing a well evidence based decision support. They should be more specific. The data collection form can be modified to include few more specific indicators. For example inclusion of social

factors, health status, reproductive factors, and lifestyle habits etc can be done. Instead of just identifying if the person has vegetarian or non vegetarian diet, inclusion of dietary products, red meat, etc. These would not only help in targeting the cases but also to provide more specific counseling and education to the population.

7 Conclusions:-

The data audit had brought to focus the low quality in the data being collected in ICS. This can be addressed by use of electronic forms (in the form of Electronic Medical Record). ICS has already started implementing this. There is still issues related to modification the form (be it manual or electronic) to include more specific, valuable indicators. The screening process by itself should be carried out such that its performance (effectiveness) can be monitored. Added to these the end users entering / collecting the data need to trained intensively and regular data audit checkups need to be done

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List of Appendices

1.1 Screening form

CANCE	DELHI - BRANCH R DETECTION CLINIC HI	STORY	
नाम श्री/श्रीमति/कुमारी Name Mr./Mrs./Miss.(in Cap	pital)	आय/Ag	je:
पिता का नाम/पति का नाम/S/o/ W/o/ D/o			SHE SOFT
URIIAdda			
प्रतिवर्ष आमदनी/Income per annum :	and the same of th	TRIT/Education:	
	197	ALISA LANGUANS	N.C.AXLT
टेलीफोन नo/Telephone No. : आफिस/Off. :			
इस केन्द्र के बारे में कहाँ पता लगा?How did u hear a			
हिन्दू/Hindu मुसलमान /Muslim	ईसाई/Christian ि सिख/Sikh	अन्य विशेष है तो क्या?/Other (S	Specify)
परिवार इतिहास : क्या आपके परिवार में किसी को तर् Family History : Has any body in your family had Ca			
पिछला रोग : यदि है /Previous illness/s; If any :		यदि है/Operation/s ; If any :	
टीक टिक करें/Tick as Appropriate	आंगरशन -	414 eroperations, it any	
दिन में कितनी बार?/How many times a day? अन्य किस प्रकार का धुम्रपान करते हैं?/What other for क्या आप खाते हैं/Do you eat अंडे/Eggs	ताजा मछली/Fresh Fish सुखी मछली।	कितनी बार?How o	often?
क्या आप गर्भवती हैं/Are you Pregnant	₹Ĭ/Yes □	ना/No 🗌	
महावारी आरम्भ आयु:/Age of onset of menses :	कितने समय म/Frequency of mens	es: कितने दिन/Dura	tion:
पिछले महीने महावारी की तिथी/Lmp:			
रजनावृति का आरम्भः /Onset of menopause :	W273	WHEEL TOROVER	
रजनावृति के लक्षणः/Symptoms of menopause :	*· □		
म्या एस्ट्रोजन थेरेपी ली हैं?/Have you received Estrog		ना/No L	
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म्या रेडिएशन थेरेपी ली हैं?/Have you received Radia			
हरा एक्सरे : प्रारम्भ तिची/Deep X-ray : Date From			
वेवाह के समय आय/Age at marriage			
हला गर्मै/Age at first pregnancyपरा/Para			
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CONSISTENCY	SOFT	DEFINED	FIRM	HARD ILL DEFINED	
FIVED TO CHILI					
FIXED TO SKIN FIXED TO PECTORAL FASCI		YES:	NO:		
TIALD TO FECTORAL FASCI	IA	YES:	NO:		
LYMPH NODES AXILLA		RT:		LT:	
E.R.		POSITIVE		NEGATIVE	
PR.					
HERR-1		HERR-2			
USG OFFICE					
U.S.G. OF BREAST					
MAMMOGRAM:					
FNAC					
EN.A.C. TRUCUT BIOPSY / BIOPSY : SURGERY CARRIED OUT HISTOPATHOLOGICAL EXA FOLLOW UP :			MY	QUADRANGLECTOMY MRM.	
TRUCUT BIOPSY / BIOPSY : SURGERY CARRIED OUT HISTOPATHOLOGICAL EXA			му	QUADRANGLECTOMY MRM.	
TRUCUT BIOPSY / BIOPSY : SURGERY CARRIED OUT HISTOPATHOLOGICAL EXA	MINATIO	ON:	му	HEAD AND NECK	
TRUCUT BIOPSY / BIOPSY : SURGERY CARRIED OUT HISTOPATHOLOGICAL EXA FOLLOW UP : GENERAL MED	MINATIO	ON:		HEAD AND NECK (Tick Symptoms as Appropriate)	
TRUCUT BIOPSY / BIOPSY : SURGERY CARRIED OUT HISTOPATHOLOGICAL EXA FOLLOW UP : GENERAL MED PULSE	DICAL)	ON:		HEAD AND NECK (Tick Symptoms as Appropriate) • White/ Red patch in mouth	
TRUCUT BIOPSY / BIOPSY : SURGERY CARRIED OUT HISTOPATHOLOGICAL EXA FOLLOW UP : GENERAL MED PULSE/mm	DICAL) /mt.	ON:		HEAD AND NECK (Tick Symptoms as Appropriate) • White/ Red patch in mouth • Non Healing Ulcer	
TRUCUT BIOPSY / BIOPSY : SURGERY CARRIED OUT HISTOPATHOLOGICAL EXA FOLLOW UP : GENERAL MED PULSE	DICAL) /mt.	ON:		HEAD AND NECK (Tick Symptoms as Appropriate) • White/ Red patch in mouth • Non Healing Ulcer • Trismus	
TRUCUT BIOPSY / BIOPSY : SURGERY CARRIED OUT HISTOPATHOLOGICAL EXA FOLLOW UP : GENERAL MEE PULSE	DICAL I	ON:		HEAD AND NECK (Tick Symptoms as Appropriate) • White/ Red patch in mouth • Non Healing Ulcer • Trismus • Painful swallowing	
TRUCUT BIOPSY / BIOPSY : SURGERY CARRIED OUT HISTOPATHOLOGICAL EXA FOLLOW UP : GENERAL MED PULSE B.P. / mm HEART LUNGS	DICAL I	ON:		HEAD AND NECK (Tick Symptoms as Appropriate) • White/ Red patch in mouth • Non Healing Ulcer • Trismus • Painful swallowing • Change in Voice	
GENERAL MED PULSE B.P. / mm HEART LUNGS LIVER	DICAL /mt.	ON:		HEAD AND NECK (Tick Symptoms as Appropriate) • White/ Red patch in mouth • Non Healing Ulcer • Trismus • Painful swallowing • Change in Voice • Difficulty in breathing (Stridor)	
TRUCUT BIOPSY / BIOPSY : SURGERY CARRIED OUT HISTOPATHOLOGICAL EXA FOLLOW UP : GENERAL MED PULSE B.P. / mm HEART LUNGS	DICAL /mt.	ON:		HEAD AND NECK (Tick Symptoms as Appropriate) • White/ Red patch in mouth • Non Healing Ulcer • Trismus • Painful swallowing • Change in Voice • Difficulty in breathing (Stridor) • Unexplained Earache	
GENERAL MED PULSE B.P. / mm HEART LUNGS LIVER	DICAL /mt.	ON:		HEAD AND NECK (Tick Symptoms as Appropriate) • White/ Red patch in mouth • Non Healing Ulcer • Trismus • Painful swallowing • Change in Voice • Difficulty in breathing (Stridor)	

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		QOL Score	
Frequency:		Urgency:	Dysuria:
Yes Day Nigl	ht	☐ Yes ☐ No	☐ Yes ☐ No
Hesitancy:		Poor Stream :	Incontinence:
Yes No		☐ Yes ☐ No	☐ Yes ☐ No
Sexually Active :		☐ Yes	□ No
		Satisfied	□ No Partner
1 (6)		☐ Not Satisfied	□ No Libido
		☐ ED	ED ED
		Others (Specify)	Others (Specify)
Examination			72500 S2350 S 235
·GPE:	Normal	Abnormal (Specify	THE RESERVE OF THE PERSON NAMED IN COLUMN TWO IS NOT THE PERSON NAMED IN COLUMN TWO IS NAMED IN COLUMN TW
Genitalia	☐ Normal	Abnormal (Specify	Grade 1/2/3/4
DRE:	Prostate	Size Median Sulcus	Felt / Not Felt
		Tenderness	Present / Not Present
		Surface	Smooth / Nodular (Specify Location)
		Consistency	Firm / Hard
		RBChpf	WBChpf Sugar
Urine R/M		mg%	
FBS		mg%	
Blood urea		mg%	
Creatinine		mg dl	
PSA	Voided vol:	_ml:PFRmis:AFR	ml/s
Oriflowmetry	THE RESERVE OF THE PERSON NAMED IN	Bladder	Prostate
USG	Kidneys Normal A	bnormal Normal	Abnormal Size: ml.
	Normai A	(Specify)	PVR: mL

