ICMR – NATIONAL CENTRE FOR DISEASE INFORMATICS AND

RESEARCH
NATIONAL CANCER REGISTRY PROGRAMME
Indian Council of Medical Research

PROCEDURE MANUAL

CODING MANUAL FOR COMPLETION OF ITEMS OF CORE INFORMATION FOR HOSPITAL BASED CANCER REGISTRIES

2025

Hospital Based Cancer Registry
INTRODUCTION

The HBCR Procedure Manual represents the cornerstone of cancer registry operations. Its overarching purpose is to provide comprehensive, standardized guidelines for the collection, management, and analysis of cancer data within the cancer registry network.

The objective of this manual therefore, is mainly to provide detailed description of each of the items of information that need to be recorded by the Hospital Based Cancer Registries (HBCRs) so as to achieve consensus in coding of the data. This code manual does not restrict the type of detailed information collected, classified or studied by the registries at the local level.

This manual essentially deals with the items (variables) in the HBCR core form and the guidelines for completing the same. It should be read along with the International Classification of Diseases (ICD – 10 and ICD-O-3)(WHO, 1994; WHO, 2000)

CANCER – History, Definition, Diagnosis.

The occurrence of cancer is recorded in the earliest writings of mankind, but it was not until the 5th century B.C. that Hippocrates first used the Greek word "Crab" to describe the malignancy that spread its pincers throughout the body to choke off life.

Cancer is the Latin or Greek word for crab.

Cancer can be defined in different ways. It is essentially a progressive, purposeless, proliferation of cells, without following any physiological order or control. [1]

Cancer or a malignant tumour should be distinguished from a non-malignant or benign tumour. A benign tumour is self-limiting in its growth, does not spread and generally does not re-grow when removed. Malignant tumours are invasive, progressive and cause significant morbidity and mortality. Thus, invasive cancers are of public health concern.

Risk Factors:

The aetiology of cancer is as complex as its diversity. Generally, this involves an interplay of multiple factors. Tobacco in all its forms has been established time and again as a major risk factor for several anatomical sites of cancer. Radiation, ultraviolet light, and some chemicals can initiate formation of a tumour. Viruses are known to be responsible for several cancers. The histological and cytological

appearances of cancer cells differ from those of normal cells. There are also differences and variations in gene structure, molecular chemistry and biology of normal and cancerous cells.

Lifestyle Factors

Tobacco Use

Cigarette smoking is a well-established risk factor for several types of cancer, including lung, throat, and bladder cancer. Additionally, exposure to second-hand smoke can also increase the risk.

Diet and Nutrition

Certain dietary habits, such as high consumption of red and processed meats, and low intake of fruits and vegetables, have been linked to an elevated risk of developing cancer.

Physical Activity

Sedentary lifestyles contribute to the risk of various cancers. Regular physical activity not only promotes overall health but also reduces the risk of certain cancers.

Environmental Factors

Exposure to Carcinogens

Occupational exposure to carcinogens, such as asbestos and certain chemicals, can significantly increase the risk of cancer. Identifying and minimizing exposure is crucial for preventive measures.

Ultraviolet (UV) Radiation

Excessive exposure to UV radiation from the sun or artificial sources, such as tanning beds, is a known risk factor for skin cancer.

Genetic Predisposition Hereditary Cancer Syndromes

Certain individuals may inherit genetic mutations that predispose them to specific types of cancer. Examples include BRCA1 and BRCA2 mutations associated with breast and ovarian cancers.

Family History

A family history of cancer, especially in first-degree relatives, can indicate a genetic predisposition. Regular screening and genetic counselling are essential for individuals with a family history of cancer.

Idiopathic Factors

Unknown Causes

In some cases, the exact cause of cancer remains unknown, leading to the classification of idiopathic factors.

Interactions and Multifactorial Causes

Cancer often results from the interplay of genetic, environmental, and lifestyle factors.

A thorough understanding of cancer risk factors, genetic predisposition, and idiopathic factors is critical for healthcare professionals and researchers. This knowledge forms the basis for personalized prevention strategies, early detection, and targeted treatments in the fight against cancer.

Early detection of cancer not only improves survival, but also greatly enhances the potential to cure. Surgery, radiotherapy and chemotherapy, are the main forms of treatment of cancer, though other types like immunotherapy, targeted therapy, stem cell transplantation etc are catching up as alternative or adjunct treatments.

There are many distinct types of cancer, each having a unique set of specific symptoms and requiring a specific course of therapy. However, these types can be grouped into following four major categories:

(1) Carcinomas
(2) Sarcomas
(3) Leukaemias
(4) Lymphomas

Carcinomas are solid tumours derived from epithelial tissues and are a major form of cancer. Epithelial tissues are the internal and external body surface coverings and their derivatives, including skin, glands, and linings of the respiratory, gastrointestinal, urinary, genital and nervous systems. According to National Cancer Registry Programme more than 90% of cancer arise from epithelial tissue. [2]

Sarcomas are solid tumours growing from derivatives of embryonal mesoderm, such as connective tissues, cartilage, bone, muscle, and fat. Leukaemias and lymphomas could be considered subgroups of sarcomas since bone marrow and lymphoid tissues are derived from mesoderm.

Leukaemias are diseases in which abnormal numbers of leukocytes (white blood cells) are produced by the bone marrow. This enhanced production resembles the body's normal response to a massive infection, but in leukaemias most of the leukocytes do not mature into functional cells. Leukaemias are one of the most common malignancies of childhood, and affect people of all ages.

Lymphomas are diseases in which abnormal numbers of lymphocytes (a type of leukocyte) are produced by the spleen and lymph nodes. The disease is thus quite similar to leukaemia, but in some lymphomas the immature lymphocytes aggregate in the lymphoid tissues. Hodgkin's disease and non-Hodgkin's Lymphoma are the two broad groups within the Lymphomas.

Metastasis is the ability of a malignant cell to detach itself from a tumour and establish a new tumour at a remote site within the host. This ability reflects both the lessened cohesiveness of cells within a tumour and the capacity of malignant cells to sustain themselves while floating freely in the blood stream or lymph ducts.

Cancer may be suspected in any of the following ways: a lump or swelling, a wound that does not heal, evidence of constant bleeding from any internal site, persistent cough or difficulty in swallowing, sudden loss of weight, unexplained continuous indigestion or changes in bowel habits. Further investigation is mandatory in order to confirm or exclude a diagnosis of cancer. A microscopic examination of the representative tumour tissue by a trained pathologist is necessary for a final confirmation of a diagnosis of cancer. All other investigations play a supportive role in the diagnosis. There is a growing role for non-invasive imaging techniques for diagnosis.

In addition, there are other alternative diagnostic methods contribute to the detection of cancer at specific locations.

Most of the diagnostic information items are restricted to information available at the initial diagnosis. However, with the passage of time the patient's medical record gets more complete information that was originally missing or uncertain. It is therefore established practice to accept the latest information or the most complete or detailed information.

This booklet is essentially a coding format. The science, art and skill of abstracting a medical record completely and accurately have to be evolved by registry staff over a period of time.

This manual informs how to complete the Hospital based cancer registry form with particular reference to classifying and coding the different malignancies that are to be encountered in clinical practice.

This manual is divided into sections as seen in the HBCR form and can be used as a guideline and for details of the codes as such one should refer to the ICD-O3 and ICD-10 manual.

International Classification of Diseases and Reportable Neoplasms.

The convention followed by most cancer registries across the world for categorising and coding is the International Classification of Diseases (ICD) published by the World Health Organization. Currently the tenth revision of the ICD (WHO, 1994) is adopted for coding all diseases and the corresponding edition for oncology (cancer) is the third revision of the ICD for Oncology: ICD-O-3 (WHO, 2000). The World Health Organization released eleventh revision of International Classification of Diseases (ICD-11) in 2019 to record and report cause of illness and death. In ICD-O-3 there are two broad divisions for coding:

One for the anatomical site (Topography), and another for the morphological description, of the type of tumour (Morphology).

The former commences for all neoplasms with the character "C" followed by two numeric digits followed by a decimal (.) and one more numeric digit. The first two

digits signify the code for the anatomical site and the digit following the decimal the sub-site of the site represented by the first two digits.

The latter commences with the letter "M" followed by four digits, followed by a slash (/) and the fifth digit, followed by one more slash (/) and a sixth digit. The first four digits represent the code of a particular morphological description. The fifth digit represents the behaviour code (see below) and the sixth digit the histological grade of the tumour.

The ICD-O-3 codes assigned for the fifth digit behaviour code are as follows:

Code '/0'	=	Benign
Code '/1'	=	Uncertain whether benign or malignant – Borderline malignancy Low malignant potential Uncertain malignant potential
Code '/2'	=	Carcinoma-in-situ Intraepithelial Non-infiltrating Non-invasive
Code '/3'	=	Malignant, primary site
Code '/6'	=	Malignant, metastatic site Malignant, secondary site
Code '/9'	=	Malignant, uncertain whether primary or metastatic site

All cases with a behaviour code of '/3', '/6' according to ICD-O-3 are considered malignant and reportable

Use of terminology in defining neoplasms and categorising them as malignant (behaviour code of '/3' or above).

Many times, the pathologist could use a variety of adjectives in describing the specific morphological diagnosis. The different terms that should be considered and taken as a malignant neoplasm or otherwise is given below:

To be regarded as malignant

Consistent with, compatible with, probably, suspicious;

Not to be regarded as malignant

Equivocal, questionable, suggestive, very close to.

When in doubt the concerned pathologist should be consulted.

The complete alphabetical list of these reportable neoplasms based on ICD-O-3 (WHO, 2000) is given in the appendix III.

CORE FORM FOR HBCRs

The list of the core items of information, its definition and description (with examples where necessary) to enable accurate, standardised and uniform completion by the registry staff is given below. A brief mention of the important quality checks that are carried out on the specific item is also given (this is not comprehensive). Short note on data-entry and the number of fields assigned are indicated. Detailed guidelines for data entry and the working of the HBCRs in the Indian context are provided separately. The HBCR core form is divided into 04 sections. In each section there are mandatory fields written in red and recommended fields written in blue. The different sections of the HBCR form are

Section I: Identifying information/ demographic details

Section II: Diagnostic details

Section III: Cancer stage and treatment

The HBCR should gather information from every department and unit within the reporting institution where cancer is diagnosed and treated. This ensures a thorough and inclusive approach to capturing data on cancer cases. By collecting data from all relevant areas, the registry can provide a holistic view of cancer diagnoses and treatments across the entire healthcare facility.

All fields in the core form of the HBCR are designated as mandatory. This means that data must be provided for each of these fields without exceptions. The decision to make all fields mandatory is intended to ensure completeness and accuracy in the registry. Social investigators should minimize the use of the option "unknown" for any given field, try to complete as much specific and detailed information as possible for each cancer case.

I. Identifying Information/ Demographic Details

1. Name of Reporting institution and Centre Code* Mandatory field

Definition and Description *(for completing core form)**:***

This has two parts-
First part you have to type out the name of the Reporting Institution (RI) in full.
Second part is the Centre code. The Centre code is the number assigned to each centre by ICMR-NCDIR, mainly to facilitate data identification and analysis at the Coordinating Unit. This is a fixed unique number given to each registry and is automatically generated by the software programme. The same code may be entered in the printed form.

Guidelines for Data Entry:

Centre Code is a static field. System will take care.

2. HBCR Registration Number* Mandatory field

Definition and Description *(for completing core form)**:***

New Registrations: Registration number is essentially and only for the use of the Registry. It is the Cancer Registry's case identifying number.

- It is a seven-digit Registration Number which is allotted to each cancer patient registered in the HBCR. and should be assigned by each Registry. The first two digits are for the year of cancer diagnosis and the remaining five digits are unique serial number allotted to cancer patient by the registry during that year.
  For example, if a case diagnosed as cancer is registered with the Date of Registration (see below) as 1.1.2014 then, the registration number of that case has to be given as 1400001. Registration number of a case must not exceed seven digits including year of registration.
- The registration number assigned by the registry could generally be as and when the diagnosis of malignancy of a given case is confirmed and the core information is complete in other respects. This may more or less follow the order of date of registration and/or diagnosis, but not necessarily so.
  For example, one may consider two cases that register in the source hospital on the same day – 20 January 2014. One may have a confirmed malignancy based on an outside pathology report and the other may undergo investigation and a microscopic confirmation of malignancy may be made on 20 February 2014. The registration number for the first case could be assigned according to the sequence

one month earlier whereas that of the second case would be a month later, which may mean that the registration number for the second case could be few numbers later.

Late Registrations: if the patient is diagnosed of cancer in year previous to the reporting year but registered in the HBCR only in the current year, it is called late registration.

- In HBCR, the Year of Registration and Year of diagnosis need not be same. For example, a patient could have the Date of First Diagnosis of cancer as 10 October, 2013 and come to or register at the hospital where a HBCR is functioning only on 10 January 2014. Then, the HBCR registration number would begin with 13 followed by the registration number and the five-digit number will be serially given after the last registration number for year 2013. (may be 1312345 (say))

Note: The coordinating unit will tabulate the data for a particular year on the basis of both year of diagnosis and year of registration.

Second or Multiple Primary Cancers: In case of second or multiple primary tumours, a separate form has to be filled in for each primary site. **However, the registration number of the patient should be the same on all forms, regardless of whether the year of diagnosis or date of attendance at diagnosis is the same or otherwise.**

For example, first primary cancer case was diagnosed on 28 March 2012 and registration number was assigned, say, 1202346. Subsequently the second primary was diagnosed in the same patient on 5 January 2014. Still the registration number to the case should be assigned as 1202346 but should be registered during the year 2014 as per date of diagnosis of second primary or subsequent primaries.

example,	Diagnosed on	Registration number
first primary cancer case	28 March **2012**	1202346
the second primary	5 January **2014**	1202346

The philosophy is that the patient is one, so that the case papers should bear the same registration number but should be counted according to number of primary cancers and year of diagnosis or date of first attendance at diagnosis. However, care must be taken while checking for duplicates within the same year or earlier years.

This procedure will help the registries in establishing a common link between multiple primary tumours occurring within the same patient but diagnosed in two different calendar years.

In general, however, while calculating incidence rate, multiple primaries will be counted as that many cancer cases. For example, if there are two primaries, viz., cancer of the breast and acute myeloid leukaemia in a patient, one case will be included as a case of breast cancer and another will be included as a case of acute myeloid leukaemia.

Guidelines for Data Entry:

Item	***Number of fields assigned for coding***
Registration Number	7

As indicated above seven numeric fields have been assigned for this item of information. The first two digits represent the year of registration and the next five digits represent the registration number assigned for each case by the registry. Thus, for the first case of the year 2014, it would be 1400001. One has to make sure that all the numeric characters have an entry and are not left blank. For example, the above number cannot be entered as 14001 or 14…01

3. Name of Department and Unit Number: * Mandatory field

Definition and Description (*for completing core form****):***

All possible departments/units etc at the hospital/institution where the HBCR is functioning should be listed and two-digit numeric codes assigned. This numeric code is applicable only to that specific hospital. The list should be mutually exclusive. In other words, the code given to one unit say Head and Neck should also not fall under ENT or Dental. Generally, this is the very first department/unit where the patient undergoes physical examination and subsequently diagnosed/treated.

Guidelines for Data Entry:

Item	***Number of characters assigned for coding***
Unit number	2

Two numeric characters have been provided for this item.

4. Hospital Registration Number* Mandatory field

Definition and Description *(for completing core form)****:***

This is the number allotted to the patient by the hospital where HBCR is functional and collects the information on a given case and is the actual unique identification number of the patient for that hospital.

Such a registration number of the hospital is useful information for retrieving medical records to update registry data, verification of duplicates, correlating multiple pathology (surgical pathology, cytology, haematology) reports, tracking suspected cancers, in patient follow-up, etc.

Guidelines for Data Entry:

Item	***Number of fields assigned for coding***
Hospital Registration Number	25

The numbers of fields, for data entry for this item are 25. There are no restrictions in the fields for data entry as each hospital may adopt their own style or format for numbering. Thus, numbers and/or alphabets may be entered. There could be intervening slashes and/or dashes or any other symbol.

Quality checks:

There are no quality checks as such for this item. However, this item should be completed in all cases.

The check programme will pick up duplicate registration numbers from the same hospital for verification of duplicates.

5. Date of Reporting at Reporting Institution* Mandatory field

Definition and Description *(for completing core form)**:***

The date item refers to the date of registration or reporting at hospital where the HBCR is located. In other words, it is the Date of First Attendance to this hospital.

Guidelines for Data Entry:

Item	***Number of fields assigned for coding***
Date of Registration	6

Six characters are provided for coding Date of Reporting. It should be coded as Day (DD)/Month (MM)/Year (YY). i.e. 15 January, 2023 should be coded as 150123.

Code	Month (MM)	Day (DD)
01	January	01 to 31
02	February	01 to 28 (29 if leap year)
03	March	01 to 31
04	April	01 to 30
05	May	01 to 31
06	June	01 to 30

07	July	01 to 31
08	August	01 to 31
09	September	01 to 30
10	October	01 to 31
11	November	01 to 30
12	December	01 to 31
99	Unknown/ Not stated	

Quality checks:

Within the date fields (day, month, year) range checks are carried out.

6. Case Registered through* Mandatory field

This variable is to record upon the type of attendance for cancer case first reporting at RI. The status of the patient is to be picked from the following guidelines.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
'Case Registered' as Codes	1

1	=	Out-Patient (OP)
2	=	In-Patient (IP) (elective)
3	=	In-Patient (IP) (emergency)
8	=	Others (specify)
9	=	Unknown

Out-patient refers to patient reported to RI as OPD case, In-patient (elective) where the cancer case was admitted after regular OPD attendance, In-patient (emergency) where the cancer case presented to emergency services and admitted to the reporting institution. If there are other scenarios, record it under other category and specify the type in field provided. If there are no information on type of attendance record it as unknown. The above Information is filled depending on the way each hospital has registered the case.

7. Type of Referral: * Mandatory field

Definition and Description *(for completing core form)**:***

This variable informs us how the cancer patient was registered at the RI. It provides the following options:

Self: A self-referral refers to a scenario where a patient initiates the process of seeking medical attention or care on his/her own preference. In this type of referral, the patient takes the initiative to contact the healthcare facility or healthcare provider directly, without being directed by another healthcare professional or institution.

Other hospital/health facility: This type of referral occurs when a patient is directed to seek medical attention or specialized care from another hospital or health facility by a healthcare professional or institution. Reasons for such referrals could include the need for advanced diagnostic tests, specialized treatments, or access to specific medical experts not available at the referring facility. A list of such sources viz., hospitals, nursing homes, pathology laboratories should be prepared by each HBCR and used for coding and these details should be periodically updated.

Usually where a cancer registry is located in a major cancer hospital, patients are generally referred to that hospital and many times the first source of registration of a given case would be the cancer hospital or Reporting Institution. However, it is advisable for cancer registries to have provision in the form to record the name, city and district with pin code of the referral hospital(s) or other sources of registration of the same patient. Date of registration to the referral hospital has also to be recorded. The date item refers to the first diagnosis by any recognized medical practitioner and/or in a hospital or pathology laboratory. Date of First Diagnosis is equivalent to Date of First Attendance to a hospital subsequent to which the patient was diagnosed as having cancer. If a patient attends two or more hospitals, the date of diagnosis should be the date of diagnosis at first hospital. Initially, this is often a clinical diagnosis and may or may not be confirmed microscopically. Even if confirmed later, the date of diagnosis should be recorded as the date of the first clinical diagnosis and not as the date of confirmation.

In the absence of an exact date of diagnosis, the best approximation is acceptable. Approximation is preferred to coding the day and/or month as unknown. Year of diagnosis must not be unknown. For approximation the day, month, year, the available information, if any, such as: date of referral, date of first cancer – directed therapy, histology review etc., may be considered.

Guidelines for Data Entry:

Item	***Number of characters assigned for coding***
Name Source of Registration	99
District	15
City	15
Hospital No.	25
Date of Registration/First diagnosis	6
Pin code	6

Ninety-nine characters have been provided for this item. Once name of departments/units have been entered into the system and saved then for subsequent records by just typing the starting few characters, names are available. Fifteen characters are provided for district and city. Twenty-five characters are provided for hospital number. Six numeric characters are provided for pin code and date of registration. One has to make sure that all the items have an entry and are not left blank if any source is available.

Quality checks:

These are mainly formatting or range checks should be as less as possible. Within the date fields (day, month, year) range checks are carried out.

8. Date of First Diagnosis* Mandatory field

Definition and Description *(for completing core form)**:***

The date item refers to the first diagnosis by any recognized medical practitioner and/or in a hospital or pathology laboratory. Date of First Diagnosis is equivalent to Date of First Attendance to a hospital subsequent to which the patient was diagnosed as having cancer. If a patient attends two or more hospitals, the date of diagnosis should be the date of diagnosis at first hospital. Initially, this is often a clinical diagnosis and may or may not be confirmed microscopically. Even if confirmed later, the date of diagnosis should be recorded as the date of the first clinical diagnosis and not as the date of confirmation.

In the absence of an exact date of diagnosis, the best approximation is acceptable. The approximation is preferred to coding the day and/or month as unknown. The year of diagnosis must not be unknown. For approximation the day, month, year, the available information, if any, such as: date of referral, date of first cancer – directed therapy, histology review etc., may be considered.

Guidelines for Data Entry:

Item	*Fields length assigned for coding*
Date of First Diagnosis	8

As for Date of Registration

Quality checks:

Within the date fields (day, month, year) range checks are carried out.

9. Full Name of Patient* Collect the full name of the patient.

Definition and Description *(for completing core form)**:***

The name of the patient should be filled in the core form. This includes Title (Mr, Mrs, Miss, Dr etc) First name, Second/Middle name and Last name. As far as possible abbreviations in the name should be avoided. Full expansion of the initials of the patient has to be recorded.

Guidelines for Data Entry:

Item	***Number of fields assigned for coding***
Title	
First Name	39
Second/Middle Name	39
Last Name	39

While entering the name of the patient into the computer, following steps may be taken:

Title as listed above should be selected from the menu. These should not be again entered in any of the fields of First, Middle or Last name. For the actual names of the patient the number of characters including blank space should not exceed the respective number given above. A full stop (.) or a comma (,) must not appear anywhere in between the name. If the name (first, middle or last) exceeds the number of characters indicated, try to adjust it within the specified number of characters by shortening the name.

Quality checks:

The names of patients are mainly used for duplicate checks. The identifying information of the patients registered during a year; like, name, age, sex, address, etc., and site help to eliminate duplicate registrations. When patients present with different order of names at different collaborating centres, such cases may be reviewed manually for identical information such as age, sex, parents' name/husband or wife's name, etc., and decision may be taken accordingly regarding duplication. The salutation entered (Mr / Mrs) shall be cross verified with the gender of the patient.

10. & 11. Age* and Date of Birth of the Patient* Mandatory field

Definition and Description *(for completing core form)**:***

Age of the patient is one of the most important items in the core form as several parameters and hypotheses are dependent on the information gathered for this particular item. This information should be elicited as accurately as possible.

As a rule, registry staff should ask the date of birth, when they are directly interviewing the patient/relative/accompanying person. The information should be elicited compulsorily when the patient is a child or when the educational and economic level makes it relatively easy for getting this information. In other instances, they should make all attempts to get information on date of birth. Only when this is not immediately possible, they should ask for the age.

While responding to age (either patient or more often the other respondent) the tendency is to say the age in digits of five, say 25, 30, 35 and so on. The registry staff should learn to question again when such answers are provided and get the accurate age in completed years. Age details can be verified from government issued identification cards.

The age of the patient in completed years is as on date of first diagnosis mentioned above.

Many a time, different social workers interview the same patient at different departments in the hospital and record patient's age differently. The rule is that the highest age of the patient should be coded. But if one form is interviewed and the other is copied from the records department, then the age mentioned in the interviewed form should be chosen for coding. Late registrations should be adjusted or corrected for age.

The completed age may be coded as follows:

Age		Code
Less than one year	=	00
01-97	=	Actual age in completed years
98 and above	=	98
Unknown	=	99

Guidelines for Data Entry:

Item	***Number of characters assigned for coding***
Age (in years)	2
Date of birth	8

Date of birth should be coded in the same way as date of first diagnosis with first two digits for day, middle two for month and the last four for year. Best efforts should be made to ascertain the date of birth of the patient.

Quality checks:

Age of the patient must be entered or coded as specified above. Boxes must not be left blank otherwise it will amount to coding error. Duration (in years) from date of birth to date of first diagnosis should be equal to the age. For date of birth column, the usual checks for date will be carried out.

Age is also used for consistency checks across primary site of tumour and morphological diagnosis. Thus, the age is checked with the ICD code for primary site of tumour and whenever such anatomical sites of tumour are unlikely to occur for the stated age, then such cases are listed for checking the age or the code given to the specific site of tumour. For example, it is highly unlikely that a female child of 5 years of age, could have tumour of the breast or cervix. Likewise, consistency checks are also done for age and morphologic type of tumour. For example, a retinoblastoma (a type of tumour of the eye) is highly unlikely in any body whose age is above 10 or 15 years.

Such inconsistencies could be due to errors during abstracting case files/reports etc., recording the same on different forms/registers, inadvertent coding or while entering data on to the computer. So, care has to be taken by registry staff at each of these steps.

12.Sex of the Patient* Mandatory field

Definition and Description *(for completing core form)**:***

This is one of the simpler items of information to record. In very rare instances of hermaphrodites or sex change this may be stated as “Others” and specifics written on the form.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Sex	1

Codes

1 = Male
2 = Female
8 = Others

Code “8 = Others”, include hermaphrodites/ intersex, transsexuals and others. These cases would be tabulated separately.

Quality checks:

Quality control checks with the code given for sex is carried out. These mainly include cross checks with primary site of tumour. For example, cancer of the prostate has to be in a male patient and cancer of the cervix has to be in a female patient. Similarly, consistency checks are carried out on morphological code that are gender specific occurring in the reproductive organs of either sex. For example, a granulosa cell tumour is a tumour of the ovary and cannot have a code for male.

13. Unique Identification / Beneficiary Number* Mandatory field

The unique identification number / beneficiary number should be recorded wherever possible. Various listed fields include AADHAR, Voter ID, Ayushman Bharat Health Account **(**ABHA- ID), Passport number, PAN number, Beneficiary health scheme name/number or any other number. Record it as unknown only if identification number is not available which should be very minimal. All of the items listed if available to be recorded.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Aadhaar	12
Voter ID	10
ABHA-Health ID	14
Passport number	8
PAN number	10
Beneficiary health scheme name/no	20
Any other number	25

14. Name of Relative/Next of Kin *(including parent)*/ Accompanying person)

Mandatory field

Definition and Description (*for completing core form****):***

These names should be completed along the same lines as was stated for the name of the patient. However, there is only one field with provision for 40 characters and not three fields. Therefore, the name should be filled in the order as first name, second name and last name. Full names have to be recorded as these are mainly for identification and elimination of duplicate registrations.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Father	39
Mobile No.	49
Mother	39
Mobile No.	49
Husband	39
Mobile No.	49
Wife	39
Mobile No.	49
Son	39
Mobile No.	49
Daughter	39
Mobile No.	49
Others	39
Mobile No.	49

The same guidelines as for 'Name of Patient' should be followed. In case of more than one son or daughter, a comma should be placed alongside the name entered. Thus, when possible duplicates are matched and listed, the staff could, wherever necessary, verify the original forms for further checking.

Quality checks:

The names of patient's relatives indicated above are mainly used for duplicate checks.

Guidelines for Interviewing

Registry staff should make every attempt to interview the patient or the family member or any accompanying person who knows about the patient.

While attempting to interview the patient, registry staff should, give due consideration to the general condition of the patient and assess whether he/she is fit to be interviewed. Then, after duly informing the nurse/ward attendant the interview could be carried out without necessarily revealing or getting into a discussion on the nature of the illness (diagnosis of cancer) or its prognosis to the patient.

There could be some instances when the patient cannot be interviewed. Usually as inpatient or as an outpatient, the patient may be available, but cannot be interviewed because of his/her disease/health condition. In a different setting such as in the pathology laboratory the patient may not come personally to collect the report. In both circumstances the person accompanying the patient who has the best knowledge about

the patient should be interviewed. The gathered information should be confirmed with the patient at the next best opportunity.

If the patient or person accompanying the patient is also not available then the maximum possible information should be abstracted from all possible records, viz., pathology report, medical case file, radiotherapy register/records etc.

The physician in-charge and the attending nurse/social worker may provide valuable information on the disease and the diagnostic details, if not about the identity of the patient.

15. Address of Residence of the patient* Mandatory field

15.1 Place of Usual Residence: *Place of usual residence (where the person has been residing for the past one year (at least))*

***Definition and Description** (for completing core form):*

A patient's address is an important item in the core form. The address should be complete including name and code of ward (if urban), postal pin code and name of district. HBCR registers cases not only India, it was registers foreign patients.
Therefore, the registry staff should ensure that the patients really belong to that particular area and must be a resident not less than one year. Rural and urban to be selected based on recent Census description.

Name of District, Tehsil/Taluk etc: For patients residing in rural areas it is important that the name of the District, the sub-unit of district, viz., taluk/tehsil/other and if possible, name of village/gram panchayat and the area's primary health centre are mentioned.

Postal PIN Code: Pin code of the patient's addresses should be entered into the computer on the six numerical characters provided for this. Efforts must be made to see that all patients must have a pin code. As the pin code relates to the post office, in cases where there is no post office in that area, code at least first two or three digits and remaining as unknown. For example, if a case is a resident of Bengaluru for more than one year and it is not possible to identify the post office then it may be coded as "560999". PINCODE: All India Directory of Postal Index Numbers, issued by Department of Posts, New Delhi – 110001. This directory should be used for coding.

Name of the district, State/UT and Pin code are the mandatory fields.

General guidelines for getting address of patients:

Obtaining and recording accurate information on place of residence is one of the most challenging tasks, especially in the Indian context. . Therefore, the registries have to study the local setting at the different sources of registration, identify the critical places/situations where such information is likely to be missed, ascertain the key personnel who could help, evolve a plan of action for each source and implement the same.

The possible steps that could be taken in different scenarios at each type of source of registration is given below:

A. Cancer Hospital

Getting and recording information on residential address of cancer patients is by far the simplest. Usually the patient coming to a cancer hospital is referred from another medical institution. This patient could have a confirmed microscopic diagnosis of cancer, who, may or may not have been commenced on cancer directed treatment. Other patients could be referred on a mere clinical or radiological suspicion of cancer. The best time and place are to meet the patient at the place of initial registration at the cancer hospital. There are good chances of the patient and the information on address being missed if this effort is pursued later. Therefore, the usual practice by cancer registries is to record the address and other details of all new patients that register in the cancer hospital through direct interview of the patient/ relative/ accompanying person, by registry staff. By all new patients means, all those who have a diagnosis of cancer or not at initial registration. This is because, it is expected that in a cancer hospital the majority of patients referred are likely to have a diagnosis of cancer. Hence it is worthwhile collecting information on address of cases even if subsequently such cases are proved not to have cancer.

The foregoing holds good, if, cancer hospitals have a single process and place for registering all new patients. The possible ways and places that a cancer hospital could record new patients and the steps that could be taken to get residential address are given below.

i) *Out-patients:* A new patient may not necessarily have a formal registration with a processed medical record and he/she may be seen by the general medical officer or examined directly by the concerned unit doctor. Thereafter, the patient may or may not be sent for the procedure of formal registration etc. Usually such patients may not have a malignancy, but when one exists it is not only likely to be missed, but the address of the patient may not be known. The help of the concerned staff (peon, nurse, social worker, doctor/unit head) of the unit has to be taken so as to direct such patient to the location of the registry staff who are routinely interviewing and recording information on the newly registered cases.

ii) *Referrals to Department of Pathology:* For reasons of expertise or availability of some special test surgeons in other institutions may send biopsies/specimens for processing and diagnosis. At other times microscopic slides may be sent for a second opinion. In such instances, it is most likely that the patient may not visit the hospital for further investigations and/or treatment, and the cases that are proved as malignant are likely to be missed by the registry. So, a system needs to be in place to capture the identifying and other demographic information of these patients. Depending on the average number of such cases being received, the registry staff should visit the department of pathology to scrutinise the reports on a daily, bi-weekly or weekly basis. The staff in the Department of Pathology should be taken into confidence for speedy communication through internal telephone of the fact that such material has been received and/or is being reported. Better still, if one of the staffs in that department could be trained to complete the demographic information by interviewing the person delivering the specimen or collecting the report. If the concerned person does not have knowledge about the patient, then the source institution from where the specimen/slide was sent should be noted. Registry staff should decide to immediately visit those institutions.

iii) *Cytology, Bone Marrow and Peripheral Blood Smears:* With diagnosis through Fine Needle Aspiration Cytology (FNAC) as an accepted diagnosis for commencing cancer directed treatment more and more of these procedures are done on an outpatient basis. This is also true for Bone Marrow Biopsy or Aspiration and Peripheral Blood Smears. If registered patients undergo this kind of investigations then there is no issue, because demographic and other identifying details (like residential address) would have been already recorded by the registry staff. However, when such laboratory tests are done for outpatients (without registrations), then the same strategy described in (ii) above has to be followed. It may be simpler here, as the patient will necessarily have to be present in person for sample collection. A Fine Needle Aspiration or a bone marrow biopsy/aspiration is generally attempted on patients who have a clinical/radiological suspicion of cancer and it would be prudent to complete the residential and other demographic details for all the patients who undergo these tests. But the same may not be possible for some routine cervical/vaginal or peripheral blood smears. The clinical notes will have to be examined and those cases that have a clinical diagnosis should only be interviewed for completion of the identifying details.

iv) *Other investigations:* With advances in medicine newer and newer investigations are done to diagnose and/or monitor the progress of cancer. Several different departments may do this. For example, this could include the radiology department for CT scan/MRI/Ultrasound etc. The biochemistry department could be involved in several such tests including tumour markers (along with department of pathology/microbiology/

virology). The department of nuclear medicine undertakes scans and measurement of T3 and T4 estimations etc for thyroid or other cancers.

Likewise, the Department of Genetics/Cell Biology could undertake various chromosomal and genetic studies. The registry staff should be aware of such investigations that go towards the diagnosis of a malignancy and these cases are likely to be missed if patients undergo these tests on an out-patient basis. The plan of action mentioned in (ii) & (iii) above needs to be followed. This would ensure coverage of all cancers in the base – cancer institution with complete information.

B. Medical College Hospital

In the setting of a medical college with a general hospital the proportion of cancer cases are relatively less compared to other diseases. However, the actual number of cases could be substantial depending on the facilities available for diagnosis and treatment of cancer. The task of interviewing the patient or the accompanying person and recording the address are far more difficult. Each registry has to evolve a set of procedures based on the local setup in the respective institution. Generally, seeing the patient/accompanying person who has been diagnosed as cancer is not too difficult for in-patients who are undergoing treatment provided this is done promptly. The latter connotes that the time intervals a) between a patient's diagnosis of cancer and this fact being identified by the registry staff and, b) the interval between registry staff having identified a cancer diagnosis and the locating the patient in the ward, should be short. Address of in-patients may also be available from the medical records. However, this information in terms of correctness of permanent address and its completeness as well as the duration of stay may not be as accurate as the registry would like.

The outpatient of a general hospital notably in the location of a government medical college is the most challenging situation for any registry to interview and/or get the residential address. This area has to be studied in detail for each situation and working methodology evolved.

C. Pathology Laboratories

Obtaining address of patients whose reports are reported as malignant is the other challenging situation in the Indian context. A little help from the pathologist and his team usually resolves this. The receptionist/technician or any other person despatching the report should be asked to get the address of the patient or at least the name and address of the hospital/nursing home etc from where the specimen was received.

Guidelines for Data Entry:

The fields length assigned for each of the sub-items under this broad heading of address is given below. Care should be taken to enter the required information against the specified sub-item, as otherwise there will be a number of problems in formatting

the data for checks and analysis. For example, against House Number only that information should be entered and not name of house.

Item	***Field length assigned for coding***
Urban / Rural	
House or building number	24
Road/street name	39
Area/locality / Panchayat	39
Ward /Corporation	3
Name of Village/ City / Town	39
Name of sub-unit of district	39
Name of district	through selection
Postal PIN code	6
State / UT	39

Quality checks:

The exact address helps easy identification of duplicate cases. A cross check of postal PIN code and name of district or its sub-unit for cases from semi urban/rural areas would greatly facilitate correctness of location.

Further Details of Residence (Patient's mobile Numbers, email id etc)

Definition and Description *(for completing core form)**:***

In order to have as many ways of contact as possible with the patient, information on the following additional items needs to be collected. This will be of great help mainly in follow-up and in some instances undertaking epidemiological studies.

Patient Mobile Number(s) and e-mail: Advances in electronic information technology and improvements in methods of communication have resulted in more and more of the population having mobile phone and possibly e-mail addresses. For completion of patient information or any clarifications thereof and for follow-up (to know patient and/or disease status) telephones and internet offer a very cost-effective way of communication. As far as possible at least one telephone number should be recorded. The mobile telephone number (if the patient, accompanying person or relative has one) should also be noted. An e-mail identity is also valuable.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Patient Mobile number 1	40
Email	49

Quality checks:

This would concern mainly checks on postal PIN code and District name and code.

15.2 Duration of Stay (*at the place of usual residence* (*in years*)) * Mandatory field

Definition and Description *(for completing core form)**:***

This item of patient information is necessary to confirm that the address gathered and recorded is as per the requirement of the registry which is the usual place of living and not the address where the patient is temporarily residing. A temporary place of stay could be because of the ailment itself wherein the patient has voluntarily sought to reside to facilitate diagnosis and treatment. Another reason could be that the patient who was temporarily residing in a given place happened to be diagnosed with cancer.

For a HBCR all cases regardless of duration of stay (even if this is less than one year) at permanent residence should be included in the registry.

In case the description given by the person being interviewed (patient/relative/other) is stated as "Many years" or 'Permanent', then duration of stay may be taken equal to the age of the patient and coded accordingly.

Duration of stay when patient is a child:

If the patient is a child and age is less than one year then duration of residence should be coded as "01". Other than this, if the patient is a child, the duration of stay of the parents has to be considered and, depending on that and the age of the child the duration of residence may be coded accordingly. For example:

i) if the child is six years of age and parents have been residing for only five years then duration of stay of the child would be five years;

ii) if the child is six years of age and parents have been residing for ten years the duration of stay of the child would be the same as the age of the child – six years;

General Guidelines for ascertaining information on duration of stay:

If the patient's duration of stay in the registration area is 'Not Known' or it is less than one year, such cases should not be included in the registry files. The following

guidelines may be followed whenever a registry has proved cancers on its files, with residential address of the registry area, but unknown duration of stay.

i) If patient has been admitted as an in-patient or is attending or scheduled to attend any of the out-patient departments/clinics for follow-up investigations or treatment, efforts may be made to contact the patient/relative/accompanying person to obtain the duration of stay;

ii) If telephone number(s) are available, the patient/relative/other person may be contacted to get the details of duration of stay;

iii) Home visits may be undertaken by registry staff to get the required information;

iv) Voters lists may be verified for residence status and duration of stay coded as from the year the voters list was prepared; for example, if the voters list is of 2007 and the patient has been diagnosed as cancer in 2014, the duration of stay would be 2007-2014 = 7 years.

If the Registry concludes that a cancer case has been residing in the registration area for a period of more than one year and the exact duration of residence is not ascertainable, then duration of residence of such cases may be coded as "98". However, these cases should be a minimum and this proportion directly reflects on the quality of the data of a registry.

Guidelines for Data Entry:

The fields length assigned for this item is only two. Thus, if the registry registers an unusual case who is 100 years of age or above and the duration of stay is also 100 years or above then the code '98' for duration of stay has to be given.

Item	***Field length assigned for coding***
Duration of stay	2

Quality Checks:

Under the range checks for duration of stay '0' ~~is~~ and '99' are invalid codes. The duration of stay (residence) of the patient in the registry area is also checked for consistency with the age of the patient. The duration of residence of the patient cannot be greater than the age of the patient except when the patient is a child and his age is less than one year. Even where the age of the patient is 100 years or above, the age of the patient is also given as 98 as also the duration of stay. Only where the age of the patient is unknown and the duration of residence is available, then, there will be disparity, if such cases are ever registered.

Other Addresses

Definition and Description (*for completing core form****):***

In order to have as many ways of contact as possible with the patient, information on the following additional items needs to be collected. This will be of great help mainly in follow-up and in some instances in undertaking epidemiological studies.

15.3 Permanent Address: This address where the patient has lived most of his/her life and which is used in legal documents as the house address.

15.4 Alternate address: Address of the Office/Caretaker/Family Doctor of the patient can be described as the alternate address and should be recorded wherever available.

Guidelines for Data Entry:

Item	*Field length assigned for coding*
Permanent Address	
Village	40
Town / City	40
District	40
Pin Code	6
State/UT	40
Alternative Address	
Village	40
Town / City	40
District	40
Pin Code	6
State/UT	40

Quality checks:

This would concern mainly checks on postal PIN code and District name and code.

16. Present Marital Status* Mandatory field

Definition and Description (*for completing core form****):***

The brief definition for each of the specific items on marital status is outlined as follows:

Unmarried is for all persons who have never married. Children would normally be included for this code, unless there has been a history of child marriage, which should be noted in the form in as many words and the appropriate code given;

Married is for persons who are currently married and are normally living with the spouse. This would include persons who have re-married after divorce or after having been widowed.

Widowed is for persons who have lost their spouse and at the time of interview (diagnosis of cancer) are single (not living together with someone else) and not remarried.

Divorced is for persons who have been legally separated from their spouse and are living separately, are single (not living together with someone else) and not remarried.

Separated is for persons who have not been legally separated from their spouse but are living separately and are single (not living together with someone else). The code for 'Others' encompasses those living together without being married.

When an interview of the patient, relative or accompanying person has not been done and the overall patient data is obtained from the medical records or other sources, it may be possible to get some information on the marital status. This could be based on C/o name which may be specified as husband of or wife of and sometimes as 'late'. Based on the best available information coding on marital status may be done. This should be indicated as such in the form. However, it is highly desirable that the accuracy of this information is confirmed through subsequent contact of the patient/relative through telephone or other means of communication.

Guidelines for Data Entry:

Item	***Number of characters assigned for coding***
Marital Status	1

Codes:

1	=	Unmarried (child also to be given this code)
2	=	Married
3	=	Widowed
4	=	Divorced
5	=	Separated (Not Divorced)
8	=	Other …… (specify), e.g., living together, gay, lesbian, more than one spouse etc
9	=	Unknown/ Not stated

***Quality Checks**:*

Logical checks will be done and any code other than that specified will amount to coding error.

17. Education* Mandatory field

This is recorded for patients above the age of 7 years

Definition and Description:

Illiterate: A person who cannot read and write but can speak his/her mother tongue. No evidence of schooling.

Literate: A person who can read, write and speak his/her mother tongue but no evidence of formal schooling. A person has no certificate from a school or University. However, it includes persons who had participated in the Adult Literacy programmes of Government of India and received a certificate of attendance.

Primary: A person who has some evidence of schooling and /or studied up to 5th standard; excluding nursery and kindergarten (1st standard to 5th standard).

Middle: Passed 5th standard with or without further study in 6th or 7th or 8th standard.

Secondary/Higher secondary: Passed 8th standard with or without further study in 9th or 10th or 11th standard i.e., Matriculation and Secondary School Leaving Certificate.

Technical after Matriculation: Certificate or Diploma awarded by Industrial Training Institute after passing matriculation or Secondary School.

Graduate and above: (include Intermediate – Science /Art/Commerce Graduation/Post-Graduation from a university such as B. A / B.Sc./ B. Com/M. A/M.Sc./M. Com/P.H.D./M.B.B.S./M.D./M.S. and include specialization from India/Abroad. Engineering Qualifications: B.E./M.E. (Civil / Electrical / Mechanical / Metallurgical)

For children below seven years of age, the above educational listing is not applicable and therefore code 0 is given.

Guidelines for Data Entry:

Item	*Number of characters assigned for coding*
Education	1

Codes:

0	=	Not Applicable (for children below 7 years)
1	=	Illiterate
2	=	Literate
3	=	Primary
4	=	Middle
5	=	Secondary
6	=	Technical after Matriculation
7	=	Graduate and Above
8	=	Others……(specify)
9	=	Unknown

Quality Checks:

The above codes will be checked for logical errors with age.

18. Habits and Co-morbidities* Mandatory field

Select all that apply

Definition and Description (*for completing core form****):***

Data related to the behavioural habits and co-morbidities of cancer patients are to be recorded in this section.

A. Habits:

1. Tobacco use:

Smoking:

History of tobacco smoking is present. Record the duration of smoking in months. Tobacco smoking is defined as use of products like Manufactured cigarettes, hand rolled bidis, Hooka, Hookli, Chhutta, Dhumti, Chillum, which contain tobacco in any form and then lit to inhale the smoke formed by simmering tobacco leaves.

Smokeless:

History of consumption of smokeless tobacco is present. Record the duration of smokeless tobacco in months.

Tobacco smokeless is defined as use of products like Betel quid, Khaini, Mawa, Gutkha, Pan Masala, Tuibur, Zarda which contain tobacco in any form and are either chewed, snuffed or ingested with water or applied as paste.

Betel Nut with tobacco:

Select yes if history of consumption of Betel Nut with tobacco is present. Record the duration for use of betel nut with tobacco in months.

Chewing of betel nut along with tobacco is recorded under this section.

Betel Nut without tobacco:

Select yes if history of consumption of only Betel Nut without tobacco is present. Confirmation of betel nut use without tobacco is mandatory. Record the duration for use of betel nut without tobacco in months.

Alcohol use:

History of alcohol intake is present.

Alcohol intake is defined as intake of 1-2 servings (more than 60ml) per day of alcoholic drinks like Beer, Rum, Vodka, Whisky, Brandy or local made alcohol Products at least two to three times a month.

Select unknown for all these habits if the information is not available.

B. Co-morbidities:

Select all that apply

Tuberculosis:

Select yes if history of present or past tuberculosis is present. Record the duration of disease in months

Tuberculosis (TB) is an infectious disease usually caused by Mycobacterium tuberculosis (MTB) bacteria. Tuberculosis generally affects the lungs, but it can also affect other parts of the body.

Hypertension:

Select yes if history of Hypertension (clinical) is present. Hypertension or high blood pressure is chronic elevation of the blood pressure above the normal range expected in a particular age group. (Systolic BP >140 mm Hg and Diastolic BP >90 mm Hg).

Patients usually give H/o Hypertension based on the onset of intake of antihypertensive medications.

Diabetes mellitus:

Select yes if history of Diabetes mellitus (clinical, and biochemical) is present.

It is a metabolic disorder that manifests as hyperglycaemia.

- Type I Diabetes mellitus – insulin deficiency.
- Type II Diabetes mellitus – insulin resistance, impaired insulin secretion, excessive hepatic glucose production.

Patients usually give H/o Diabetes mellitus according to the onset of intake of anti-hypoglycaemic (oral, injectable) medications.

Ischemic heart disease:

Select yes if history of Ischemic heart disease is present.

Ischemic heart disease also known as coronary heart diseases is a condition in which there is an inadequate supply of blood and oxygen to the muscles of heart. Diseases included under ischemic heart disease are angina (stable & unstable), myocardial infarction and chronic coronary disease.

Bronchial asthma/COPD:

Select yes if history of Bronchial Asthma or chronic obstructive pulmonary disease (COPD) is present.

Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease that causes obstructed airflow from the lungs. Emphysema and chronic bronchitis are the two most common conditions that contribute to COPD. . Major risk factor is cigarette smoking while certain occupational exposures (mining, cotton textiles, etc.) also cause COPD. Manifests clinically as cough with sputum, severe dyspnoea (on exertion), chest tightness, wheeze, etc. Presence of airflow obstruction is determined by reduced FEV1/FVC ratio on spirometry.

Bronchial asthma is a chronic, inflammatory diseases of the airways characterized by airflow obstruction, bronchial hyperactivity and a mucus production. It is clinical syndrome characterized by recurrent episodes of airway obstruction which resolve spontaneously or as a result of treatment.

Stroke:

Select yes if history of stroke is present.

Stroke is defined as rapidly developing clinical signs of focal or global disturbance of cerebral function with symptoms lasting for 24 hours or longer, or leading to death with no apparent cause other than of vascular origin.

Depression:

Select yes if history of Depression is present. Record the presence of depression if diagnosed by psychiatrist or by mental health physician.

Depression is a common illness characterized by persistent sadness and a loss of interest in activities that one normally enjoys, accompanied by an inability to carry out daily activities, for at least two weeks. Other symptoms include loss of energy; change in appetite; sleeping more/less; anxiety; reduced concentration; indecisiveness; restlessness; feelings of worthlessness, guilt or hopelessness; and thoughts of self-harm or even committing suicide.

Chronic hepatitis B:

Select yes if history of Chronic hepatitis B is present.

Hepatitis B is a viral infection that attacks the liver and can cause both acute and chronic disease. It is not possible on clinical grounds to differentiate hepatitis B from hepatitis caused by other viral agents; hence laboratory confirmation of the diagnosis is essential. Chronic infection with hepatitis B virus, with presence of hepatitis B demonstrated by positive hepatitis B surface antigen, (HBsAg) for ≥ 6 months (variable presence of hepatitis B e antigen (HBeAg) and HBV DNA).

Chronic Hepatitis C:

Select yes if history of Chronic hepatitis C is present.

Hepatitis C is an inflammation of the liver caused by the hepatitis C virus. Diagnosis of Chronic hepatitis C include testing for anti-HCV antibodies with a serological test and if the test is positive for anti-HCV antibodies, a nucleic acid test for HCV ribonucleic acid (RNA) is needed to confirm chronic infection.

Non-alcoholic Fatty Liver Disease (NAFLD):

Select yes if history of NAFLD is present.

Non-alcoholic fatty liver disease (NAFLD) is defined as the presence of fat in the liver (hepatic steatosis) either on imaging or on liver histology after the exclusion of secondary causes of fat accumulation in the liver (e.g., significant alcohol consumption, certain medications, and other medical conditions). Confirmation of

NAFLD is done through Ultrasound, CT scan, MRI scan, MR elastography and liver biopsy.

Chronic Kidney Diseases:

Select yes if chronic kidney disease (clinical, biochemical) is present.

CKD is defined as long standing, irreversible impairment of kidney function. Clinical spectrum depends on the extent of reduction of Glomerular filtration rate (GFR). Common causes are nephropathy (diabetic, hypertensive, ischemic, HIV, etc.), polycystic kidney disease, etc. Manifests clinically as decreased urine output, peripheral oedema, loss of lean body mass, etc., and laboratory findings show Uraemia.

Human Immunodeficiency Virus (HIV):

Select yes if HIV (serological test is positive) is present.

Human immunodeficiency virus (HIV) is an infection that attacks the body's immune system. Acquired immunodeficiency syndrome (AIDS) is the most advanced stage of the disease. Serology test for HIV is positive.

Hypothyroidism:

Select yes if Hypothyroidism (clinical, biochemical) is present.

Hypothyroidism is a state of underactive thyroid due to thyroid failure (primary), or pituitary or hypothalamic disease (secondary). Common causes include small thyroid (hypoplasia or aplasia), Iodine deficiency, drug- induced / iatrogenic, autoimmune thyroiditis, pituitary or hypothalamic tumours / trauma, etc. Manifests clinically manifests as lethargy, weight gain, cold intolerance, thinning of hair, loss of lateral eyebrows, slow physical and mental activity, etc., and biochemically as raised TSH (> 4 milliunits/litre) and reduced free
T4 (< 0.8 ng/dl);

Select unknown for all these co-morbities if the information is not available.

C. Anthropometric measurements:

Height:

Height is measured in centimetres; field with integers; measured in centimetres

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Height	4

Range check- 70-250

Weight:

Weight is measured in Kilograms; numeric field with integer; measure in kilogram',

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Weight	4

Range check (30-200).

19. HISTORY OF FAMILIAL CANCERS (for cancers of breast, ovary, colon, prostate, endometrial, melanoma, thyroid, pancreas) *

* Mandatory field

Definition and Description (*for completing core form****):***

Record the history of familial cancer for cancers of breast, ovary, colon, prostate, endometrial, melanoma, thyroid, pancreas. Should ask if there is presence of these cancers in the family.

If these cancers were present, record the type of cancer and the relatives who have got these cancers. First degree relative and second-degree relatives have to be categorized accordingly. First degree relatives include parents, sibling and offspring. [3] Second degree relatives include maternal and paternal grandparents, grandchildren, nieces and nephews. Other relatives to be categorized under others category. Age and date of diagnosis have to be recorded in the respective fields.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
History of Familial cancers	01

Codes:

1	Yes
2	No
9	Unknown

If yes, then the codes to the following responses are

If yes, Type of cancer

1	Diagnosed with same type of cancer
2	Other type of cancer

If yes, Type of relative

1	First degree relative
2	Second degree relative
8	Others specify

Guideline for data entry

Item	***Field length assigned for coding***
Primary site of tumour	25
Age at diagnosis	2
Date of Diagnosis	6

II Diagnostic Details

20. Method of Diagnosis* Mandatory field

Definition and Description *(for completing core form)**:***

This is one of the most important items of information.
In over 80% of cases a microscopic pathology report, whether histopathology, cytology or haematology (peripheral blood smear or bone marrow smear) is at hand. Thus, the following will be a microscopic confirmation of the diagnosis of cancer. These include – Histology of Primary, Autopsy with concurrent or previous histology, histology of Metastasis, Bone marrow, Blood film and Cytology including fine needle aspiration cytology. This report would routinely be available in the medical case record. Such information could also be obtainable from the pathology department (registers or reports) or laboratories (private and government). The advent of fine needle aspiration cytology has considerably improved the proportion of cases having a microscopic diagnosis. Sometimes more than one or one type of microscopic report may be available for a single patient. Thus, a patient with breast cancer could have a biopsy of the axillary lymph node with a diagnosis of metastatic carcinoma. Soon after, a simple mastectomy could be performed with a diagnosis of infiltrating duct carcinoma in the histopathology report. The same patient could have a diagnosis of metastatic carcinoma based on fine needle aspiration cytology of the lymph node.

In all such cases with more than one microscopic diagnosis and where no variation is observed between or among the reports in the different types of specific microscopic diagnosis the order of the most valid basis is as follows:

i) Histopathological diagnosis of the primary site of cancer including that obtained through autopsy;
ii) Histopathological diagnosis of metastatic site that is anatomically closest to the primary site;
iii) Bone marrow biopsy (that has undergone usual histo-pathological processing);
iv) Bone marrow aspiration smear;
v) Peripheral blood smear;
vi) Fine needle aspiration cytology of primary anatomical site of tumour;
vii) Direct smear from any bodily fluid e.g., ascitic/pleural fluid for Cytological examination;
viii) Smear made from secretions/excretions, e.g., vaginal/cervical smear;
ix) Fine needle aspiration cytology of metastatic sites;
x) Imprint smear preparations;
xi) Serial no's vii to x could be interchanged if any of them, reveal the primary anatomical site of tumour based on the cell morphology.

Sometimes, where there is more than one microscopic report, variations in diagnosis between or among the reports could be observed. This could be either with reference to the primary site of tumour or with reference to the morphological diagnosis. The concerned pathologist and/or treating clinician for primary site and the concerned pathologist(s) for the differences in morphological diagnosis latter should be consulted to arrive at a final diagnosis. The latter instance is not unusual in patient who have undergone biopsy/surgery outside and have a microscopic diagnosis from a pathology laboratory other than the reporting institution. At other times there could be variation between different forms of microscopic diagnosis, even with reference to confirmation of malignancy. In few other cases the wording of the final diagnosis in the pathology report may not be clear / unequivocal. In all such cases the pathologist / pathologists who report on the slide / slides have to be consulted for the final diagnosis.

As a general rule the method of diagnosis for those cases (of solid tumours) without a primary histopathology diagnosis should be constantly verified for a possible more valid basis of diagnosis at a later date and updated accordingly. For example, a patient with advanced cancer of stomach may be diagnosed through fine needle aspiration cytology of a metastatic lymph node. The patient may stabilize after a course of chemotherapy and an endoscopic biopsy may be done or even an open abdominal surgery with resection of the tumour may be done. With this a subsequently primary histo-pathological diagnosis may be available. The general condition of the patient may not have permitted such procedures before initiating chemotherapy. Registries are advised to review the case records of all such patients especially those with a cytology diagnosis, where further investigations are likely periodically or at least once when the data of a particular year is being finalized, and accordingly update the registry records.

Guidelines for handling cases without a microscopic diagnosis of cancer:

As stated above, under usual circumstances, a microscopic diagnosis is the basis of diagnostic confirmation of cancer. However, due to several reasons a microscopic diagnosis may not be available for all cancers in a given centre or the cancer registry.

Some of these reasons could be that cases of cancers could present at an advanced stage, where an invasive procedure like a biopsy may be difficult or not possible to perform. These cases could have just a clinical diagnosis or at best a radiological diagnosis. Sometimes, internal malignancies like those of cancer of the oesophagus or anywhere else in the gastrointestinal tract or like cancer of the lung or that of the brain, the surgeon may have difficulties in doing a biopsy. Even if a diagnostic procedure such as introducing a scope is done, the tissue obtained may be inadequate or not representative of the tumour in question. These cases however may have a clear diagnosis based on imaging techniques. Such imaging techniques range from simple X-ray, Barium Swallow or a CT / MRI scan. On other occasions an endoscopist (usually a surgeon) is able to actually visualise the tumour, but is unable to take an

adequate representative sample for microscopic diagnosis. Then, there can be other instances where certain biochemical or immunological tests or tumour marker studies may reveal the presence of tumour and no microscopic confirmation of diagnosis is available. In all of the above instances, the case has to be registered as a cancer case with code according to the appropriate method of diagnosis.

As a general rule the method of diagnosis for those cases without a microscopic diagnosis should be constantly verified for a possible microscopic diagnosis at a later date for such a diagnosis and updated accordingly. For example, a patient with advanced cancer of stomach may stabilise after a course of chemotherapy and an endoscopic biopsy may be done subsequently with a microscopic diagnosis of adenocarcinoma. The general condition of the patient may not have permitted an endoscopy before initiating chemotherapy. Registries are advised to review the case records of all patients that do not have a microscopic diagnosis periodically or at least once when the data of a particular year is being finalised.

In all instances where the microscopic diagnosis is not available the following steps are recommended before including the case in the cancer registry:

a) This case record has to be reviewed by a Medical Officer or a trained and experienced tumour registry staff. If cancer directed treatment has been commenced then that case should be included;
b) Where no information on cancer directed treatment is available on the record, then the concerned physician, who is In-charge of the patient, has to be consulted in order to confirm whether it is actually a cancer case. Once that physician confirms, this patient can be included as a cancer case;
c) Should such a confirmation be not possible, then the clinical diagnosis if unequivocal should be taken as the final diagnosis;
d) If all of the above have not led to a confirmation of cancer, such cases should be followed up over a period of time and if required home visits / contact must be made to confirm the diagnosis;

The last can be minimized or totally avoided if timely action is taken by the registry staff in order to ascertain the diagnosis.

Accordingly, in the absence of a microscopic diagnosis of cancer the order of the most valid basis of diagnosis is as follows:

i) Specific biochemical and / or immunological tests including tumour markers;

Human Chorionic Gonadotrophin (HCG)	In diagnosis of choriocarcinoma (usually > 100,000 iu in urine)
Prostate Specific Antigen (PSA)	In diagnosis of prostate carcinoma (usually >10 g/l serum)

Alphafetoprotein (AFP)	In diagnosis of hepatocellular carcinoma (usually > 200 ng/ml serum)
Catecholamine degradation products	In diagnosis of neuroblastoma (HVA, VMA)
Elevated serum immunoglobulins	Myeloma (IgG>35 g/l or IgA >20 g/l)
Waldenstrom's macroglobulinemia	(IgM>10g/l)
Urinary immunoglobulins	Myeloma (light chain excretion > 1 g/24 hr) \

ii) Exploratory surgery or autopsy without histology;

iii) Endoscopic diagnosis again without histology (including inadequate sample);

iv) Imaging techniques, which include isotopes, CT & a MRI scan, Ultrasonography and X-ray.

v) Clinical diagnosis only.

In most cases the diagnosis of cancer would be more or less clear and straight forward with agreement between clinical imaging techniques and microscopic diagnosis. However, in some instances, variation could arise. Generally, the microscopic diagnosis (both primary site and morphology diagnosis) is taken as the final diagnosis and on that basis, cancer directed treatment is initiated. Occasionally, this may not be clear. In such cases where variation is observed between different forms of investigation and the treatment details are also not clear or available, the treating physician should be consulted. The abstractor may then find it difficult to conclude whether the case is indeed a malignant neoplasm and whether the case needs to be included in the cancer registry. Here also, the concerned pathologist and if necessary the clinician has to be consulted.

Code 4: Death Certificate Only (DCO), is used when no other medical reports are available – the DCO is the only source of information.

Guidelines for Data Entry:

Item	***Fields length assigned for coding***
Most valid Method of Diagnosis	1
Detailed Method of Diagnosis	1

Most valid Method of Diagnosis

Codes:

1. Clinical Only
2. Microscopic
3. X-Ray/Imaging Techniques
4. DCO
8. Others (Specify ……)
9. Unknown

Detailed Method of Diagnosis

If Microscopic (2 above) *Codes:*

01	=	Histology of primary site
02	=	Histology of metastasis
03	=	Autopsy with histology
04	=	Bone marrow
05	=	Blood film
06	=	Cytology of Primary
07	=	Cytology of metastasis
08	=	Immunohistochemistry
09	=	Cytogenetics
10	=	Flowcytometry
88	=	Others

If X-Ray/Imaging Techniques (3 above)
Codes:

01	=	X-Ray
02	=	Isotopes
03	=	Angiography
04	=	Ultrasonogram
05	=	CT scan
06	=	MRI
07	=	PET scan
88	=	Others (specify)

If Others (8 above) *Codes:*

01	=	Endoscopy
02	=	surgery without histology
03	=	Specific biochemical and / or immunological tests
04	=	Biological markers
88	=	Others (specify)

Quality Checks:

The usual range checks are carried out.

The code for method of diagnosis is checked with the primary and/or secondary histology. Generally, microscopic diagnosis must not have histological coding that represents a morphological diagnosis of cancer. Likewise, microscopic confirmation of diagnosis should have a histology (primary or that of metastasis) code with a morphological diagnosis of cancer. This is further discussed under the coding of anatomical sites.

21. Longest duration of symptoms related to cancer * Mandatory field

Definition and Description *(for completing core form)**:***

The maximum or most extended period during which symptoms associated with cancer persist in an individual. Cancer symptoms can vary widely depending on the type of cancer, its stage, and other factors. Common cancer symptoms may include unexplained weight loss, fatigue, pain, changes in skin or moles, persistent cough, changes in bowel or bladder habits, and more.

However, it's important to note that the duration of symptoms can be influenced by various factors, such as the type and stage of cancer, the effectiveness of treatment, and individual variations in how the disease progresses. Some cancers may have a relatively slow progression with mild symptoms, while others can be more aggressive and lead to more rapid and severe symptoms. Duration of present symptoms have to be recorded in months.

Guidelines for Data Entry:

Item	*Field length assigned for coding*
Maximum period of symptoms in months	2

22. Complete pathological diagnosis *(With complete Description of Primary Site of* Tumour *and Morphological Diagnosis)*

22.1 Anatomical Site of Specimen/Biopsy/Smear* * Mandatory field

Definition and Description *(for completing core form)**:***

For a histopathology diagnosis, the exact topographical site of biopsy or of the resected specimen should be clearly stated in words. The biopsy taken for histopathological examination could be from the primary site of tumour, lymph node biopsy (primary in lymphomas or metastatic site) or organ where metastasis has occurred. Similarly, when surgical resection of the tumour and/or organ has been performed the precise anatomical site of surgery or organ operated on should be clearly noted.

Where a cytological examination is the basis of diagnosis the nature of smear should be specified in as many words with complete description. Cytological examination of the smear could range from a sputum or ascitic fluid to fine needle aspiration of an organ site or lymph node. For a haematological diagnosis the smear examination could be a peripheral blood smear or a bone marrow aspiration smear.

It is particularly important for the abstractor to observe whether the primary site of tumour has been the point of tissue sampling or it is the secondary/metastatic site.

A given patient may have more than one tissue sample taken for diagnostic investigation. In such instances, the sample that was taken as the basis for arriving at the final diagnosis should be the one that is stated.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Anatomical site of Specimen/Biopsy/Smear	99

Quality Checks:

The quality checks on this item pertain to verifying the information provided with that of the description on the primary site of tumour and the codes for method of diagnosis.

22.2 Pathology Slide No and Date of Reporting: # Optional field

Definition and Description *(for completing core form)**:***

This is the number allotted to the slide in the pathology lab. It can be from surgical pathology/cytology/ haematology. date of reporting is the specimen taken date.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Pathology slide No	50
Pathology Date	6

22.3 & 22.4 Primary Site of Tumour Topography and Morphology*

Mandatory field

Definition and Description *(for completing core form)**:***

Primary Site identifies the site of origin of a tumour. A primary cancer is one that originates in a primary site or tissue and is not an extension, a recurrence, or a metastasis.

The exact primary anatomical site of the tumour including the sub-site wherever relevant should be written. This should be followed with the morphological description of the tumour when a microscopic diagnosis is made. Where there is no microscopic diagnosis and the most valid basis of diagnosis is through other means the final diagnosis as mentioned in the clinical records may be written. Normally this is not a morphological description except in some types of tumours. Such combinations of specific morphology description followed by such codes where there is no microscopic diagnosis but is acceptable are given in the next section on coding.

For all other diagnoses without a microscopic examination, care should be taken not to state a morphological term. For example, a cancer of the cheek that has been diagnosed as 'Clinical Only' should not be noted in the description as carcinoma of the cheek. Again, for example a cancer of the oesophagus diagnosed through 'X-ray' cannot be written as carcinoma of the oesophagus though many times this may be stated as such in the clinical record. The term 'carcinoma' denotes a morphological diagnosis that can only be certified with a microscopic examination and which cannot be stated based on other methods of diagnosis.

Statements on diagnosis in the case file or report could be 'Metastatic carcinoma of the lung'. This could mean two things – a) a carcinoma of the lung that has metastasized to any other site/organ(s) or b) that the lung has a metastatic carcinoma from another site/organ. The abstractor should carefully review the case file and if necessary consult the medical officer. Accordingly, the description statement should be unambiguous, thus for the scenario a) it should be Carcinoma of the lung with secondaries/metastases in some other site; and, for scenario b) it should be Unknown primary site (if the primary site cannot be identified) with metastasis to the lung.

MPNST can be Malignant Peripheral Neuroectodermal Tumour (Morphology code: 9364/3) or Malignant Primitive Neuroectodermal Tumour (Morphology code: 9473/3). As the morphology codes of these two tumours are different, signifying distinct disease entities, care should be taken to verify with the pathologist and write the expanded form of the diagnosis.

When a morphological (microscopic) diagnosis is available and the primary sits indicated is an ill-defined site, effort should be made to obtain the exact primary site of origin. Thus, when a diagnosis is mentioned as 'low grade tumour of arm' the

reporting pathologist and/or surgeon who did the biopsy/resection should be contacted for the exact tissue of origin (whether skin or connective tissue-muscle/bone etc). If this same diagnosis is mentioned as 'low grade sarcoma of arm', then, one may possibly assume that it is from the connective tissue, but it may be better to clarify.

Guidelines for Identification of Primary site of tumour:

Every effort must be made by the concerned staff to get to know the primary topographic site of tumour. Usually, this is readily available from the medical case record or the pathology report. In a cancer centre also, this information is available in most cases. The possible scenarios where the primary site of cancer may not be readily available and the recommended timely action expected to be taken by the concerned staff is given below:

a) In a cancer centre, despite the best of investigations the exact primary site of cancer may remain unknown. The concerned clinician and pathologist have to be contacted and the grounds on which cancer directed treatment is initiated may provide some leads;

b) In any hospital, patients could come at an advanced stage of malignancy when active work-up of the patient for identifying the primary site of tumour may not be possible and a clinical examination may not reveal the primary site. However, a diagnosis of malignancy may be arrived at based on the clinical examination and/or a sample of smear or biopsy may show malignant cells under the microscope. If the patient survives to undergo further investigations, the concerned staff should follow-up the case. As in a) above the concerned clinician has to be immediately contacted for primary site of tumour.

c) Many a time the pathologist either in a hospital or a private pathology laboratory receives specimens or biopsies without the nature of suspected illness/disease condition or the site of biopsy/surgery. If the tissue sample is small and after due processing a clear-cut morphological diagnosis of malignancy is arrived at, the concerned pathologists may send the report as such without mentioning the primary site of tumour. In such cases, the registry staff should immediately look for the respective case record and if necessary contact the concerned clinician. Based on the case record the medical officer assisting the registry or experienced registry staff, may per se be able to identify the primary site of tumour. The details of the actual site of biopsy could be available in the case record or other investigations can indicate the primary site. For example, a patient with a biopsy of the neck node that has a diagnosis of metastatic squamous cell carcinoma, may have a barium swallow that indicates a cancer of the oesophagus.

d) The above scenario may become more difficult to tackle if the patient has had a biopsy on an outpatient basis. The respective department/unit that conducted the biopsy has to be immediately identified. The doctor who performed the biopsy should be consulted for arriving at the primary site of tumour; if

necessary, the patient has to be kept track of for his/her follow-up visits to the same or other departments.

e) The above may become still more difficult if a private pathology laboratory that receives specimens and samples from diverse sources is the source of registration of the cancer case. The nursing home or hospital from where the sample was received and the concerned clinician should be immediately contacted. In such situations (as also in c & d above) it would be helpful if the local registry 'educates' the pathologist to:
    i) either accept samples with complete details (disease condition, site of biopsy etc.) mentioned in the requisition slip; or
    ii) at least contact the concerned clinician (for details of primary site etc.) before signing out the report.

Matching with existing central data bases or records or with that of other sources of registration may also help in identifying duplicate case records which could provide information on the primary site of tumour. This is especially true for cases obtained through death certificates.

All of the foregoing situations can meet with considerable success if registry staff, are collating and abstracting current (maximum one week) cases and prompt immediate action along the above lines in a systematic manner is undertaken. However, the issue becomes much more difficult and complex in direct proportion to the delay in abstracting cancer cases and the time taken for action. A registry should, over a period of time, identify the weak zones in data collection where identifying the primary site in a substantial number of cases poses a problem. For example, this could be in the outpatient unit of the ENT department. Therefore, whenever a biopsy or specimen with a suspicion of malignancy is received from such units for pathological examination, registry staff should immediately be alerted and the concerned surgeon contacted for details of primary site of tumour.

Whenever action is taken and discussions are held with the concerned clinician/pathologist the summary of discussions and the conclusion should be recorded in the core form.

Guidelines for Identification of sub-site of tumour

In certain anatomical sites (see list below), the sub-site from where the tumour has originated is an important qualitative attribute of the data available and collected. Information on the sub-site is of value in analysis of relative proportions of cancers according to different sub-sites and calculation of incidence rates. It could also be consequential while undertaking case-control studies in epidemiology where different risk factors with reference to a cancer of a particular anatomical site are looked into. Therefore, registry staff who is assigned the task of data collection and abstraction

should make persistent efforts along the lines listed above for gathering information on primary site of cancer.

For coding of overlapping sub-sites or multiple lymph nodes see below under coding.

Guidelines for Data Entry:

Item	*Field length assigned for coding*
Primary Site of Tumour – Topography	99
Morphology	254

The exact description of the primary site of tumour followed by the morphological description should be written without abbreviations in the forms and entry into the computer done accordingly. For example, squamous cell carcinoma of skin is written as well differentiated squamous cell carcinoma and not SCC, where SCC is also written for small cell carcinoma of lung. Whenever a microscopic diagnosis is not available the morphological diagnosis should be replaced with the description given by the clinical/radiological or other method of diagnosis as the case may be. This description generally cannot connote a morphological diagnosis. For example, a cancer of the oesophagus diagnosed through X-ray cannot be called carcinoma of the oesophagus assuming it to be so. However, there are certain specific morphology descriptions or codes that are considered acceptable even if there is no microscopic diagnosis (see table in the next section).

Quality Checks:

The quality checks on this item pertains to verifying the information provided with that of the description on the anatomical site of specimen/biopsy, the codes of primary /secondary site of tumour (both topography and morphology) with the primary site of tumour and the codes for the method of diagnosis. Some coding consistencies within and between registries can also be verified. This pertains to especially some specific combination of topography sites where misclassification or miscoding is possible. These include codes under Oropharynx (C10) and those under Larynx (C32). For example, anterior surface of epiglottis has a code of C10.1 whereas epiglottis NOS has a code of C32.1. Similarly, some sub-sites under Hypopharynx (C13) could be coded as one of the subsites under Larynx (C32). Another combination of sites where one code could be given for the other is Corpus Uteri (C54) and Uterus, NOS (55.9). Further instances could be where ambiguous statements (example given above) in diagnosis could lead to incorrect coding. Another example could be carcinoma cheek. The experienced registry staff would automatically code (either after verification or without verification) to ‘cheek mucosa’ (C06.0), whereas a fresh coding clerk may code to ‘skin of cheek’ (C44.3). Hence, the correct description should be entered in the form and subsequently onto the computer.

23.Coding according to ICD–O–3 & ICD-10

23.1 & 23.2 PRIMARY SITE OF TUMOUR – TOPOGRAPHY (Include sub-site if any**) and**
PRIMARY HISTOLOGY – MORPHOLOGY* Mandatory field

23.3 & 23.4 SECONDARY SITE OF TUMOUR & MORPHOLOGY OF METASTASIS[#] Optional field

Definition and Description *(for completing core form)**:***

The detailed description of the coding according to ICD-O-3 is given in the WHO publication: International Classification of Diseases – Third Edition.

These include, the 'Structure and Format of ICD-O-3' (pages 8-19); 'Summary of Principal Rules for using ICD-O-3' (pages 20-22) including 'Coding of Overlapping sub-sites (page 20); 'Coding guidelines for Topography and Morphology' (pages 2334), 'The WHO grading system for Central Nervous System Tumours' and the ICDO3 grade code (pages 39-40).

Staff working in the registry, have to closely and strictly follow the guidelines mentioned there-in. A couple of areas that are done differently by NCRP and in a little more detail pertain to codes for method of diagnosis (which has been detailed above) and in coding secondary site of tumour (given below). For these as well as for a few other common items (where ready reference to details is required) with some additional guidelines particularly those specific to NCRP are spelt out below:

Reportable Neoplasms

As mentioned in the introduction all neoplasms with a 5th digit behaviour code of /3 according to ICD-O-3 are considered malignant and reportable to the registry and the NCRP. Cases, where the diagnosis is not conclusive, should be followed by the concerned registry staff. Case files of such patients should be reviewed again when finalising the data of the particular calendar year and included/excluded.

Coding when Primary Site of Tumour is unclear

The guidelines and efforts required for Identification of Primary site of tumour when this is not readily available has been spelt out in detail under the previous item 'Description of Primary Site of Tumour and Morphological Diagnosis'. If the precise site of origin cannot be determined, it may be possible to use the "NOS" category of an organ system or the ill-defined site codes C76.0 to C76.8. When the only available information on the malignancy pertains to metastatic involvement and one cannot

ascertain from pathology report or clinical diagnosis the origin of the primary site of cancer then the code for 'unknown primary site' has to be given. This will be C80.9 under ICD-O-3 and C77 to C79, as per metastatic involvement, in ICD-10. This information can be corrected when better information becomes available during the course of the patient's disease and/or treatment. If sarcoma is the morphology the primary site can be soft tissue after due consultation with treating physician/oncologist.

Provision for additional coding of Secondary – Metastatic Site of Tumour

One major difference or supplementary item in NCRP is the additional coding done whenever a diagnosis is based on secondary – metastatic site of tumour. Thus, whenever a patient has a diagnosis based on a biopsy of a secondary or metastatic site of tumour without any biopsy or specimen of the primary site this information is mentioned in the description and coding done accordingly.

Example 1:

A biopsy of the neck node may reveal a metastatic carcinoma of cervical lymph node with a primary tumour in the larynx. This patient may not undergo a biopsy of the laryngeal tumour or undergo surgery for the same. In such cases the primary site of tumour should be coded as:

Primary Site: Larynx, NOS ⟶ ICD-O-3 Code:

Topography- C 32.9
Morphology – 8000/3/9

Secondary Site: Cervical Lymph Node ⟶ ICD-O-3

Code: Topography – C 77.0
Morphology – 8000/6/9

However, this coding of secondary topography and morphology should be left blank and not coded when coding for primary site of tumour and morphology can be done based on a morphological diagnosis of the primary site of cancer. Thus, if a patient has a mastectomy with axillary lymph node removal for a breast cancer and the lymph nodes show metastatic infiltrating duct carcinoma along with the same diagnosis of the tumour in the main breast tissue (mastectomy specimen) coding should be done only for the primary site and primary morphology and the secondary site/morphology left blank. Similarly, where a patient has had a microscopic diagnosis of the primary site of tumour, and has other investigations like X-ray or CT-scan that show metastases in other organs (like lung, brain etc), only the primary site and morphology has to be coded and the secondary site/morphology left blank.

The foregoing practice is to enable analysis of the metastatic topography sites that form the basis of diagnosis.

Topography coding when certain Cytological smears alone constitutes the basis of Diagnosis

ICD-O-3 and ICD-10 do not provide code for cytology diagnosis separately. The topography code does not include code numbers for sputum, vagino-cervical secretions and fluids such as spinal fluid, urine, pleural effusion or ascitic fluid. However, such a diagnosis should be coded using morphology code as given in ICDO.

It is advisable to look into the case records and consult the treating physician for primary site. If such efforts have not proved successful, the following codes may be used when only cytology report is available and this is positive for malignant cells and it is not mentioned that it is metastatic. The recommended coding according to ICDO3/ICD-10 is as follows:

Sputum:	C34.9
Vaginal/ Cervical smears:	C57.9
Cerebral-spinal fluid:	C71.9
Pleural Effusion:	C38.4
Ascitic /Peritoneal fluid:	C48.2

Differences between ICD-O and ICD-10 (pages 5-8). A few additional guidelines for ICD-O-3 and ICD-10 are given below:

For most of the sites ICD-O-3 and ICD-10 codes are similar except for few sites. The sites that are same in the two systems are as follows:

ICD-O-3= ICD-10

C00, C01, C02, C03, C04, C05, C06, C07, C08, C09, C10, C11, C12, C13, C14, C15, C16, C17, C18, C19, C20, C21, C22 (C22.0 and C22.1 only), C23, C24, C25, C26, C27, C28, C29, C30, C31, C32, C33, C34, C35, C36, C37, C38, C39, C40, C41, C47, C48, C49, C50, C51, C52, C53, C54, C55, C56, C57, C58, C59, C60, C61, C62, C63, C64, C65, C66, C67, C68, C69, C70, C71, C72, C73, C74, C75, C76

The sites that differ in two systems are (ICD-O-3 not equal to ICD-10):

In ICD-10, C22.2 (Hepatoblastoma), C22.3 (Angiosarcoma of liver), C22.4 (Other sarcomas of liver), C22.7 Other and unspecified carcinomas of liver and C22.9 (Liver, unspecified) are not used in ICD-O-3. Such cases in ICDO3 are coded as C22.0 but are identified by morphology and behaviour code

while coding Sr. Nos. 54 and 56 in Population-Based Cancer Registry, if histopathology report is available. HBCR software will provide the appropriate code.

In ICD-10 site C26.1 for "Malignant neoplasm of spleen does not appear in ICD-O-3. In ICD-O-3, malignant tumours of spleen are coded as C42.2 followed by appropriate morphology.

Under ICD-O-3, Site Code C42 is for Haematopoietic and Reticuloendothelial Systems. No such code exists under ICD-10. These code numbers are used for the topography sites for most of the leukaemias and related conditions in ICDO that are coded to rubrics C81 to C96 in ICD-10. All leukaemia cases are coded as C42 under ICD-O-3 while they are coded as C91 to C95 under ICD10. Four-digit sub-classification of rubric C42.1- in ICD-O-3 is as follows:

C42.0 Blood
C42.1 Bone Marrow
C42.2 Spleen
C42.3 Reticuloendothelial Systems, NOS
C42.4 Haematopoietic system, NOS

If leukaemia cases are diagnosed through Blood Studies and/or Bone Marrow then all these cases should be coded as C42.1 under ICD-O-3 and C91 to C95 under ICD – 10.

Under ICD-O-3, Skin cancers are coded as C44. Under ICD-10, Skin cancers are coded as C43 and C44; C43-Malignant melanoma of skin; C44-Other malignant neoplasm of skin. In ICD-O-3, malignant melanoma of skin is identified by morphology and behaviour code (872-879 Nevi and Melanomas, ICD-O-3).

Under ICD-O-3, code numbers C77. – are used for both primary and metastatic neoplasm of lymph nodes. Thus, most of the malignant lymphomas (C81 to C88 in ICD-10) are classified as C77.– in ICD-O-3. Under ICD-10, Secondary neoplasms are coded to C77, C78 and C79 as follows.

Rubrics C77: Secondary and unspecified malignant neoplasm of lymph nodes.
C78: Secondary malignant neoplasm of respiratory and digestive systems.
C79: Secondary malignant neoplasm of other specified sites.

In ICD-O-3, malignant neoplasms of unknown primary site are coded as C80.9 while under ICD-10 such cases are classified to C80.

The C81 to C96 section of ICD-10 (pages 215 to 221) is used for malignant neoplasms with primary in lymphatic or haematopoietic tissues. These are coded in ICD-O-3 by their specific morphology code number and the behaviour code /3, combined with the appropriate site codes C00 to C80. The behaviour code /3 is used in ICD-O-3 for all primary malignant neoplasms, /6, is used to code metastatic neoplasms.

Under ICD-10, Malignant neoplasms of lymphatic and haematopoietic tissue are coded to C81 to C96 as following (Excludes: secondary and unspecified neoplasm of lymph nodes C77.-). Such codes do not exist in ICD-O-3; these tumours are coded as per the topography and morphology.

Rubrics : C81: Hodgkin's disease
(in ICD-10) : C82: Follicular (nodular) non-Hodgkin's lymphoma
: C83: Diffuse non-Hodgkin's lymphoma
: C84: Peripheral and cutaneous T-cell lymphomas
:C85: Other and unspecified types of non-Hodgkin's lymphoma
: C88: Malignant immunoproliferative diseases

: C90: Malignant myeloma and malignant plasma cell neoplasms
: C91: Lymphoid leukaemia
: C92: Myeloid leukaemia
: C93: Monocytic leukaemia
: C94: Other leukaemias of specified cell type
: C95: Leukaemia of unspecified cell type
: C96: Other and unspecified malignant neoplasms of lymphoid, haematopoietic and related tissue

Site Specific Histologies

Some terms for neoplasms are specific for certain sites or types of tissue. In other words, the identity (either in Latin or otherwise) of the anatomical site is already incorporated in the term. Some examples, are given here:

Nephroblastoma (Wilms' tumour) (8960/3) and hypernephroma (renal cell carcinoma) (8312/3), by definition, always arise in the kidney (C64.9) (*nephro: kidney*).

Hepatocellular carcinoma or hepatoma (8170/3) is always primary in the liver (C22.0) (*hepato: liver*).

Basal cell carcinoma (8090/3) usually arises in the skin (C44.-), the fourth digit be coded as appropriate (basal cell: occurs only in skin).

A number of histologies listed in the ICD-O-3 are associated with specific sites. These sites are given in parenthesis with the appropriate histology code (ICD-O-3, page:21, Rule:H). In general, if the case has a histology associated with a specific site in the ICD-O-3, this site code is used. However, it should be verified that there is not contradictory evidence to the use of the site. Thus, a patient diagnosed with metastatic hypernephroma with no mention of primary site should be coded to C64.9 (Kidney, NOS, ICD-O-3; Kidney, except pelvis, ICD-10).

In cases where no specific primary can be assigned clinically, the histology report may enable coding to organ systems such as "Gastrointestinal tract, NOS" C26.9 (ICD-O-3; ICD-10) or "Connective tissue, NOS" C49.9 (ICDO3; ICD-10).

Leukaemias are coded to "C42.1 Bone marrow "in ICD-O-3; Under ICD-10, Leukaemias should be coded, as per cell type, C91 to C95.

Mesotheliomas arise in mesothelial tissue such as the pleura (C38.4), the peritoneum, (C48.1 to C48.2) or rarely in the pericardium (C38.0) or ovary (C56.9). The primary site of a mesothelioma should normally be coded to one of those sites. In the specific case of "Mesothelioma of the lung", the primary site should be coded to pleura (C38.4) rather than lung (C34.-), since the origin of the tumour is from the pleura (visceral pleura) closely covering the lung rather than the lung parenchyma.

Choriocarcinoma of the female genital tract is a malignant tumour of trophoblasts that are found either in placental tissues ("Fetal membranes C58.9") or in rare cases in the ovary (C56.9). The tumour may also occur in the male testis (C62. _). It is suggested that these three sites be used to code primary site for such tumours.

When no information regarding the origin of the primary is available for a case with "metastatic malignant melanoma", the primary site should be coded to "Skin, NOS C44.9" in ICD-O-3 and "Malignant melanoma of skin, site unspecified C43.9" under ICD-10.

When a site is given in a diagnosis that is different from the site indicated by the site-specific code, in such cases before ignoring the site-specific code a careful and thorough review of the case along with the concerned clinician/pathologist is required before using a different code.

Hepato-cellular carcinoma of lung: In all probability, this diagnosis really means that the hepatocellular carcinoma (carcinoma of the liver) is metastatic in the lung, even though the word "metastatic" does not appear in the diagnosis. If it is so, the proper code for this diagnosis would be Lung, NOS (C34.9; Under ICD-O-3) and histology code (8170/6). In such cases also registry staff should discuss with concerned persons.

Lymphomas should be coded as generalized unless specified to a site.

Extra-nodal Lymphomas

As mentioned above lymphomas generally arise in lymph nodes. However, they could arise per-se in any other organ of the body like stomach, intestine, brain etc. In such cases the registry staff have to make sure (by consulting the concerned pathologist or clinician) that the origin of the tumour- lymphoma from an anatomical site other than the node is indeed true. Spread of the lymphoma to other organs from a nodal site should be ruled out.

Once it is confirmed that the case is truly an extra-nodal lymphoma the ICDO-3 Topography site code for that respective site should be given. For example, the codes to be given for a "small cell diffuse non-Hodgkin's Lymphoma" of the Stomach, Not Otherwise Specified (NOS) is as follows:

ICD-O-3: Primary Site: C16.9
Morphology: M9670/3/9
ICD-10: C83.0.

Fifth Digit Behaviour Code

The fifth digit behaviour code as listed in ICD-O-3 (page 66) is as follows:

/0 Benign
/1 Uncertain whether benign or malignant
Borderline malignancy Low malignant potential
Uncertain malignant potential
/2 Carcinoma in situ
Intraepithelial
Non-infiltrating
Non-invasive
/3 Malignant, primary site
/6 Malignant, metastatic site Malignant, secondary site
/9 Malignant, uncertain whether primary or metastatic site

As already indicated only neoplasms with a behaviour code of /3 are included in the registry. It may be noted that the ICD-O behaviour code /9 is inapplicable in an ICD-10 context because all malignant neoplasms are presumed to be primary (/3) or secondary (/6) according to other information on the medical record, as stated in ICD-10 (Volume 1, page 1180). Thus, all cancer cases are either primary or secondary as per ICD-10.

It is suggested that cases with behaviour code /3 and /6 be registered and sent to the Coordinating Unit. In case the HBCR is interested in cases with behaviour code /0, /1 and /2, they may collect such cases but these should not be submitted to the Coordinating Unit.

Guidelines for the selection of the proper histology codes are found in ICDO3 (pages 27-34).

Sixth Digit Code

The sixth digit code for histologic grading and differentiation as listed in ICDO-3 (page 67) is as follows:

Code		**Description**
1	Grade I	Well differentiated, Differentiated, NOS
2	Grade II	Moderately differentiated, moderately well differentiated, Intermediate differentiation
3	Grade III	Poorly differentiated
4	Grade IV	Undifferentiated, Anaplastic
9	Grade or differentiation not determined, not stated or not applicable	

The sixth digit code for immunophenotype designation for lymphomas and leukaemias is as follows:

Code	Description
5	T-cell
6	B-cell (Pre-B, B-precursor)
7	Null cell (Non-T-non-B)
8	NK cell (Natural Killer cell)
9	Cell type not determined, not stated or not applicable

(See ICD-O-3 for detailed description and coding rules)

Some examples of histology coding along with behaviour code and grade and differentiation on HBCR proforma are given below:

807032: Squamous cell carcinoma, grade II or Moderately well differentiated squamous cell carcinoma.
807034: Anaplastic squamous cell carcinoma
802134: Anaplastic type carcinoma
807064: Metastatic anaplastic squamous cell carcinoma
807039: Epidermoid carcinoma
807033: Moderately differentiated squamous cell carcinoma with poorly differentiated areas (the higher number in the grading code should be used when diagnosis indicates two different degrees of grading or differentiation)

The words such as "well differentiated ", "poorly differentiated" are many times used as an integral part of the histologic names for certain neoplasms. Thus "well differentiated lymphocytic lymphoma be coded as "967039". Malignant lymphoma" should be coded as (959039).

908239: Malignant teratoma, anaplastic type (ICD-O-3)
833139: Follicular adenocarcinoma, well differentiated type (ICD-O-3)

951239: Retinoblastoma, undifferentiated type (ICD-O-3)

Coding for "No Morphological Diagnosis of Tumour"

If the microscopic diagnosis is based on cytology or blood film or bone marrow examination, the specific morphology diagnosis given by the pathologist should be used for coding morphology. For cases where there is no histology or morphological nomenclature or description of diagnosis by the pathologist despite microscopically confirming the diagnosis of malignancy, then, one of the following codes should be used:

8000/3 - Neoplasm, malignant
8001/3 - Tumour cells, malignant (Diagnosed mainly by cytology)

Coding for "No Microscopic Confirmation of Tumour"

For cases with no microscopic confirmation of diagnosis (diagnosed by any of the means such as clinical, x-ray, Isotopes, endoscopy, angiography, exploratory

surgery or autopsy without histology, specific biochemical and /or immunological tests, ultrasound), codes 8000/3 or 9990/3 should be used.

(*Note: Since the morphology code 9990/3/9 (given in ICD-O-1) was a familiar code for coding primary neoplasms without a morphology of the primary site of tumour this code is also permitted instead of 8000/3/9. However, registries should be uniform in putting this into practice. In other words, one rule – code 8000/3 has to be used for all the cases in a given calendar year).*

However, there are certain exceptions where a morphological expression and code is accepted in the absence of a morphological diagnosis through microscopic verification. This is given in the succeeding paragraph.

"Specific" histology (morphology) codes in absence of microscopic verification

The ICD-O M code is not allocated for the purpose of specifying the basis of diagnosis. However, it would be extremely unlikely (or impossible) for some specific morphological diagnosis to have been made without a histological (or cytological) examination. However, certain combinations are exceptions to this general rule, as shown in the table below.

Combinations of specific morphology codes, and non-microscopic basis of diagnosis codes, which are considered acceptable *(The code for method of diagnosis will be utilised for distinguishing those cases with a microscopic diagnosis).*

MORPHOLOGY Code	**Description**
8800	(Sarcoma NOS)
9590	Lymphoma NOS
9800	Leukaemia NOS
8720	Melanoma
9140	Kaposi's sarcomas
8960	Nephroblastoma
9100	Choriocarcinoma
9500	Neuroblastoma
9510	Retinoblastoma
9732	Myeloma
9761	Waldenstrom's macroglobulinemia

8170	Hepatocellular carcinomas
8150-8154	Islet cell tumours, gastrinomas
9380	Glioma
9384/1	Subependymal giant cell astrocytoma
9530-9539	Meningioma
9350	Craniopharyngioma
8270-8281	Pituitary tumours

Please note that the term "carcinoma" can be used and coded only when there is a morphological – microscopic diagnosis. Clinical notes or a clinical diagnosis without such substantiation should be considered as 'cancer' and coded accordingly (8000/3 or 9990/3 – see below).

Coding for Compound Histology Diagnosis

When a pathology report has more than one histologic component, use the **higher code** unless there is a special ICD-O-3 code for this diagnosis (ICD-O-3).

Some illustrations of coding of most common combinations are given below:

Mixed adenocarcinoma and squamous cell carcinoma:	856039
Papillary and follicular adenocarcinoma:	834039
Mixed basal-squamous cell carcinoma:	809439
Transitional cell epidermoid carcinoma:	812039
Lymphosarcoma cell leukaemia:	982039

<u>Some Guiding Rules:</u>

1. A single lesion of one histologic type is considered a single primary even if the lesion crosses site boundaries

2. A single lesion with multiple histologic types is to be considered as a single primary and is coded to the highest histology code number in the absence of an appropriate "mixed code".

3. Simultaneous multiple lesions of the same histologic type within the same primary site will be considered a single primary. Further, if one lesion has a behaviour code of in-situ and another a behaviour code of malignant, still consider this to be a single primary whose behaviour is malignant.

4. Multiple lesions of the same histologic type occurring in different sites are considered to be separate primaries unless stated to be metastatic.

5. Multiple lesions of different histologic types within a single site are to be considered separate primaries whether occurring simultaneously or at different times.

   Similarly, multiple lesions of different histologic types occurring in different sites are considered separate primaries whether occurring simultaneously or at different times.

   Exceptions: "Adenocarcinoma in an adenomatous polyp" (821039) and "adenocarcinoma" (not arising in a polyp) (814039). By definition, "adenocarcinoma in an adenomatous polyp" is an earlier stage of disease than is a frank "adenocarcinoma". This latter tumour is the one in which the physicians will be concerned with and the one which will determine the treatment. Therefore, when both an "adenocarcinoma" and "adenocarcinoma in an adenomatous polyp" arise in the same segment of the colon within two months of diagnosis, code as "adenocarcinoma" (814039).

   Within each breast the following combinations of ductal and lobular carcinoma occurring within two months of each other are to be considered a single primary and the histology coded accordingly.

   (a) Infiltrating duct carcinoma (850039) and lobular carcinoma (852039), code to histology (852039).
   (b) Infiltrating duct carcinoma (850039) and lobular carcinoma-in-situ (852029), code to histology (850039).
   (c) Intraductal carcinoma (850029) and lobular carcinoma (852039), code to histology (852039).

6. If only one histologic type is reported and if both sides of a paired site are involved, a pathologist must be consulted in order to determine as to whether the patient has one or two independent primaries. If it is determined that there are two independent primaries, two proformas are to be filled with same registration numbers and other details.

   Exceptions: There are two exceptions to this rule.

i) Bilateral involvement of the ovaries in which a single histology is reported. ii) Bilateral retinoblastomas are always considered to be singe primaries.

Guidelines for Data Entry:

Item	*Number of fields assigned for coding*
ICD-O Coding (Primary Site)	3 (without "dot (.)" and "C")
Primary Histology	6 (without "M" & two slashes (/))
ICD-O Coding (Secondary Site)	3 (without "dot (.)" and "C")
Secondary Histology	6 (without "M" & two slashes (/))
ICD-10 Coding (Primary and Metastatic Site / Disease)	3 (without "dot (.)" and "C")

Apart from the actual numeric codes for topography and morphology there are other characters that form part of the coding that have to be considered while entering data. For the Topography code this includes the character 'C' and the 'dot' that follows two digits before the digit of the sub-site. Also, no space should be left after the C and before the numeric code. So, data entry has to be done in a uniform way. Thus, the code C15.9 for a cancer of the oesophagus could be entered in several ways:

C15.9
C159
159
C 15.9 and any permutation of these.

Similarly, topography codes up to C10 are coded C01, C02 etc and not as C1 or C2 ignoring the '0' before the second digit. Thus, the code for base of Tongue should be given as C01.9 and not C1.9 or C19 or C 1.9 etc.

Likewise, the code for morphology has several components other than the numeric digits. For example, in the code M-8070/3/9 could exclude all the characters 'M' the dash (-), and the two slashes (/) while doing the data entry and without any space between M and the dash or after the dash. Data entry should therefore be done in a consistent way.

The data entry software automatically fills the 'C' and the 'dot' for the topography code and for the ICD-10 code. Similarly, for the morphology code the software automatically fills the 'M' and the two 'slashes'. No provision has been made for the dash and the fields will not accept any such character or alphabet other than a numeric.

Quality Checks:

This is one of the most important key items of information collected by the registry. Several range, consistency and unlikely checks are carried out on the basis of this data. The quality control check programme of the International Agency for Research on Cancer has been further modified and many checks added so as to be applicable to the data collected by NCRP. Method of diagnosis and histology codes will be checked for consistency of coding, allowing for exceptions indicated above.

International Classification of Diseases for Oncology (ICD-O), Third Edition, Morphology Section: Numerical List () provide numerical codes for histological diagnosis.

The same rules and guidelines need to be followed for coding ICD-10. There is one additional difference. In ICD-10, some major sites have no '.9' following the first two digits which is existing for ICD-O-3 topography of the same site. The list of such site where '.9' following the first two digits exists in ICD-O-3 but not in ICD-10 is given below:

International Statistical Classification of Diseases and Related Health Problems (ICD), Tenth Revision, Vol.1, Morphology of Neoplasms Section also gives morphology code numbers by five digits (pages 1179-1204).

Sex code must not conflict with primary site code. Male cancer patients should not be classified under rubrics C51 (Vulva), C52 (Vagina), C53 (Cervix uteri), C54 (Corpus uteri), C55 (Uterus, NOS), C56 (Ovary), C57 (Other and unspecified female genital organs), C58 (Placenta). Female cancer patients should not be classified under rubrics C60 (Penis), C61 (Prostate gland), C62 (Testis), C63 (Other and unspecified male genital organs).

25. Laterality* Mandatory field

Definition and Description *(for completing core form)**:***

The topography sites that are considered as paired organs and qualify for coding for laterality (with ICD-O-3 codes in parentheses) are: Parotid gland (C07.9), Submandibular salivary gland (C08.0), Lung (C34.9), Bone, Joints, Articular cartilage of limbs (C40), Breast (C50), Ovary (C56.9), Kidney (C64.9), Eye and adnexa (C69) and Adrenal gland (C74).

Laterality and Second Primary: If it is determined that there is only one primary, laterality should be coded according to the side in which the single primary originated. If it is impossible to determine in which of the pair the single primary originated, laterality should be coded as "4". Bilateral involvement of the ovaries in which only a

single histology is reported, bilateral retinoblastomas and bilateral Wilms' tumour should be coded as '4'.

Guidelines for Data Entry:

Item	***Number of fields assigned for coding***
Laterality	1

Codes

0	=	Not a Paired Site
1	=	Paired Site
9	=	Unknown

If Paired Site,

Codes

1	=	Right
2	=	Left
3	=	Only one side involved, right or left origin, unknown
4	=	Bilateral involvement, laterality origin unknown
5	=	Paired Site Midline Tumour
6	=	Paired site, but no information concerning laterality

Quality Checks:

The usual range and consistency checks will be carried out.

26. Sequence* Mandatory field

Definition and Description *(for completing core form)**:***

It is not unusual for a given patient to have more than one primary site of cancer. Generally, the code '0' is given against this variable when the patient is registered as a case for the first time with a single site of cancer.

There are several rules regarding definition of more than one primary. Only a brief summary is provided here. This is to ensure consistency of reporting by each HBCR.

The factors that are considered in order to determine whether a given patient has more than one primary site of cancer are:

a) The anatomical site of origin of the tumour;
b) The date of first diagnosis;
c) The histological or morphological type of tumour;
d) The laterality.

Generally speaking, if there is a difference in the anatomical site where the malignant tumour originates, or when there is a clear-cut difference in the histology or morphological diagnosis identifying two separate cancers is easy. This would be regardless of the dates of diagnosis.

The following definition and rules (adapted from IARC/IACR) are given below:

1) Recognition of the existence of two or more primary cancers does not depend on time;
2) A primary cancer is one that originates in a primary anatomical site or tissue that is neither an extension, nor a recurrence, nor a metastasis;
3) Only one tumour shall be recognised as arising in an organ or pair of organs or tissue. The codes (ICD-O-1 and 2/3) are given in the following Table 1.

   For example: bilateral involvement of the ovaries in which only a single histology is reported is only one tumour; likewise, bilateral retinoblastomas are always considered to be a single primary cancer.

   Multi-focal tumours – that is discrete masses apparently not in continuity with other primary cancers not originating in the same primary site or tissue, for example, bladder cancer is counted as a single cancer.

   Similarly, skin cancers of the same histological type occurring anywhere on the skin is counted of as a single cancer, except say one primary malignant melanoma and another basal cell carcinoma.

4) Rule 3 does not apply in two circumstances:

   a) for systemic or multi-centric cancers potentially involving many discrete organs, four histological groups are included – lymphomas, leukaemias, Kaposi's Sarcoma and mesothelioma. Thus, a patient with Hodgkin's disease or HNL again developing another morphologic type of lymphoma in another lymph node or organ is considered to have a single tumour. However, a myeloid leukaemia developing in a patient with NHL is considered to have two primaries.
   b) Other specific histological groups given in Table 2 (1,2,3,4,6 and 11) are considered to be different for the purpose of defining multiple tumours. Thus, a tumour in the same organ with a different histology is counted as a

new tumour. Groups 5 and 12 in the Table 2 are not typed histologically and therefore cannot be considered as separate tumours.

If it is determined that there are two independent primaries, two HBCR proformas are to be prepared.

Guidelines for Data Entry:

Item	***Number of fields assigned for coding***
Sequence	1

Codes:

0	=	One Primary Only
1	=	First of two or more primaries
2	=	Second of two or more primaries
3	=	Third of three or more primaries
9	=	Unspecified sequence number(unknown)

Sequence number codes the chronological appearance of all primary malignant tumours as defined in this manual.

If two or more independent primaries are diagnosed simultaneously, the lowest sequence number should be assigned to the diagnosis with the worst prognosis. This means consideration of stage of extent of disease and also the grade or degree of malignancy. If no difference in prognosis is evident, the decision must be arbitrary.

Quality Checks:

The usual range and consistency checks will be carried out.

27. Clinical Extent of Disease Before Cancer Directed Treatment

*Mandatory field

Definition and Description** (for completing core form**):

Gathering precise information on this subject for all cases recorded by a HBCR poses a considerable challenge. The task would be more manageable in primary registration sources, particularly within the environment of a cancer hospital. However, when dealing with data obtained from pathology laboratories and other sources, significant effort is needed to connect with the records. This involves obtaining necessary consent from the relevant clinician before accessing the information.

The condensed TNM for coding extent of disease as published by the SEER may be followed. This is given in Appendix II.

Guidelines for Data Entry:

Codes:

Item	***Field length assigned for coding***
Clinical Extent of Disease *(Before commencing initial cancer directed treatment)*	1

01 = In-Situ/benign/borderline/pre-invasive

02 = Localised

03 = Direct extension

04 = Regional nodes

05 = Direct extension with regional node involvement

06 = Distant metastasis

07 = Not palpable

08 = Too advanced

09 = Not applicable

10 = Recurrence

88 = Others (Specify)

99 = Unknown

Coding for 'In-Situ/benign/borderline/pre-invasive cases' has been given as a convention for registries that may be interested in recording and following such cases.

However, these cases are not reportable and should be included in the cancer registry as a case. Consequently, these cases should not be reported to the Coordinating Unit.

Quality checks

Logical consistency checks between clinical extent of disease and site codes will be done; combination such as in situ leukaemia are impossible and will amount to coding error

'07=Not palpable' applies only to primary malignant tumours & not to lymph nodes;

'09=Not applicable' refers to lymphomas, leukaemias and multiple myelomas.

Cases obtained through death certificates/registers and not matched are classified as 'Death Certificate Only'. These should be coded as unknown for clinical extent of disease. However, if the cause of death specifies the involvement of metastasis then it should be coded as per assigned codes under clinical extent of disease.

For ALL SITES, extent of disease is based on clinical assessment only, before first treatment of a cancer patient.

The above coding system applies to solid neoplasms only. It does not apply to leukaemias and lymphomas; these should be coded as 09 = "Not applicable

Tabulation: While tabulating the data of a HBCR, the Coordinating Unit will group the codes of extent of disease as follows:

Localised (LOC)	: 02 Localised
Regional Lymph Node (RLN)	: 03 Direct Extension 04 Regional Node 05 Direct Extension with RLN
Distant Metastasis (DIS MET)	: 06 Distant Metastasis 08 Too Advanced
Others (OTH)	: 07 Not Palpable 09 Not Applicable 10 Recurrence 88 Others specify 99 Unknown

28.1 Staging System * Mandatory field

Definition and Description ***(for completing core form):***

(1) TNM staging: Generally, the UICC/AJCC TNM staging system is followed for staging of cancer. This may be ticked unless, otherwise.

(2) FIGO staging: FIGO denotes the International Federation of Gynaecology and obstetrics. Usually FIGO system of staging is followed in almost all centres. This has to be ticked when FIGO staging or FIGO staging with modification is used in the staging of cancer cervix.

(3) Ann Arbor: This is applicable for staging of Hodgkin's & Non-Hodgkin's Lymphoma and has to be ticked when this system of staging is followed for the above malignancies

(4) Toronto stage system for childhood cancers: This is applicable for staging of and has to be ticked when this system of staging is followed for the childhood/paediatric malignancies

(5) Not Applicable: When none of the above are applicable.

(8) Others (specify).....: This has to be ticked specifying the type of staging employed, when staging system other than FIGO system is used at the RI, e.g. UICC TNM staging or if the malignancy is other than carcinoma.

(9) Unknown

Conditions:

In General, the staging system followed at the Reporting Institution (RI) takes precedence over the staging done outside RI.

Specifically,

a). If patient is not treated with surgery or radiotherapy or chemotherapy or combination of any of these three, prior to registration at RI, then the staging system followed at RI is recorded, overriding the staging system followed outside the RI. These patients might have undergone some or all the investigations outside the RI.

a) In patients who underwent partial treatment with surgery or radiotherapy or chemotherapy or combination of any of three, prior to registration at RI;

i. ***if earlier details are available,*** with or without further investigations at RI for conclusive staging, then the staging system followed at the RI is recorded, ignoring the staging system followed outside the RI,

ii. ***if earlier details are <u>not</u> available*** with or without further investigations at RI for conclusive staging, then staging done outside the RI is recorded.

Guidelines for Data Entry:

Staging System Followed

Item	***Number of fields assigned for coding***

Staging System

Codes:	1	=	TNM
	2	=	FIGO
	3	=	Ann Arbor
	4	=	Toronto stage system for childhood cancers
	5	=	Not applicable
	8	=	Others (Specify.)
	9	=	Unknown

28.2 TNM (Tumour, Node, Metastasis) (888 if not applicable**)** # Optional field

Definition and Description *(for completing core form**):***

One of the following of T has to be ticked as per the guidelines of TNM UICC/AJCC staging system.

TX T0 Tis T1

T2 T2a T2b T3 T4 T4a T4b

One of the following of N has to be ticked as per the guidelines of TNM UICC staging system.

NX N0 N1 N1a N1b N2 N2a N2b N2c N3

The size of the largest node in its greatest diameter and in a line perpendicular to the greatest diameter (WHO) in centimetres for ipsilateral (same side of primary) and contralateral (opposite side of primary) node(s) has to be recorded. The location of enlarged nodes is classified into various levels as per UICC. The levels of the enlarged nodes have to be ticked separately for ipsilateral and contralateral nodes.

One of the following of M has to be ticked as per the guidelines of TNM UICC/ staging system.

Mx M0 M1

Conditions:

a) Recording of the staging is as per the availability of data and the recommendations of the staging system followed. All-out effort should be made to record the lowest sub-stage rather than higher or the main stage – e.g. recording should be T1a or T2a or N2a rather than TI, T2 or N2.

b) When in doubt the staging should be preferably done by the tumour board / Joint clinic. If the consensus cannot be evolved regarding stage, then lower category ("downstage") should be chosen as per General Rule number 4 of TNM. E.g. if there is a doubt between stage T1a and T1b in a particular patient, then the stage is entered as T1a.

c) Stage may be recorded as unknown if the patient is treated in the prior institution without proper staging, although every effort should be made to collect the clinical information and staging should be done based on the information made available.

Guidelines for Data Entry:

Item	***Number of fields assigned for coding***
T	4
N	4
M	4

If Staging System is selected as TNM then the TNM Coding has to be Given.

28.3 Composite Stage* Mandatory field

Definition and Description *(for completing core form)**:***

The stage grouping corresponds to the clinical TNM staging and not pathological TNM.

Guidelines for Data Entry:

Item	***Number of fields assigned for coding***
Composite Stage	4

Stage Grouping Should be entered and if it is not applicable then 888 should be entered.

29. Details of Treatment given prior to Registration at RI/Outside RI

Definition and Description *(for completing core form)**:***

a) Patients who undergo either surgery / radiotherapy / chemotherapy or any combination therapy, outside the reporting institution, are ticked as (1) YES.

b) Patients who ***do not*** undergo either surgery / radiotherapy / chemotherapy / any combination therapy, outside the reporting institution, are ticked as (2) No.

c) Very rarely, a patient may not be in a position to give the specific details of the prior treatment and despite the efforts of the concerned staff this may not be available. In such instances (9) Unknown has to be ticked.

Guidelines for Data Entry:

Item	***Number of fields assigned for coding***
Treatment given prior to Registration at RI/Outside RI	1

Codes: 1 = Yes
2 = No
9 = Unknown

29.1 if Yes, Type of Treatment Given* Mandatory field

Definition and Description *(for completing core form)**:***

a. Allopathic: Allopathic medicine, also known as conventional medicine or Western medicine. It is based on the principles of using drugs and therapies that produce effects opposite to the symptoms of a disease. Allopathic medicine relies heavily on evidence-based practices, scientific research, and clinical trials to diagnose, treat, and prevent various illnesses and health conditions.
b. Non-allopathic: Non-allopathic medicine refers to a wide range of medical practices that are not part of conventional Western medicine. This category includes various alternative, complementary, or traditional medical systems. Some examples of non-allopathic medicine include Ayurveda, Homeopathy, Naturopathy, Siddha, Unani, chiropractic and herbal medications.
c. Both

Intention to Treat * Mandatory field

Definition and Description *(for completing core form)**:***

(1) Curative/radical: When the intention of treatment is to get rid of the disease, even if the tumour is not expected to respond to treatment completely, (1) curative should be ticked.

(2) Palliative: This treatment is to relieve the patient of distressing symptoms. Even if the radical procedure(s)/dose is adopted to treat a patient and if the intended purpose is to relieve the patient's symptoms (so called "radical treatment with palliative intent") over shorter or longer duration, (2) palliative should be ticked.

(3) Symptomatic (includes pain relief): Treatment given for symptomatic relief of conditions and pain.

(9) Unknown: None of the above.

Conditions:

Plan of treatment refers to initial documentation ***on the day of start of the treatment***. Any change in the policy of management subsequently, either from curative to palliative or vice versa will not alter the initial intention on the day of start of treatment.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Intention to Treat at RI	1

Codes:

1 = Curative/Radical

2 = Palliative

3 = Symptomatic includes pain relief

9 = Unknown

Role of treatment* Mandatory field

Definition and Description *(for completing core form)**:***

1. ***Neo adjuvant*:** Treatment given before the primary treatment.
2. ***Definitive*:** Any treatment prescribed in intention to cure. The treatment plan for a disease or disorder that has been chosen as the best one for a patient after all other choices have been considered
3. ***Adjuvant:*** Adjuvant treatment is given to enhance the effectiveness of another form (modality) of treatment. For example, adjuvant chemotherapy for breast cancer after mastectomy
4. **Concurrent**: Therapy where two or more therapeutic modalities (e.g., chemotherapy, radiotherapy, immunotherapy) are administered at the same time

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Role of treatment	1

Codes:

1 = Neoadjuvant

2 = Definitive treatment

3 = Adjuvant

4 = Concurrent

Cancer Directed Treatment details* Mandatory field

Definition and Description *(for completing core form):*

1. ***Completed treatment*:** When an individual receives more than 80% of planned chemotherapy and more than 90% of the radiotherapy dose
2. ***Incomplete treatment*:** When an individual does not receive all the prescribed cycles of treatment

Guidelines for Data Entry:

Item	***Field length assigned for coding***
CDT details	1

Codes:

1 = Completed treatment

2 = Incomplete treatment

For (1), (2) & (3): Depending on whether or not Surgery and/or Radiotherapy and/or Chemotherapy are part of the prior treatment, the appropriate box may be ticked Yes or No.

(8). Others(specify): When any individual treatment or combination of treatment mentioned other than the above is given e.g. hormone therapy / Immunotherapy alone or in combination with surgery/ radiotherapy/ chemotherapy/, code (8) others*(specify)* should be ticked and the type of therapy has to be recorded.

(9). Unknown: Very rarely patient may not be in a position to give the specific details of the prior treatment and in that case should be ticked as (9) Unknown.

Conditions:

a) As indicated above every effort should be made to get all the treatment details received by the patient in the earlier institution and entered accordingly.

Start date and end date of treatment needs to be recorded

Guidelines for Data Entry:

Item	***Number of fields assigned for coding***
Type of Treatment Given	2

Codes:

01 = Surgery(S)
02 = Radiotherapy(R)
03 = Chemotherapy(c)
04 = Hormone therapy
8 = Others (specify)....
9 = Unknown

29.2 DETAILS / TYPES OF TARGETED THERAPY *Mandatory field

Definition and Description *(for completing core form)**:***

Targeted therapy is a type of cancer treatment that focuses on specific molecules or pathways involved in the growth and spread of cancer cells. Unlike traditional chemotherapy, which can affect both cancerous and healthy cells, targeted therapies are designed to specifically target cancer cells, minimizing damage to normal tissues. Record the type of targeted therapy as per codes given below.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Details / types of targeted therapy	***2***

Codes:

01= Tyrosine Kinase Inhabitor KI: Tucatinib, Lapatinib
02= Immunotherapy: Aterzolizumab, pembrolizumab
03=Monoclonal antibodies (Trastuzumab or Pertuzumab)
04=Antibody drug conjugate (Adc Trastuzumab Emtansine)
05= CDK 4/6 inhibitor (Palbocictib)
06= mTOR inhibitor (Everolinus)
07= PARP inhibitor (Olaprib)
08=Not given
88=Others (specify)
99=Unknown

29.3 Performance status (ECOG)* Mandatory field

Definition and Description *(for completing core form)**:***

This is as per the ECOG recommendation**.** Codes to be ticked are self-explanatory.

Conditions: While the treating clinician should ideally record this information, a trained nurse or social investigator could also record it under the guidance and supervision of the treating oncologist. If in doubt, the performance status should be assigned a lower category, to give the benefit of doubt so as to consider more aggressive therapy.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Performance status (ECOG)	1

Codes:

(1) = Known
(9) = Unknown

If Known (1) above

0 = Fully active, Able to carry out all pre-disease performance without restriction

1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature

2 = Ambulatory and capable of all self-care but unable to carry out any work activity; up and above more than 50% of waking hours

3 = Capable of only limited self-care; confined to bed or chair more than 50% of waking hours

4 = Completely disabled; cannot carry on any self-care; totally confined to bed or chair

5 = Dead

30. Treatment at RI

30.1 Type of treatment given

Definition and Description *(for completing core form):*

a. Allopathic: Allopathic medicine, also known as conventional medicine or Western medicine. It is based on the principles of using drugs and therapies that produce effects opposite to the symptoms of a disease. Allopathic medicine relies heavily on evidence-based practices, scientific research, and clinical trials to diagnose, treat, and prevent various illnesses and health conditions.
b. Non-allopathic: Non-allopathic medicine refers to a wide range of medical practices that are not part of conventional Western medicine. This category includes various alternative, complementary, or traditional medical systems. Some examples of non-allopathic medicine include Ayurveda, Homeopathy, Naturopathy, Siddha, Unani, chiropractic and herbal medications.
c. Both

Intention to Treat at RI* Mandatory field

Definition and Description *(for completing core form):*

(1) Curative/radical: When the intention of treatment is to get rid of the disease, even if the tumour is not expected to respond to treatment completely, (1) curative should be ticked.

(2) Palliative: This treatment is to relieve the patient of distressing symptoms. Even if the radical procedure(s)/dose is adopted to treat a patient and if the intended purpose is to relieve the patient's symptoms (so called "radical treatment with palliative intent") over shorter or longer duration, (2) palliative should be ticked.

(3) Symptomatic (includes pain relief): Treatment given for symptomatic relief of conditions and pain.

(4) No treatment: When no treatment is intended.

Conditions:

Plan of treatment refers to initial documentation ***on the day of start of the treatment***. Any change in the policy of management subsequently, either from curative to palliative or vice versa will not alter the initial intention on the day of start of treatment.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Intention to Treat at RI	1

Codes:

1	=	Curative/Radical
2	=	Palliative
3	=	Symptomatic includes Pain Relief
4	=	No treatment

Role of treatment* Mandatory field

Definition and Description *(for completing core form)**:***

1. ***Neo adjuvant*:** Treatment given before the primary treatment.
2. ***Definitive*:** Any treatment prescribed in intention to cure. The treatment plan for a disease or disorder that has been chosen as the best one for a patient after all other choices have been considered
3. ***Adjuvant:*** Adjuvant treatment is given to enhance the effectiveness of another form (modality) of treatment. For example, adjuvant chemotherapy for breast cancer after mastectomy
4. **Concurrent**: Therapy where two or more therapeutic modalities (e.g., chemotherapy, radiotherapy, immunotherapy) are administered at the same time

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Role of treatment	1

Codes:

1	=	Neoadjuvant
2	=	Definitive treatment
3	=	Adjuvant
4	=	Concurrent

Cancer Directed Treatment details* Mandatory field

Definition and Description *(for completing core form):*

1. ***Completed treatment*:** When an individual receives more than 80% of planned chemotherapy and more than 90% of the radiotherapy dose.
2. ***No treatment***: A Patient for whom no specific treatment is advised or specified.
3. ***Treatment. Advised but not accepted*:** Act of families or individual declining or discontinuing medical interventions recommended.
4. ***Incomplete treatment*:** When an individual does not receive all the prescribed cycles of treatment.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
CDT details	1

Codes:

1 = Completed treatment
2 = No treatment
3 = Treatment advised but not accepted
4 = Incomplete treatment

(Adopted from "Manual for Cancer Registry Personnel", IARC pages 22-24).

Surgery:

This involves the total or partial removal of a primary tumour or its secondary – metastatic site. It does not include incisional or excisional biopsy where only a part of the tumour is removed for examination in order to establish a diagnosis.

Examples:
- Hysterectomy for uterine cancer
- Mastectomy for breast cancer
- Gastrectomy for stomach cancer
- TUR (Trans-urethral Resection) with removal of cancer tissues for bladder and prostate cancers
- Local excision with removal of cancer tissue (including wide excision and excluding incisional/excisional biopsy).
- Surgery removing metastatic malignant tissue (not therapy if done for diagnosis only)

Exceptions: Exploratory surgical procedures are excluded. Laparotomy, thoracotomy, craniotomy are surgical investigations that are not considered treatment.

Radiotherapy:

This includes all beam and other ionising radiation directed to cancer tissues regardless of source of radiation. Ionising radiation can be delivered in the following ways:

1) External beam radiation from sources at a distance from the body:
   - X-ray (exclude diagnostic x-rays)
   - Cobalt
   - Linear accelerator
   - betatron
   - neutron
   - electron

2) Brachytherapy refers to local irradiation from sources in contact with or near target tissue:
   - Intra-cavitary radium insertion for cervical cancer;
   - Interstitial radon seed implants in breast cancer;
   - Surface placement of radioactive isotopes

3) Internal or systemic irradiation from radioactive administered intravenously or parenterally.

Chemotherapy

This involves the use of any chemical or cyto-toxic drug towards the treatment of cancer. The cyto-toxic effect is exerted directly on the tumour and does not result from a change in the hormonal imbalance (hormone therapy) nor a change in the hosts immune response (immunotherapy).

Chemotherapy may be:

a. curative: aims to achieve a cure
b. palliative: aims to reduce the bulk of disease to relieve symptoms and to prolong life
c. adjuvant: aims to control microscopic spread of cancer following other forms of treatment such as surgery or radiotherapy

Some of the chemotherapeutic agents used are:

Actinomycin D	L-asparaginase
Biomycin	Lomustine (CCNU)

Carboplatin	Melphalan
Carmustine (BCNU)	6-Mercaptopurine(6-MP)
Chlorambucil	Methotrexate
Cisplatin	Mitromycin C
Cyclophosphamide (endoxan)	Mitoxantrone
Cytarabine	Nitrogen mustard
Daunorubicine	Procarbazine
Doxorubicin(adriamycine)	Semustine (Methyl - CCNU)
Etoposide (VP 16)	Thiotxepa
5-Fluorouracil(5FU)	Vinblastine
Hexamethylmelamine	Vincristine (oncovin)
Hydroxyurea	Vindesine
Isofamide	

Hormone therapy

Hormones are chemicals produced in the body which help regulate body mechanisms including growth, metabolism, and reproduction. Used in the treatment of cancer, hormonal withdrawal or hormonal interference may alter the growth of malignant neoplasms.

Hormone therapy is defined as the use of any type of therapy, which exercises its effect on cancer tissue via change of the hormone balance of the patient. The administration of hormones, anti-hormones or steroids, surgery for hormonal effect on cancer tissue, and radiation for hormonal effect on cancer tissue are included in hormone therapy.

Immunotherapy

This refers to the use of any type of therapy which exercises its effect on cancer tissue through a change in the hosts immune response, e.g., interferon, interleukins, vaccine therapy etc.

No Cancer Therapy - Non-cancer directed treatment:

Non-cancer directed therapy may also be given to cancer patients to relieve symptoms and alleviate pain and distress but such therapy does not treat the cancer, e.g., by-pass operation to relieve obstruction such as gastro-jejunostomy in a patient with obstructed tumour of the stomach.

If the patient receives the above form(s) of treatment or receives symptomatic /supportive therapy only, this is classified as ‘No cancer-directed therapy’.

Palliative Treatment

The term “palliative” is normally used in two senses:

(i) non-curative, and (ii) alleviating symptoms

Thus, some of the treatments termed palliative fall within the definition of cancer directed treatment and others are excluded because they treat the patient.

Many times, it is not possible to determine from the medical record whether or not the treatment falls within the definition of cancer-directed therapy. It is not always clear whether the treatment was given to attack or to control the cancer or to provide symptomatic/supportive therapy only. It is essential that a physician interpret the medical record in problem cases.

Examples of Palliative procedures that are not considered definitive therapy include:

* Bypass surgery: surgical procedure to divert a passage around a tumour or obstruction.
* Lobotomy: Division of one or more nerve tracts in a lobe of the cerebrum
* Cranial decompression: Removal of a piece of cranium to relieve intra-cranial pressure.
* Tracheotomy: Surgical incision into the trachea.
* Tractotomy: Surgical resection of a nerve fibre of the central nervous system.

Start date and end date of treatment needs to be recorded

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Type of Treatment Given	2

Codes:

01 = Surgery(S)

02 = Radiotherapy(R)

03 = Chemotherapy(c)

04 = Hormone therapy

08 = others (specify)....

30.2 DETAILS / TYPES OF TARGETED THERAPY (if given) - (Codes given in 29.2**)** *Mandatory field

Definition and Description *(for completing core form)**:***

Targeted therapy is a type of cancer treatment that focuses on specific molecules or pathways involved in the growth and spread of cancer cells. Unlike traditional chemotherapy, which can affect both cancerous and healthy cells, targeted therapies are designed to specifically target cancer cells, minimizing damage to normal tissues. Record the type of targeted therapy as per codes given below.

Guidelines for Data Entry:

Item	***Field length assigned for coding***
Details / types of targeted therapy	***2***

Codes:

01= Tyrosine Kinase Inhabitor KI: Tucatinib, Lapatinib
02= Immunotherapy: Aterzolizumab, pembrolizumab
03=Monoclonal antibodies (Trastuzumab or Pertuzumab)
04=Antibody drug conjugate (Adc Trastuzumab Emtansine)
05= CDK 4/6 inhibitor (Palbocictib)
06= mTOR inhibitor (Everolinus)
07= PARP inhibitor (Olaprib)
08=Not given
88=Others (specify)
99=Unknown

vided by the software based on ICD-10 selected for underlying cause of death.

31. Name of Person Completing the Form* Mandatory field

Definition and Description *(for completing core form)**:***

The name of the person who has abstracted the patient information from case file is to be filled.

Guidelines for Data Entry:

Item	***Number of characters assigned for coding***
Name of Person Completing the Form	40

32. Date of Completing this Form & Signature* Mandatory field

Definition and Description *(for completing core form)**:***

Date of completing the form with signature have to be entered in the core form.

Guidelines for Data Entry:

Item	*Number of characters assigned for coding*
Date of completing this form	6

Quality checks:

Within the date fields (day, month, year) range checks are carried out.

APPENDIX I

Proforma **Multiple Neoplasms (See ICD-O-3, pages: 35–37)**

Multiple malignant tumours in the same individual at the same site present many coding difficulties and specific solutions to all problems cannot be listed here. Whenever such types of problems encountered, attending physician should be consulted for proper coding in order to ascertain the site of origin, if possible. Such problems may also be sent to Coordinating Unit for inclusion in the manual.

The general rules for coding multiple neoplasms are as follows (based on ICD-O-3):

1. Two or more separate neoplasms of different three- or four-digit sites should be coded on separate core form even though the morphologic type is the same for all but registry's identification number i.e., HBCR registration number should remain same. For example, squamous cell carcinoma of forehead and arm be coded as:

HBCR registration No.	ICD-O-3	ICD-10	Histology
0302345	C443	C44.3	807039
0302345	C446	C44.6	807039

2. Two or more separate cancers of different histology should be coded on separate proformas even though arising in the same site in the same individual. For example, adenocarcinoma and malignant carcinoid of transverse colon, should be coded as:

HBCR registration No.	ICD-O-3	ICD-10	Histology
8601234	C184	C184	814039
8601234	C184	C184	824039

3. If multiple tumours of the same histology are diagnosed in sub-sites within a three-digit site code, the topography is coded to the rubric that includes them all. For example, multiple tumours of the same histology of different sub-sites of the bladder would be coded to C678 (ICD-O-3; ICD-10).

4. There are some sites covered by some groups of codes that are considered to be a single organ for the purposes of defining multiple tumours. These topography code groups listed in table 24 (page:36) of ICD-O-3.

5. Each side of a paired site is considered a separate site unless stated to be metastatic. For example, Ca breast (left) and Ca breast (right) in a female should be coded separate sites. An exception to this rule is made for ovarian primaries in which there is bilateral involvement of the ovaries and for which only a single histology is

reported. Such involvement is considered a single primary unless there is medical documentation of multiple tumours.

6. In case of skin cancer, a person may have many such neoplasms over a lifetime. According to IARC/IACR rules, only the first tumour of a defined histological type anywhere on the skin is counted as an incident cancer, unless, one primary was a malignant melanoma and the other a basal cell carcinoma.

Primary site must be stated as accurately as possible, e.g. UOQ breast right, middle lobe lung right, vocal cord, etc. If primary site is not known, the site of the main secondary must be specified. If there is more than one secondary given, select the more important of the organs, such as liver, lung or specified bone. For leukaemia, no site needs to be stated, but try to find the cell type such as myeloid, lymphatic and state whether 'chronic' or acute.

Ca testis (186.9) may occur in a girl (hermaphrodites).

Special care is required in dealing with the Paget's Disease of the nipple. Strictly speaking Paget's Disease of the breast consist of two primaries, because there are usually two tumours. One is the Paget's Disease proper that occurs in the nipple, the other is an infiltrating duct carcinoma that can occur anywhere in the breast. The latter may not be apparent when the Paget's Disease is diagnosed, developing up to two years later. When coding Paget's Disease of the breast, often referred to as Paget's disease of the nipple, first find out from the pathology report whether the infiltrating duct carcinoma is present or not. If both tumours are present, the patient forms should be filled with histology diagnosis as "Paget's Disease and infiltrating duct carcinoma (8541/3" and if possible specifying the site of the duct carcinoma, otherwise record the site as "breast (C50.-). If no infiltrating duct carcinoma can be found, record the histology as "Paget's Disease (8540/3)", site "nipple (C50.0)", and make a note in the remarks stating that the infiltrating duct carcinoma is absent. Paget's Disease is registered only once unless it occurs in both breasts when two forms should be filled with same registration number.

There is also a rare condition, "extramammary Paget's Disease" Which is Paget's Disease of the breast occurring in another organ. It may be coded in the appropriate site and code histology as (8542/3). It should be noted that Paget's Disease of bone (osteitis deformans) is an entirely unrelated disorder that is not registerable although an osteosarcoma can occur independently in the affected bone.

Thus, Paget's Disease of bone can be associated with an osteosarcoma in the affected bone; the site code is C40.- or C41.- and histology code (9184/3).

The natural history of certain malignancies may show a progression from one histology, and primary site to another histology and associated site. This is particularly

true for lymphomas and leukaemias. As a general rule, such cases should be coded to the site/histology diagnosis at the time of initial diagnosis and should not be changed because of conversion to another histologic type. However, it should be noted that the site/histology may be changed in the light of a review of the diagnosis, if the initial diagnosis was incorrect. Then the Registry should note such correction. It is important to know that the correction in the diagnosis is not the same as a change to another histologic type as the disease progresses.

Chemotherapy and Hormones

The treatment of a cancer patient by hormones and chemotherapy has become such an extremely complex field of therapy that the details for the drugs used should be confined to the following:

(1) Up to two single agent drugs given either separately or together.

(2) "Recognized protocols"

(3) Other combinations of drugs such as 'multiple drug scheme' may be used.

Note: There is no standard list of type of treatments such as Surgery, Radiotherapy, Chemotherapy and Hormone therapy is available for India.

In view of difficulties encountered by the data abstractors and coders, it is suggested that each HBCR should collect information on types of treatment details. That is a list of surgical operations done in their institutions and in collaborating hospitals, in the treatment of a malignant neoplasm, be prepared and sent to Coordinating Unit for preparing a standard list.

To be more specific, the under mentioned lists be prepared by each HBCR and sent to Coordinating Unit:

(1) List of surgical operations

(2) List of radiotherapy treatment

(3) List of chemotherapy agents

(4) List of hormone therapy

OUTPATIENT MEDICAL RECORDS

The cancer registry staff should know where exactly in each outpatient department, the cancer cases are sent. Getting the address of these patients is the most difficult aspect of working of the cancer registry in the Indian setup. Many a times, the patients who have had a biopsy diagnosis or any other form of diagnosis including clinical diagnosis turn up at the outpatient and it becomes difficult to trace them. Ideally the

clinical who is the in-charge of the respective units should instruct the resident to note down the name and address of such patients in a log book. It may not be practical to do this for all patients in a general hospital set up and therefore only those patients with a clinical suspicion of cancer could be listed and address note.

While addressing their pathology records, the registry staff should systematically go through surgical pathology, haemato-pathology and cytopathology reports and log books. Like in the out-patient's department once again determining the address of all patients may be extremely difficult especially when biopsy / cytological or haematological examination is done on an outpatient basis. Therefore, it is important to create a system where such procedures are performed to records the address of all such patients where there is a clinical suspicion of cancer and record the address in a log book or better still through a computerised system.

Radiotherapy Records: It is possible in a setup with several patients would go directly this department and receive radiotherapy based on a microscopic diagnosis made outside the reporting institution. Such cases also need to be identified by the registry staff and system to be evolved to record the address of these patients.

*Imaging Department***:** Generally, patients who come to this department (X-ray, Nuclear Medicine, CT / MRI scan, Ultrasound) have a provisional diagnosis and are sent back to the parent departments for several investigations. In order not to miss any suspected cancer case, the registry staff are advised to go through the listing of suspected or confirmed cancers in this department.

Hospital Based Cancer Registry:

A hospital-based cancer registry (HBCR) is primarily oriented towards administrative concerns and patient treatment and as such collects data which are different from those of a population-based registry. It also collects data items which are of use to the population-based cancer registry, and when available the hospital-based cancer registry is a very important source of information. To complete case-finding, the HBCR cases should be reviewed, matching them with the cases gathered from other departments within the hospital and paying special attention to patient identification data items (name, age, sex, address, hospital case number), as well as diagnosis and basis of diagnosis.

Cases with behaviour code "0' (Benign) or "1" (Uncertain whether benign or malignant – Borderline malignancy) or "2" (Carcinoma-in-situ) may be registered by the HBCR if the Registries are so interested but such cases are not reportable to the Coordinating Unit. Thus, cases of papilloma bladder, pleomorphic adenoma of thyroid gland, mixed salivary gland tumour etc., may be registered locally and should not be reported to Coordinating Unit.

As far as possible, all non-microscopically diagnosed cancer cases should be approved for reporting to Coordinating Unit after consultation with the physician in charge of the patient /tumour board /Senior Research Officer (Medical).

All cases that receive cancer directed treatment would be considered as cancer cases regardless of the language used for a definitive diagnosis of cancer. For example:

Some examples are given below:

? Ca buccal mucosa: treated with Radiotherapy or Chemotherapy or both should be registered as cancer case and it is reportable to Coordinating Unit.

? Ca buccal mucosa: "no treatment, no follow-up, no further management" is not reportable.

However, the case needs to be followed up.

Exception: Certain benign lesions are also treated by Radiation and Chemotherapy, e.g., Keloid. The medical officer should be consulted regarding these. The ICD-O morphology code may also be a guiding factor in such a situation.

REPORTABLE NEOPLASMS

These would include:

(a) All carcinomas and sarcomas ;

(b) All tumours specified as malignant in ICD-O-III (2000 edition);

(c) All tumours not specified as malignant but with /3 behaviour codes;

The complete alphabetical list of these reportable neoplasms based on ICD-O-III (2000 edition) is given in the appendix.

DEATH CERTIFICATES

It so happens in our system of registration that some cancer patients are not registered in the hospitals when they were alive. The information about these patients can be obtained through death certificates.

All the death certificates irrespective of cause of death for a particular year should be collected for processing.

The cases obtained from death certificates might have been cases diagnosed in any previous years. It is therefore necessary that a scrutiny of the entire data files maintained from the inception of the registry be done. In other words, all the cases obtained from death certificates of current year should be matched with all the cancer cases registered till current year. This is done using computer by checking through name index, diagnostic index and other patient identification details. In case of a certificate matched with a case of previous or current year, additional (or more accurate) information available on the certificates is updated in the matched incident record.

The death certificates remaining unmatched are classified as unmatched death certificates. These unmatched death certificate cases of cancer are registered as DCO (Death Certificate Only) cases on the basis of their date of death. It is an accepted method that date of death is taken as date of first diagnosis in such type of cases. Death Certificates can be classified as follows and should be registered as specified:

(1) MATCHED DEATH CERTIFICATES: Death certificates MATCHED with morbidity proformas with current year or previous years. Thus, MATCHED DEATH CERTIFICATES should carry the same registration number as that of the morbidity proforma matched for a specific year. For example, if a person died of cancer as per death certificate during the year 2003 but was diagnosed and registered during 2001 then this is a matched case and should bear the registration number of 2001 (0101234, say). All such cases should be resident of the registry area by definition. A minimum period of one year of stay is mandatory for HBCR.

(2) UNMATCHED DEATH CERTIFICATES: Death certificates could not be matched with the morbidity proformas for any year and they are all residents (residing at least one year or more in the registration area). Such cases should be registered as DCO cases as specified above and continuous registration number be given as that of morbidity proformas for that particular year beginning with last two digits of the year. Thus, if a person died of cancer on 24 April 2003 (say) and could not be matched with existing registry proformas then it should be registered during 2003 with registration number beginning with 0360001 (say); 60001 being the registry number.

(3) Persons died of cancer, matched with morbidity proforma but death certificate issued by the municipal corporation does not indicate cancer as cause of death. The CHENNAI HBCR observed such cases during 1982 and 1983 when the social workers made a house visit or the registry staff came to know through the follow-up letters. These cases should be classified under matched category and the same procedures as in (1) should be followed for their registration.

(4) NON-RESIDENT CANCER DEATHS: Such deaths should be classified separately and entered into the computer with the registration number beginning with last two digits of the year of death.

(5) RESIDENT STATUS NOT KNOWN OF CANCER DEATHS: Follow the same procedures as specified above in (4)

The method of diagnosis especially those without a microscopic diagnosis should be constantly updated for any microscopic diagnosis.

If cases with behaviour code "0" (Benign) or "1" (Uncertain whether benign or malignant – Borderline malignancy) or "2" (Carcinoma-in-situ) subsequently become cancer with behaviour code "3" (malignancy), they are also reportable and date of diagnosis should be taken as the date when it became reported as malignant. In such cases, registries should cancel the first registration and register the malignant one with a note in the remark column to indicate that it had previously been registered as benign or in-situ.

APPENDIX III

Alphabetical list of reportable neoplasms based on ICD-O-3 Refer to page 95 of International Classification of Diseases for Oncology – Third edition available at https://apps.who.int/iris/bitstream/handle/10665/96612/9789241548496_eng.pdf

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