

# **NATIONAL CANCER REGISTRY PROGRAMME**

*Indian Council of Medical Research*

## **PATTERN OF CARE AND SURVIVAL STUDIES - CANCER BREAST**

### **General Principles and Concise Guidelines (Instruction Manual) for Completion of Patient Information Form**

# Contents

- 1. Introduction**
- 2. Registration at the NCRP website:**
- 3. Patient information Form**
  - A. Identifying, Demographic, Diagnostic and Follow-up Information
  - B. Details of socio-economic status, family income, occupation etc.
  - C. Details of Stage
  - D. Details of Cancer Directed Treatment (CDT)
  - E. Follow-up Information
- 4. Appendix**
- 5. References**

## 1. Introduction

This brief instruction manual is a limited explanation of the format and definitions of data collected by the participating institutions. Participating institutions are those who sign the agreement with the NCRP to participate in the pattern of care and survival studies. It is mandatory that the data should either be **entered online** (preferable) or on - portable media (floppy, CD, USB port etc.) entered on a offline program provided by the NCRP.

The format of the Patient Information Form (PIF) has been designed after the consensus meetings held earlier and a review will be done from time to time in consultation with the participating institutions. The NCRP is responsible for quality checks, tabulations and statistical analysis for comparison purposes and is therefore, concerned only with providing description and detail sufficient to achieve consensus in coding the data. This manual does not restrict the type of detailed information collected, classified or studies undertaken by the participating institutions at their level.

Smaller details in the collection of data have been left out to achieve the broader consensus by the participating institutions, since the purpose of this study is to assess overall pattern of care and survival of the leading cancers prevalent in India.

This manual is intended to be a loose-sheet publication so that revisions can be substituted easily whenever there is a further evolution of consensus among the participating institutions with consequent modifications.

## 2. Registration In NCRP Website

All the authorised and valid users from participating institutions can access the NCRP **PATTERN OF CARE AND SURVIVAL STUDIES** proforma online, and enter the data as per the following guidelines. For any further clarification regarding the proforma entry, one can contact [ncrpblr@canceratlasindia.org](mailto:ncrpblr@canceratlasindia.org).

### i) Registration :

Registration should be preferably done online. This will help in evolving into an Indian National Data Network System for instant analysis of pattern of care and survival results at any given point of time. Survival results could be made available with comparative figures for centres all over India, helping to formulate better treatment strategies dynamically.

Using linkage techniques will result in the following:

- 1) Improved handling of large databases and the precision of estimates.

- 2) The data becomes less subjective to influence by occasional misclassification.
- 3) Study of rare outcomes.
- 4) data would not be subject to biases such as recall, non-response and effects on the procedures used.
- 5) Will have the possibility to study the data over a long period of time (Ref1, Available data sources and linkage possibilities using cancer registry data in the evaluation of clinical cancer care, Storm HH, Chapter 4, page 21-22, 2003).

Above all, the online registration and subsequent follow-up will add validity to the data so collected and published, by the participating centres. In addition, such on-line documentation will add to the transparency, taking away the possibility of inadvertent or unknown manipulation of data during the analysis. Consequently, publications from the participating institutions are more likely to withstand international critical review.

**ii) Eligibility for registration (which patients to register?) :**

1. All cases of malignant neoplasms of breast diagnosed microscopically or otherwise should be registered, irrespective of the method of treatment (radical/palliative/no specific treatment).
2. Formal consent by patient for registration at NCRP, with clear description of the principles of confidentiality as related to:
  - (a) Identification of individual patient (patient's name).
  - (b) Protection of data/clinical findings/management confidentiality.
  - (c) Security of data in terms of both paper based and electronic based data systems.
  - (d) Data releases for research.
  - (e) Express statement that the study should help in fostering cancer research and treatment outcome that would be of benefit to both individual and community.. Patients who cannot be persuaded to give consent for documentation at NCRP are not eligible for registration. The number and record of such patients should be maintained
3. The registration should be done for **all patients without exception** fitting to the criteria given in point no. 1 and 2 of ii).
4. The registration should be done ***on the day of registration (at the reporting institution)***.

### iii) Patient consent

The Patient has to be given an assurance that data entered here is for scientific purpose only. The information given by the patient and the diagnosis and management details of the patient are absolutely confidential and cannot be held against the patient at any time in the future within the legal purview. Reasonable care will be taken in collection, transfer and storage of the data with special effort to hide the identity of the patient.

### iv) Data Entry :

1. The first data entry is on the day of registration (at the reporting institution).
2. The data has to be updated, in stepwise fashion, section wise, at the completion of each type of therapy.
3. On the day of completion of all forms of treatment planned, the PIF update **should be complete**, except for the follow-up details.
4. On the day of every follow-up visit of registered patients, the follow-up data should be updated on the same day of follow-up visit, in order to keep the data up to date.

### v) Quality of Data assessment :

1. Online entry would be an indicator of assessment of quality of data.
2. One of the primary criteria for assessment of quality of data will be based on entry in the code “unknown”. Number of “unknown” entries in the fields should be minimum.
3. Regularity of the follow-up & period of follow-up: The most important objective of the study is to have data with proper follow-up. The lost for follow-up cases should not exceed 15% at 5 years follow-up period. Both regularity and periodicity of follow-up are important indicators of the quality of data of a particular participating institution.

## 3. Patient Information Form (PIF)

### A. Identifying, Demographic and Diagnostic Information

The items of information under this broad heading are as per the core fm used by Hospital Based Cancer Registries (HBCRs) under the NCRP. To facilitate other institutions other than the HBCRs that are also participating the brief guidelines are given below. If additional information or clarifications are required the Procedure Manuals of NCRP may be referred.

**1) Centre Name and Number:**

The respective centre's name with the respective code numbers provided by NCRP should be entered.

**2) (a) Registration Number**

Registration number is the Participating Institution's - Reporting Institution (RI) identifying number. Registration Number of a case should be assigned by each RI beginning with year of diagnosis. For example, if a case (diagnosed as cancer) is seen on 1.1.2006 then the registration number of the case may be given as 0600001 i.e. first two digits for year of diagnosis and remaining five digits for the serial number of a cancer case registered during the year. Registration number of a case must not exceed more than seven digits including year of diagnosis.

*Late Registrations:* If a cancer case has been diagnosed on 10 October 2005 but it came to the Registry files only on 10 January 2006, the registration number should begin with 06 and the registration number may be for example 0600345.

Therefore in some cases the Year of Registration may differ from Year of Diagnosis, especially if the Parlins is a referral hospital for cancer patients.

**2) (b) Hospital Registration Number**

Different hospitals have different ways of stipulating and recording the hospital registration number or just hospital number. This could be the same for out-patient and in-patient or it could be different. Depending on the way each hospital records this number and if a given patient is admitted as an in-patient, preference may be given to the in-patient number. The data entry application provides entry of either letter or numeral in each of the seven fields assigned for this item of information.

**2) (c) Web-site Generated Number**

This number is automatically generated and displayed on the computer screen, as soon as, data entry of a given form is completed through the on-line data entry application programme. This is the unique number for every Patient Information Form that is entered. The number generated through the application on the web-site, should be noted in the hard copy (in the specified boxes) of the form, by the person keying in the data. This number will be required for future reference of data entered and data search.

### **3. Date of Registration at the Reporting Institution (RI)**

*NOTE: The terms Reporting Institution (RI) and Participating Institution (ParIns) are used synonymously in this manual.*

The earliest date on which the patient first came to the RI with either a confirmed or even a clinical suspicion of cancer should be recorded. The date could be based on the one recorded in out patient slips or inpatient register/medical record. The date of registration is considered in most cases by the HBCRs under the NCRP as also the Date of First Diagnosis, especially in the setting of a referral cancer hospital. This is because the majority of the patients are referred to a cancer hospital on the basis of a clinical suspicion or provisional diagnosis of cancer. Such patients undergo further investigations to confirm or refute the diagnosis.

### **4. Name of Patient**

The name of the patient has to be filled in the proforma in the order as first name middle name (second name) and family name (third name). As far as possible abbreviations in the name should be avoided. The full name of the patient has to be recorded. While entering the name of the patient into the computer, following steps may be taken:

Mr/Mrs/Dr/Shri/Shrimati/Miss/Baby/Baba/or any other prefix should not be entered into the computer, unless it forms a part of the name of the patient. In case it is necessary to identify the name of the patient then above prefix may be entered at the end of the name. For example, Mrs. Ram Lal may be entered as Ram Lal (Mrs). Baby Roop Kala be entered as Roop Kala (Baby); Late Harbans Singh be entered as Harbans Singh (Late); Dr. Shyam Sunder Jain be entered as Shyam Sunder Jain (Dr);

However, while entering the name of the patient into the computer, it must be remembered that the full name (first name and family name) of the patient must not exceed 30 characters including a blank space after first name, family name, last name and prefix if any.

Where there is a similarity of names in both sexes, Mr/Mrs etc., as the case may be, be specified at the end of the name as stated above.

A full stop (.) or a comma (,) must not appear anywhere in between the name. If the name of the patient is longer than 30 characters, try to adjust it within 30 characters by shortening the middle and last name in that order.

### **5. Name of Father**

This item of information should also be completed as for Name of Patient.

**6) Name of Husband/Mother (if single)**

This item of information should also be completed as for Name of Patient.

**7) Name of the Caretaker**

This item of information should also be completed as for Name of Patient.

These items are useful for better identification of the case and for elimination of duplicates. These can also be used in tracking the patients for follow-up.

**8) Address – a) Local; b) Permanent**

The address may be completed as given. A clear distinction should be made between the local address and place of permanent residence of the patient. In some instances both may be the same, whereas, in others this could be different. The place of permanent residence is the usual home or dwelling where the patient normally lives and has domiciled in that address for at least one year, prior to the diagnosis of cancer. The registries under the NCRP use the criteria of 'one year' to determine and define the permanent place of residence of a patient. Many times patients may have to travel outside their permanent place of residence to have a diagnosis and subsequent treatment of cancer. In such circumstances, out of ignorance or convenience a local friend or relative's address may be given. The registry or other staff who interview the patient and/or accompanying person should make sure that the address recorded against local and permanent are indeed what is required. For this it may be helpful to ask the question (Question 11 below) 'as to how long the patient has been residing at the address just mentioned'. This would guide the interviewer to know whether the patient is actually residing at that address for the past year or is just a guest in someone's house who has come for treatment.

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 addresses have a pin code. As the pin code relates to the post office, in cases where there is no post office in that area, at least first two or three digits should be coded and remaining coded unknown. For example, if a case is a resident of Bangalore and it is not possible to identify the post office then it may be coded as "560999".

The All India Directory of Postal Index Numbers, issued by Department of Posts, New Delhi – 110001, should be used for coding.

**9) Name & Address of a) Caretaker; b) Referring/Family Doctor**

The key requirement of a HBCR and more so of the present study on 'Patterns of Care and Survival' is Patient Follow-up. Towards this end attempts should be



made and a system evolved to have as many contacts as possible to ensure timely and complete follow-up of all patients commenced on cancer directed treatment. In order to enable evolving such a system the details of care-taker/ accompanying person (relative or otherwise) and the family or referring doctor is noted. The addresses of such persons may be noted along the lines indicated above.

#### **10) a) Other Contact Address I; b) Other Contact Address II**

These are recorded as per guidelines listed above.

#### **11) Duration of Stay (*in years*) at Place of Usual Residence**

This information is best obtained by direct conversation with the patient, if adult and with the parent if the patient is a child. If that is not possible due to the disease condition of the patient, then this item of information (like others) should be accurately obtained from the closest relative or accompanying person.

In case the patient describes his/her residence period as “Many years” or ‘Permanent’, then, the duration of stay may be taken as equal to the age of the patient and coded accordingly. If the patient is a child and age is less than one year then, the duration of residence is coded as “01”. This is an exception for children below one year of age.

#### **12) Telephone No(s)**

As many telephone numbers as is possible, including numbers of mobile telephones should be noted. Since we are in an era of rapid rise in the availability and use of telephones, at least two telephone numbers for every patient record is mandatory. The identity of the person(s) to whom the telephone number belongs should also be indicated. This could be that of the patient or any other.

#### **13) E-mail ID**

This also should be recorded wherever possible and the identity of the person to whom the e-mail belongs should also be indicated.

#### **14) Age**

Age of the patient has to be recorded and coded in completed years on the date of first attendance to a hospital subsequent to which a diagnosis of cancer was made. This should be correlated and checked with the date of birth (see below) when available.

It may be coded as follows:

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

Accurate information on age is critical for any type of analysis and interpretation. Therefore, as for eliciting facts on place of permanent residence and the duration of stay therein, the age of the patient, especially in illiterate patients or families should be carefully elicited.

### **15) Date of Birth**

Knowledge of the date of birth would not only enhance but also provide an indication on the quality of data. Every attempt should be made to get this information at least in those patients who have a level of education above matriculation and when patients are children.

Date of birth may be coded with the first two boxes for day, middle two for month and the last two for year. Despite the best of efforts, if the date of birth of the patient cannot be ascertained, it may be coded as 999999.

### **16) Sex - Male Females**

### **17) Basis of Diagnosis**

The most valid basis of final diagnosis should be provided and the specific code box ticked accordingly. This may or may not be the diagnosis based on which the cancer directed treatment was initiated. Thus a patient with breast cancer could have an FNAC followed by mastectomy as part of the surgical treatment. The surgical histopathology diagnosis has to be taken as the final diagnosis and therefore histopathology will be the basis of final diagnosis. For further details the 'Procedure Manuals of NCRP' could be referred.

### **18) Date of Diagnosis**

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 the first hospital. Initially, this could be a clinical diagnosis and subsequently there could be a microscopic confirmation. Even if confirmed later, this date of clinical diagnosis should be recorded as the date of first diagnosis.

Six boxes are provided for coding Date of First Diagnosis. It should be coded as Day (DD)/ Month (MM)/ Year (YY). i.e. 15 January, 2003 be coded as 150103.

***For items 19-22 coding according to the International Classification of Diseases for Oncology, Third Edition (ICD-O-3), WHO may be followed. The general rules for coding neoplasms according to ICD-O-3 as stated therein, along with that of the NCRP Procedure manual should be followed.***

**19) Primary Site of Tumour (ICD-O-3) (Topography)**

The primary anatomical site of tumour may be stated in words and coded here.

**20) Primary Site of Tumour (ICD-O-3) (Morphology)**

The microscopic diagnosis of the primary site of tumour should be described in words and the morphology code given.

***If complete diagnosis (with histological diagnosis of primary) is available then items 21 and 22 should not be coded and should be left blank. Items 21 and 22 should be coded only when:***

- a) the most valid basis of diagnosis is confirmed through microscopic diagnosis of a metastasis; or,
- b) the morphological diagnosis through the metastatic site provides additional or better definition (or higher morphology code) of the diagnosis than that of the primary site of tumour.

***NOTE: Items 21 and 22 are not given with the purpose of assessing the spread of the primary tumour to other organ sites.***

**21) Secondary (Metastatic) Site of Tumour (ICD-O-3) (Topography)**

The secondary (metastatic) site of tumour may be stated in words and coded here

**22) Histology (Morphology) of Metastasis (ICD-O-3)**

The microscopic diagnosis of the secondary (metastatic) site should be stated in words and morphology code given here.

**B. DETAILS OF SOCIO-ECONOMIC STATUS, FAMILY INCOME, OCCUPATION ETC.**

In this section, details of the income of the patient and that of the family, occupation and an assessment of the Socio-economic status are noted. Here the format is

“free hand”. Depending on the local situation and practice in the RI either short or detailed information can be collected.

*Co-Morbid Conditions: Importance:*

Besides affecting the life expectancy, comorbid conditions may influence the clinical management of cancer patients during or after treatment. Further, these patients are often excluded from clinical trials, thus little is known about the best way to treat these patients or the outcome of the treatment, such as complications, quality of life and survival (Ref1. Co morbidity: aims and methods for recording and analysis, Chapter 6, p 27, Janssed-Heijnen MLG & Coebergh JWW, 2003). The outcome may not be predictable since, according to linear assumptions, one plus one is two, but in case of a multiplicative mechanism, one plus one might be three or one plus one may be one.

The presence or absence of the list of co-morbid conditions has to be completed with the help of the examining physician.

### **C. DETAILS OF STAGE**

#### **1) Staging System Followed**

Under item number 1, either (1) TNM staging or (8) others (specify).....or (9) Unknown, is to be ticked.

*Explanation:*

- (1) TNM staging: Generally, the UICC TNM staging system (2003) is followed for staging of breast cancer. This may be ticked unless, otherwise.
- (8) Others (specify).....: This is to be ticked specifying the type of staging employed, when staging system other than the UICC TNM staging has been used. This item should be ticked if the diagnosis of malignancy of the breast is of a morphological type other than a carcinoma – epithelial tumour.
- (9) Unknown: When the data is not available despite reasonable effort.

*Conditions:*

*(This may be read along with that give below (2) Staging Done at)* In General, the staging system followed at the Reporting Institution (RI) takes precedence over the staging system followed outside the RI.

Specifically,

- a). If a 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

recorded/followed outside the RI. These patients might have undergone some or all of the investigations outside the RI.

- a) In patients who have undergone 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 staging system followed at the RI is recorded, ignoring the staging system followed outside the RI,
  - ii. **if earlier details are not available** with or without further investigations at RI for conclusive staging, then staging done outside the RI is recorded.

## 2) Staging Done At

Under Item number 2, STAGING DONE AT, one of the below is to be ticked.

- (1) Reporting institution
- (2) Previous institution
- (8) Others (specify).....
- (9) Unknown

### *Explanation:*

- (1) If the stage in the referral letter does not correlate with clinical details given in the referral letter, then the restaging is done at RI from the clinical details given in the referral letter (if possible in consultation with the referral institute) and “staging done at” is entered as 1.
- (2) Previous institution: If the patient has received partial treatment\* prior to registration at reporting institution (RI), “staging done at” is entered as 2, if the clinical data correlates correctly with the staging mentioned in the referral letter.  
  
[If the stage in the referral letter does not correlate with clinical details given in the referral letter, then the restaging is done at RI from the clinical details given in the referral letter (if possible in consultation with the referral institute) and “staging done at” is entered as 1].
- (8) Others (specify).....: If the staging was done in situations other than mentioned above, e.g. at another specialized cancer management centre, before coming to the RI, the “staging done at” is entered as (8) with details.
- (9) Unknown: If the proper staging cannot be arrived at from the referral letter or if repeated attempt fails in getting the earlier clinical details then the “staging done at” is entered as 9.

**\* NOTE: The Patient Information Form allows identification of patients who receive Cancer Directed Treatment outside the Reporting Institution and this aspect will be taken into account in the analysis.**

**3) Clinical Stage - UICC**

Under this TNM stage should be documented as per UICC system. The details listed from item numbers 3.1 to 3.5 may be ticked as observed.

**3.1 TNM with description**

Under item 3.1, the following details have to be recorded.

(i) Tumour Size (in cms.): .....X.....

(ii) Axillary Lymph Node(s): 1) Not Present 2) Present  
 If present, Number:  
 Size (in cms.) of largest node.....x...  
 Whether Matted : 1) No 2) Yes  
 Whether Fixed : 1) No 2) Yes

(iii) Supra-Clavicular Node(s): 1) Not Present 2) Present  
 If present, Number:  
 Size (in cms.) of largest node:.....x.....  
 Whether Matted: 1) No 2) Yes  
 Whether Fixed: 1) No 2) Yes

(iv) Skin Involvement: 1) No 2) Yes  
 If yes, *not present Present*  
 Ulcer  
 Peau-de-orange  
 Infiltration  
 Satellite Nodule  
 Others (specify).....

*Explanation:*

(i) Tumour Size (in cms.): .....X.....: The size of the primary in its greatest diameter and in a line perpendicular to the greatest diameter (WHO) in centimetres has to be recorded.

(ii) Axillary Lymph Node(s): Careful clinical examination of the ipsilateral axilla is mandatory. Depending on whether the nodes are palpable or not the respective box may be ticked.

If present,

Number: Number of palpable node(s) is recorded.

Size (in cms.) of largest node:.....x.....: The size of the node in its greatest diameter and in a line perpendicular to the greatest diameter (WHO) in centimetres has to be recorded.

Whether Matted: Ticked as either 1) No or 2) Yes

Whether Fixed: Ticked as either 1) No or 2) Yes

In case of doubt, with any of the above findings, the “lower stage” is to be ticked.

- (iii) Supra-Clavicular Node(s): Careful clinical examination of the ipsilateral supraclavicular area is mandatory and if the nodes are palpable, ticked as present otherwise ticked as not present. In case of doubt enlargement of node(s), the code is ticked as not present.

If present,

Number: Number of palpable node(s) is recorded.

Size (in cms.) of largest node:.....x.....: The size of the node in its greatest diameter and in a line perpendicular to the greatest diameter (WHO) in centimetres has to be recorded.

Whether Matted: Ticked as either 1) No or 2) Yes

Whether Fixed: Ticked as either 1) No or 2) Yes

In case of doubt with any of the above findings the “lower stage” is to be ticked.

- (iv) Skin Involvement: Should be ticked either 1) No or 2) Yes

If the skin involvement is 2) yes, the following codes are to be ticked as *not present* or *present*. This is to document the exact nature of skin involvement.

Ulcer: Ulceration of the skin over the breast as not present or present.  
Peau-de-orange: Peau-de-orange appearance of the skin over the mass as it is or when the skin over the swelling is “pinched”, is recorded as present or not present.

Infiltration: Induration or thickening of epidermis of the skin over the swelling is recorded as not present or present. Tethering of the skin to the swelling, without induration or thickening of skin, is coded as infiltration not present.

Satellite Nodule(s): Presence of tumour nodules discrete from the primary *in the skin of ipsilateral breast* is recorded as not present or present.

Others (specify).....: Any other clinical findings not fitting to the above codes e.g. inflammatory carcinoma, is recorded here as not present or present.

### 3.2 TNM stage

Under item number 3.2, clinical T, N, M and details has to be documented. One of the following of T has to be ticked as per the guidelines of TNM UICC/ AJCC staging system.

TX T0 Tis Tis (DCIS) Tis (LCIS) Tis (Paget)  
T1 T1a T1b T1c  
T2 T3  
T4 T4a T4b T4c T4d

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

NX N0 N1 N2 N2a N2b  
N3 N3a N3b N3c

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

Mx M0 M1: The site of metastases in the presence of M1 disease is documented as per the coding of TNM staging UICC.

#### *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 only the higher or the main stage – e.g. recording should be T1a or T2a, rather than T1, T2.
- 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.

### 3.3 Stage grouping

One of the items below may be ticked as per the recommendations of TNM staging, UICC 2003.



0 I IIA IIB IIIA IIIB IIIC IV

*Explanation:*

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

**4) Investigations for Staging**

Under item 4, all the investigations done primarily to assess the extent of the disease (stage of disease), and the investigations to assess the status of the patient are documented.

Yes	No		
Mammography*			
Chest X-ray film			
Ultrasound – Abdomen & Pelvis			
Bone Scan			
Others (specify).....			
*If Mammography is done:	Normal	Abnormal	Inconclusive

*Explanation:*

The following codes are to be ticked yes and no depending on the workup.

- a) Mammography: This is an important investigation, recommended for routine screening for breast cancer in Western countries. If the mammography is ticked as yes, then the findings are categorized to normal, abnormal, inconclusive and recorded accordingly.
- b) Chest x-ray in postero-anterior (PA) view, taken either in miniature or regular film.
- c) Ultrasonogram of abdomen and pelvis should be recorded.
- d) Bone Scan: Bone scan in symptomatic patients with early stage disease and routinely in advanced stage disease is recommended.
- e) Others (specify).... Includes investigations not listed above and the said investigation(s) should be documented e.g. ultrasonograph of the primary lesion, CT scan, MRI etc.

List of the above investigations should be ticked as not done or normal. When an investigation shows abnormality, impression/summary of the findings are documented, in brief, in the space provided. No provision has been made to record the details of the findings in any particular standardised format.

*Conditions:*

- a) Haemogram (haemoglobin, total WBC count, differential WBC count, and platelet count) and Biochemical investigations are considered as routine and it is presumed that treatment is instituted when they are normal. Hence, no

column is provided to record the findings of these two investigations. If there are any abnormalities, they can be recorded. Biochemistry investigations include the following: estimation of blood sugar (fasting/random & post prandial); blood urea & serum creatinine (renal function tests); total protein, albumin & globulin; serum bilirubin, alkaline phosphatase, SGOT & SGPT (liver function tests).

- b) The criteria for TNM staging are by physical examination and imaging (e.g. mammography for the primary). There are no specified imaging investigation criteria in Breast Cancer unlike in carcinoma cervix FIGO staging. There are no fixed criteria about CT scan, MRI or ultrasound imaging in the staging criteria for Breast cancer.

#### **5) The actual assessment of staging was done by**

The process of consensus reached in documenting staging is recorded here and the appropriate item ticked.

- (1) One Consultant Oncologist (CO) only
- (2) Two COs from same department
- (3) Two COs from different departments
- (4) Tumour Board/Joint Clinic
- (8) Others (specify).....
- (9) Unknown

*Explanation:*

- a) In cancer cervix, FIGO recommends staging by two CO's from different departments but may not be feasible in all situations. As an extension of the same principle, the format has included the same criteria in breast cancer to highlight the need for inter-observer consensus in the staging procedure.
- b) The staging assessment done at Tumour Board/Joint clinic will be accorded highest quality followed by two COs from different departments. This will be one of the points for the assessment of the quality of the data.

#### **D. DETAILS OF CANCER DIRECTED TREATMENT (CDT)**

Under section D all the details of the treatment at is documented.

#### **6) Treatment Given Prior to Registration at RI**

Under this, one the following items below has to be ticked.

- (0) No
- (2) Yes
- (9) Unknown

*Explanation:*

- a) Patients who undergo either surgery / radiotherapy / chemotherapy or any combination therapy, outside the reporting institution, are ticked as (2) YES.
- b) Patients who **do not** undergo either surgery / radiotherapy / chemotherapy / any combination therapy, outside the reporting institution, are ticked as (0) 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.

**6.1 TYPE OF PRIOR TREATMENT GIVEN**

- (1) Surgery Yes/ No/ Unknown / If yes. Date
- (2) Radiotherapy
- (3) Chemotherapy
- (8) Others (specify)....

*Explanation:*

*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 ticked accordingly.

If yes, DATE

Under this Item, the date of commencement of first treatment either surgery or radiotherapy or chemotherapy or any other therapy outside the RI is entered here.

*Conditions:*

This is an important column in terms of future analysis, since the date of start of treatment is used for comparison of survival and hence the date should be accurate.

## 6.2 DETAILS OF PRIOR TREATMENT

All the details of the treatment given prior to further treatment at RI is entered.

### *Explanation:*

Patients, who have undergone treatment before registration at reporting institution, may represent a different set of patients in terms of diagnostic work-up and treatment given. Details of stage and treatment may not be completely available for all patients in this category. Lastly, in terms of assessing disease outcome and survival they may not be truly representative of the experience of the patients of the reporting institution. Point number 6.2 allows a “free hand” entry of as much complete data as possible in brief, about the previous treatment in this group of patients. The data of this group of patients will be analysed separately for obvious reasons.

## 7. TREATMENT GIVEN AT REPORTING INSTITUTION

Items 7.1 to 14, provide a framework to record the various types of treatment given at the reporting institution. It also includes recording of few other observations like performance status prior to and after treatment and details of surgical histopathology findings. The delivery of different modalities of treatment could be spread over a period of time. However, it is desirable that on every occasion when treatment is given, that, the updated information is transmitted forthwith to NCRP.

### 7.1 INTENTION TO TREAT

Under sub-item 7.1 one of the following has to be ticked

- (1) Curative
- (2) Palliative
- (3) No treatment \*[Wrongly printed in form as (4)]
- (9) Unknown

### *Explanation:*

- (1) *Curative*: 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 patients symptoms (so called “radical treatment with palliative intent”) over shorter or longer duration, (2) palliative should be ticked.

- (3) *No treatment*: When no treatment is intended. \*[Wrongly printed in form as (4)]
- (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.

## **7.2 IF PALLIATIVE YES,**

*Importance:*

In order to study the pattern of palliative care, this item is necessary. The palliative care could be any of the specific therapy of surgery radiotherapy, chemotherapy, pain relief or management of patient with the general palliative measures e.g. symptomatic management. The extent of provision of palliative care would be one of the important indicators of quality of cancer care delivery.

**NOTE: This item number 7.2 is not filled (should be left blank), if code number (4) (Pain & Symptom Relief) in Item number 7.1 is ticked.**

Item number 7.2 could be the only portion to be ticked when no curative treatment is given. With substantial number of patients presenting with advanced disease in our set up, it is desirable to have follow-up of these patients as scrupulously as possible, on similar lines of radically treated patients.

*Explanation:*

- (1) Palliative RT only:
- (2) Palliative RT + CT
- (3) Palliative CT only
- (4) Pain and symptomatic relief drugs (specify)
- (5) Palliative surgery
- (8) Others, specify.....
- (9) Unknown

The given codes are self-explanatory. Multiple ticking is allowed, e.g. palliative RT and palliative surgery.

## **7.3 TYPE OF CDT PLANNED AT RI**

Under the sub-item of 7.3, one of the following has to be ticked. **Item number**

**7.3 is not filled, if code number (3) in Item number 7.1 is ticked.**

- (1) Surgery
- (2) Radiotherapy
- (3) Chemotherapy
- (8) Others (specify)....
- (9) Unknown

*Explanation:*

*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, code (8) others (*specify*) should be ticked Yes, and the type of therapy has to be recorded. If no other therapy is given then No has to be ticked
- (9) *Unknown:* when the type of treatment given is unknown.

Conditions:

This refers to the initial plan of treatment as decided by the consultant or tumour board/joint clinic. Subsequent addition or deletion of a particular modality does not alter the initial entry.

## **8. PERFORMANCE STATUS (WHO) BEFORE TREATMENT AT RI**

Under item 8, one of the following has to be ticked.

- (0) Able to carry out all normal activity without restriction
- (1) Restricted in physically strenuous activity but ambulatory and able to carry out light work
- (2) Ambulatory and capable of all self-care but unable to carry out any work; up and about 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
- (9) Unknown

*Explanation:*

This is as per the WHO 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 code i.e., better performance status should be selected. This is to give the benefit of doubt so as to consider more aggressive therapy.

## **9. Surgery**

### **9.1 Under item 9.1, one of the following is to be ticked.**

- (0) Surgery not planned
- (1) Yes, done as planned
- (2) Surgery planned but not done
- (8) Others (specify).....
- (9) Unknown

*Explanation:*

- (0) *Surgery not planned:* This code is ticked when surgery is not selected as an option of treatment, alone, or in combination.
- (1) *Yes, done as planned:* This code is ticked when patient undergoes surgery as planned (alone or in combination).
- (2) *Surgery planned but not taken:* This code is to be ticked when surgery is selected as an option of therapy (alone or in combination) but, either patient refuses surgery or patient is not taken up subsequently for surgery or is not done due to cancellation of procedure for any reason.
- (8) *Others (specify):* This code has to be ticked in situations mentioned other than code (1) and (2). e.g. when patient is planned and taken up for radical/conservative surgery but changed to palliative on the table.
- (9) Unknown

*Conditions:*

- a) Surgery yes, done as planned/advised is to be ticked;
  - i) If the type of surgical procedure is modified or deviated from what was initially planned, while performing the surgery e.g. radical to conservative or vice versa, then also this item has to be ticked. This is

because the intention, which is curative treatment, of both the procedures is the same. However, this cannot be ticked if the change is from radical to palliative type or vice versa.

- ii) This item has to be ticked also for patients who have undergone Surgery outside the RI and subsequently undergo revision surgery at the RI. This could be because of incomplete surgery done outside the RI. For example, extended simple mastectomy could be carried out for inadequate wide excision done outside.
- iii) This item has to be ticked also for patients who have undergone Surgery outside the RI and subsequently undergo salvage surgery for either macroscopic or microscopic residual lesion, before or following radiotherapy.
- iv) This item has to be ticked also for patients who have undergone Surgery of primary outside, and axillary dissection at RI.
- v) If patients undergo salvage surgical therapy, planned at the outset or decided subsequent to chemotherapy/radiotherapy (e.g. primary radiotherapy\*) for residual disease.

Primary radiotherapy by definition is the form of radiotherapy given in organ preservation therapy of carcinoma of the breast.

- b) Patients treated earlier at RI and undergoing salvage Surgery for **recurrence of disease** do not come under the category of Surgery per se. The details of salvage Surgery does not come, here, under the point no. 9, but is entered in the treatment of residual /recurrent lesion under point no.16.3.

## 9.2 If Surgery yes, TYPE OF SURGICAL PROCEDURE

Under item 9.2 types of surgical procedure(s), code as given below is to be ticked along with date(s) (in the order of date/month/year) of the surgical procedure.

Date(s)

- (1) Lumpectomy/Quadrantectomy
- (2) Lumpectomy/Quadrantectomy + Axillary clearance
- (3) Simple Mastectomy
- (4) Simple Mastectomy + Axillary clearance (ESM)
- (5) Modified Radical Mastectomy
- (6) Radical Mastectomy
- (7) Toilet Mastectomy



- (8) Others (specify)....
- (9) Unknown

*Explanation:*

- (1) Lumpectomy/Quadrantectomy: This code is to be ticked when the surgery is the removal of mass with margin or removal of one quadrant of breast.
- (2) Lumpectomy/Quadrantectomy + Axillary clearance: This code is to be ticked when the surgery is the removal of mass with margin or removal of one quadrant of breast along with removal of Level I and/or II, and/or III axillary nodes.
- (3) Simple Mastectomy: This code is to be ticked when the surgery is removal of the entire involved breast.
- (4) Simple Mastectomy + Axillary clearance (ESM): This code is to be ticked when the surgery is the removal of the entire involved breast along with removal Level I and/or II, and/or III axillary nodes.
- (5) Modified Radical Mastectomy: This code is to be ticked when the surgery is the removal of the entire involved breast along with removal of Level I, II, & III axillary nodes and pectoralis minor muscle.
- (6) Radical Mastectomy: This code is to be ticked when the surgery is the removal of the entire involved breast along with removal of Level I, II, & III axillary nodes, pectoralis minor and pectoralis major muscle.
- (7) Toilet Mastectomy: This code is to be ticked when the surgery is the removal of lump with or without clear margin as a palliative procedure.
- (8) Others (specify) : This code is to be ticked when the surgery is other than listed above e.g. skin sparing mastectomy.
- (9) Unknown

There could be more than one surgical procedure, in which case name of the procedures with dates (in the order of date/month/year) has to be recorded.

*Conditions:*

Under item 9.2 the date of patient undergoing surgery at RI only, is recorded. In case the re-surgery is done at RI for inadequate surgery done prior to registration at the RI, then the date of **re-surgery only** is entered under item 9.2 (procedure and date of surgery done outside is entered under item number 6).

### **9.3 Axillary Clearance**

Under item number 9.3 one the following codes has to be ticked

- (0) Not Done

- (1) Done
- (2) Sentinel
- (9) Unknown

If Done,  
Date(s)  
Level I  
Level II  
Level III  
Unspecified

*Explanation:*

With the conservatism being the vogue in the removal of axillary nodes, axillary surgery in cancer breast is more appropriately called as axillary clearance (in lieu of older term - axillary dissection). With the development of sentinel node biopsy the axillary clearance is further categorized to three levels in relation to pectoralis minor.

Level I: This code is to be ticked when the axillary nodes below the level of pectoralis minor muscle are cleared.

Level II: This code is to be ticked when the axillary nodes behind the pectoralis minor muscle are cleared.

Level III: This code is to be ticked when the axillary nodes above the level of pectoralis minor muscle are cleared, with or without apical nodes (retroclavicular node(s)).

Unspecified: This code is to be ticked when the clearance of axillary nodes is not clear in relation to pectoralis minor muscle.

The provision is made for entry of dates for each Level code, in case the axillary clearance of nodes of different levels are done during different dates.

#### **9.4 Reconstruction**

Under item number 9.4, one of the codes is ticked and the date (in the order of date/month/year) is entered whether the reconstruction procedure is done or not.

- (0) Not Done
- (1) Done
- (9) Unknown

If Done, type ..... Date- dd/mm/yy

*Explanation:*

Self-explanatory

Importance:

Reconstruction procedure is becoming more common consequent to quality of life issues in recent years.

## 10. Surgical Histopathology Findings

When surgery is part or the sole treatment modality in a patient with breast cancer, the histopathological details for the following codes are recorded.

10.1) pT size (in cms.) .....X.....

10.2) Tumour Origin: (1) Single 2) Multicentric

10.3) Modified Richardson Bloom Score .....

Not Applicable      Positive      Negative      Unknown

10.4) EIC

10.5) Cut Margin

10.6) Lymphatic Invasion

10.7) Nipple/Skin Involvement

10.8) Oestrogen Receptor Status

10.9) Progesterone Receptor Status

10.10) Cerb B2

10.11) Number of Axillary Nodes Removed      Number showing tu-  
mour

*Explanation:*

The codes are self-explanatory.

### !0.12) Pathological stage

Under item number 10.12, pathological as pT, pN, pM and details has to be documented.

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

- pTX pT0 pTis
- pT1 pT1a pT1b pT1c

pT2 pT3  
pT4 pT4a pT4b pT4cpT4d

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

pNX pN0 pN1 pN1mi pN1a pN1b pN1c  
pN2 pN3 pN3a pN3b pN3c

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

pMx pM0 pM1: The site of metastases in the presence of pM1 disease, is documented as per the coding of TNM staging UICC.

*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 the higher or the main stage – e.g. recording should be pT1a or pT4a rather than pT1, pT4.
- b) When in doubt the staging should be preferably done by the Tumour board / Joint clinic. If 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 pT1a and pT1b in a particular patient, then the stage is entered as pT1a.
- 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.

**10.13) R Classification**

Under item 3.4 presence of residual disease after treatment may be described by the symbol R and one of the following is to be ticked.

RX R0 R1 R2

*Explanation:*

- a) RX : When presence of residual tumour cannot be assessed, this code is to be ticked.
- b) R0: When there is no residual tumour this code is to be ticked.

- c). R1: When there is presence microscopic residual tumour this code is to be ticked.
- d) R2: When there is presence of macroscopic residual tumour this code is to be ticked.

**11) Radiotherapy**

**11.1 Under item 11.1, one of the following codes is to be ticked**

- (0) Radiotherapy (RT) not planned
- (1) Yes, RT given as planned
- (2) Yes, RT given, but incomplete (*specify reason*).....
- (3) RT planned but not taken (*specify reason*).....
- (8) Others (*specify*).....
- (9) Unknown

*Explanation:*

- (0) *Radiotherapy (RT) not planned:* This code is ticked when Radiotherapy is not selected as an option of treatment alone or in combination.
- (1) *Yes, RT given as planned:* This code is ticked when patient undergoes Radiotherapy as planned (alone or in combination).
- (2) *Yes, RT given, but incomplete (specify reason):* This code is to be ticked when Radiotherapy is selected as an option of therapy (alone or in combination) but the patient discontinues treatment before the planned dose completed. The reason for the discontinuation is to be documented.
- (3) *RT planned but not taken (specify reason):* This code is to be ticked when Radiotherapy is selected as an option of therapy (alone or in combination) but either patient refuses Radiotherapy or patient is not taken up for Radiotherapy for any recorded reason.
- (8) *Others (specify):* This code is to be ticked in situations mentioned other than code (1) and (2). e.g. when patient is planned and taken up for radical external/ Brachytherapy, but changed to palliative midway during the therapy.
- (9) *Unknown:* When the treatment status of radiotherapy is unknown.

*Conditions:*

- (0) Radiotherapy (RT) not planned: This code has to be ticked:
  - (a) If radiotherapy is not planned or not indicated for any reason.

- (b) If the patients were treated outside the RI and present with recurrence/metastasis and who are taken up for RT at the RI. In such instances, the details of radiation does not come under this Item no. 11, instead it is entered in the treatment of recurrent lesion under the Item no.16.
- (1) Yes, RT given as planned: This code is to be ticked,
    - (a) Even if the type of Radiotherapy procedure is modified during Radiotherapy from the initial planned Radiotherapy e.g. external to brachytherapy or vice versa (since intention of both the procedures are the same),
    - (b) Patients treated partially outside RI and subsequently undergoing additional radiotherapy, e.g. boost radiotherapy with electron beam.
    - (c) Patients treated initially outside RI and subsequently undergoing additional radiotherapy for residual disease.

The details of re-radiation does not come under this Item, instead, it is entered in the treatment of recurrent lesion under the Item 16 (no 16.3,16.5 and 16.6).

## **11.2. Type of RT**

Under item number 11.2, one of the following codes is to be ticked.

- (1) Teletherapy (External RT)
- (2) Brachytherapy
- (3) 3D Conformal
- (4) IMRT
- (5) Electron Beam
- (8) Others (*specify*).....
- (9) Unknown

### *Explanation:*

- (1) Teletherapy (External RT): This should be ticked when the patient has received external radiotherapy (EXT). Source used in EXT could be either linear accelerator or 60-Co machine. The type of EXT is usually photon or rarely per-operative electron beam therapy.
- (2) Brachytherapy (BT): This should be ticked when the patient receives BT alone or with EXT. The BT is usually afterloading technique and could be manual or remote, interstitial, low dose rate (LDR) or High Dose Rate (HDR).
- (3) 3D conformal: This is to be ticked when conformal therapy is used.

- (4) IMRT: This is to be ticked when Intensity Modulated Radiotherapy (IMRT) is used.
- (5) Electron beam: This is to be ticked when Electron beam is used. (8) Others (specify)....: This is to be ticked when types of radiotherapy other than the above mentioned are used e.g. radioisotopes for bone metastases.
- (9) Unknown:

**11.3 Details of External RT:**

Under the item number 11.3, the following entry is to be recorded.

Breast /Chest	Axilla	Supra Clav	Boost Others
Wall	Int.mammary	Specify	

Technique specify).....

Type of beam (Photon/Electron)

.....  
 Energy .....

Field Size .....

Field/day .....

Total Tumour Dose (cGy)  
 .....

Total No. Of Fractions  
 .....

Fractions/week.....

Regions of Irradiation  
 Interruption – Yes(y) / No (N)  
 .....

Date first started  
 Date last ended

*Explanation:*

Details for each of the following codes (given vertically) should be entered separately for the 5 sub-codes (given horizontally);

Codes given vertically:

**Technique (specify)**

Under this code, the technique for each of the sub-codes is to be recorded. The

technique could be tangential technique with or without wedge pair; vertical, appositional or arc technique for electron beam. For axillary & supraclavicular irradiation, it could be direct antero-posterior or oblique antero-posterior. For internal mammary node it could be antero-posterior or matched (to tangential breast/chest wall portal) oblique technique.

Type of beam (Photon/Electron)

Type of beam used i.e. linear accelerator (LA) or 60-Co beam (Co) or electron beam (EB). In case multiple beams are used e.g. LA and/or EB, the same entered as LA/EB for each sub-codes given horizontally.

### **Energy**

Energy of the photon/electron beam used i.e. 4 MeV, 6 MeV, 9MeV, 12 MeV, 18 MeV etc.;

### **Field size: in centimetres.**

Dimensions of all fields are to be recorded. Size/area of the shielded area can be mentioned as optional.

### **Field(s) per day:**

Has to be recorded when all the fields are not treated daily.

### **Total Tumour Dose (cGy):**

The prescribed dose of radiotherapy is to be recorded in cGy for each of the sub-codes. If the dose is prescribed at a certain depth the same should be recorded.

### **Total number of fractions:**

This is to be recorded separately for each of the horizontal sub-codes.

### **Fractions /week:**

Number of fractions per week should be recorded here which could be conventional 5 fractions per week or <5 fractions per week or more than 1 fraction per day (hyper fractionation).

### **Regions of irradiation:**

Here the structures included in the portal should be listed e.g. breast or chest wall, axillary nodes levels, supraclavicular nodes, internal mammary nodes, area



of lung (0 or 1 or 2 cm of lung), mediastinum or cardia etc.

Date first started:

This is the date of start of first fraction of EXT in the order of date/month/year.

Date last ended:

This is the date of last fraction of EXT, including that of boost radiotherapy in the order of date/month/year.

Sub-codes given horizontally:

- i) Breast: Applicable when RT is given to intact breast after conservative surgery.
- ii) Chest wall: Applicable when RT is given after the removal of the breast,
- iii) Axilla (ipsilateral): Applicable when radiation delivered to ipsilateral axillary Level I and II are included in the tangential portals.
- iv) Supraclavicular: Applicable when supraclavicular nodes are irradiated, including the apical node of the axilla.
- v) Boost to the chest wall/intact breast/ tumour bed (excluding axilla).
- vi) Others specify; Applicable when ipsilateral internal mammary nodes are radiated or when axillary boost is delivered or radiation in situations other than that mentioned above.

Note: The first two sub-codes of i).breast and ii).chest wall are mutually exclusive.

**11.4. Details of Brachytherapy:**

Under item 11.4 details of the Brachytherapy has to be entered. In breast cancer, the type of Brachytherapy is usually interstitial. If not, the type of Brachytherapy should be recorded.

	I	II	III	IV	V	>V
Date						
Type of Dose Rate (LDR/MDR/HDR)	.....	.....	.....	.....	.....	.....
Prescribed dose in cGy	.....	.....	.....	.....	.....	.....
Dose rate in cGy.	.....	.....	.....	.....	.....	.....
Volume of treatment	.....	.....	.....	.....	.....	.....
Date first started	Date last ended					

**Date:**

Date(s) for the single or more than single sessions of BT are recorded (indicated with roman letters I to >V), which could be as much as >5 sessions in HDR Brachytherapy. In case more than 5 sessions are used the date of last session has to be recorded in the last column.

**Type of Dose Rate:**

If type of dose rate used is similar in all sessions then only in the first column the data need to be entered, and by default entry in the other columns are considered as ditto.

**Prescribed Dose in cGy:**

The method adopted for the prescription of dose and the prescription point for the BT must be entered in this code.

**Dose rate in cGy:**

Actual dose rate of the dose prescription point should be entered here.

**Volume of treatment**

The calculated volume of dose prescribed is entered here.

**Date first started:**

This is the date of start of first session of BT in the order of date/month/year.

**Date last ended:**

This is the date of last session of BT, in the order of date/month/year.

**12) Chemotherapy****12.1 Under item 12.1, one of the following codes has to be ticked.**

- (0) Chemotherapy (CT) not planned
- (1) Yes, CT given as planned
- (2) Yes, CT given, but incomplete
- (3) CT planned but not taken
- (8) Others (specify).....
- (9) Unknown

*Explanation:*

- (0) Chemotherapy not planned: This code is ticked when Chemotherapy is not selected as an option of treatment alone or in combination.
- (1) Yes, CT given as planned: This code is ticked when patient undergoes Chemotherapy as planned (alone or in combination).
- (2) Yes, CT given, but incomplete: This code is ticked when patient does not complete the scheduled course of CT.
- (3) Chemotherapy planned but not taken: This code is to be ticked when Chemotherapy is selected as an option of therapy (alone or in combination) but either patient refuses Chemotherapy or does not receive the planned CT.
- (8) Others (specify)..... : This code is to be ticked in situations mentioned other than code (1) and (2) e.g. when patient is planned and taken up for radical chemotherapy, but plan is changed to palliative therapy.
- (9) Unknown

*Conditions:*

- (a) Patients who undergo chemotherapy outside the RI and subsequently undergo chemotherapy for recurrence of disease at RI do not come under this category of chemotherapy and therefore this group of patients are not eligible to be entered in the item number 12.1. In fact the details of chemotherapy in this group of patients is entered in the treatment of recurrent lesion under the point no.16.3.
- (b) The item 12.1 should be entered,
  - i) If the patient undergoes CT afresh at RI;
  - ii) If the patient undergoes part of the CT outside RI and part of treatment at RI or vice versa;
  - III) Patients undergoing salvage chemotherapy for residual disease, either treated outside the RI with initial CT or treated at RI from the beginning.

**12.2 If Yes, Type of CT**

Under item 12.2, one of the following code is to be ticked

- (1) Anterior/neo-adjuvant/induction
- (2) Concurrent
- (3) Adjuvant
- (4) Combination of any of the above
- (8) Others (specify).....
- (9) Unknown

*Explanation:*

- (1) Anterior/neo-adjuvant/induction: This is to be ticked when CT is given before radiotherapy or surgery.
- (2) Concurrent: This is to be ticked when CT is given during radiotherapy/ surgery concurrently.
- (3) Adjuvant: This is to be ticked when CT is given after surgery or radiotherapy.
- (4) Combination of any of the above: This is to be ticked when patient receives combination of any two or three of the above CT schedules.
- (8) Others (specify).....: This is to be ticked when the patient receives treatment other than the one mentioned above e.g. patient receiving palliative chemotherapy only in the metastatic stage. / treatment of residual disease.
- (9) Unknown

**12.3 Other Details of CT**

Under item 12.3, the following details of chemotherapy are to be recorded.

Height in cms.	Weight in Kg.						
Cycles	I	II	III	IV	V	VI	>VI
Regimen	_____	_____	_____	_____	_____	_____	_____
Date(s)							
Day(s)	_____	_____	_____	_____	_____	_____	_____
Drug (s) (Name & Dose)	.....						
	.....						
	.....						
	.....						
	.....						

Date of start of First Cycle of CT  
Date of completion of Last Cycle of CT

*Explanation:*

**Cycles:** The cycles (I II III IV V VI >VI) received by the patient should be rounded of. If more than 6 cycles are given, the last code is rounded.

**Regimen:** In this code type of regimen in each cycle should be written since

different regimen could be given with each cycle. Name (if not well known)/acronym (if well known) of the drug if single, or names (if not well known)/acronym (when well known) of the combination CT schedule, should be entered here.

**Date(s):** Dates of each cycle is entered here. If more than 6 cycles are given, then the date of the last cycle is entered, ignoring the dates between cycle 5 and the last cycle.

**Day(s):** For each cycle the first day of administration of that particular cycle is entered as Day 1 and subsequent days are entered in relation to first day e.g. Day 1 & 8.

**Drug (s)**

**(Name & Dose):** Here the name/acronym (if well known) of each drug for each cycle with dosage is written. Use of non-proprietary name is recommended. The dose per meter square area and total dose received should be specified. If the patient receives more than 6 cycles, then the name and dose of the drugs used in the last cycle is given ignoring the name and dose between cycle 5 and the last cycle. Reasons for dosage modification or delays in drug administration are recorded in the last line.

**Date of start of First Cycle of CT:** Here the date of first day of first cycle of CT is entered. The entry should be in date/ month / year format.

**Date of completion of Last Cycle of CT:** Here the date of last day of last cycle of CT is entered. The entry should be in date/ month / year format.

12.4 If Neo-Adjuvant CT is given, response of Disease (Adopted from WHO)  
Under item 12.4, one of the following codes has to be ticked when the treatment given is Neo-Adjuvant CT. This item applies to the response of the primary and axillary nodes together

- (0) Neo-Adjuvant CT not received
- (1) Complete response –  
No Evidence of Disease
- (2) Partial response
- (3) No change
- (4) Progressive disease
- (9) Unknown

*Explanation:*

- (0) CT not received – when Neo-Adjuvant CT is not given.

- (1) Complete response –No Evidence of Disease: This code is to be ticked when there is complete disappearance of all known disease, determined by 2 observations not less than 4 weeks apart.
- (2) Partial response: This code is to be ticked when estimated decrease in tumour size is 50% or more, determined by 2 observations not less than 4 weeks apart.
- (3) No change: No significant change for at least 4 weeks. This includes estimated decrease of less than 50%, stable disease without any change in the size of the lesion or increase of <25% in size.
- (4) Progressive disease: This code is to be ticked when there is appearance of any new lesion not previously identified or estimated increase of 25% or more in existing lesions.
- (9) Unknown

*Conditions:*

In case of multiple lesions of primary or axillary/supraclavicular nodes the poorest of responses will have to be ticked.

12.5 Date (s) of assessment of response to Neo-Adjuvant CT:

*Explanation:*

The two dates, recorded in the order of date/month/year, will show the interval between the two observations in the assessment of the response. To fulfil the WHO criteria of assessment of response the interval between the two dates should not be less than 1 month.

**13) Hormone Therapy**

Under item 13, one of the following codes is to be ticked.

- (0) Hormone therapy (HT) not given
- (1) Yes, HT given as adjuvant
- (2) Yes, HT given, as Neo-adjuvant
- (3) Yes, given for metastasis
- (4) Yes, HT given, but incomplete (*specify reason*).....
- (5) HT advised/planned but not taken (*specify reason*).....
- (8) Others (*specify*).....
- (9) Unknown

*Explanation:*

- (0) HT not given: This code is ticked when HT is not selected as an option of treatment alone or in combination.
- (1) Yes, HT given as adjuvant: This code is ticked when patient undergoes adjuvant HT as planned (alone or in combination).
- (2) Yes, HT given, as Neo-adjuvant: This code is ticked when patient undergoes Neo-adjuvant HT as planned (alone or in combination).
- (3) Yes, given for metastasis: This code is ticked when patient undergoes adjuvant HT as planned (alone or in combination) in the treatment of distant metastases.
- (4) Yes, HT given, but incomplete (*specify reason*).....: This code is ticked when patient is started on HT (alone or in combination) but does not complete the intended course.
- (5) HT advised/planned but not taken (*specify reason*).....: This code is to be ticked when HT is selected as an option of therapy (alone or in combination) but either patient refuses HT or not given for other reasons.
- (8) Others (*specify*)..... : This code is to be ticked in situations mentioned other than code (0) to (5).
- (9) Unknown

*Conditions:*

- (a) Patients who have undergone HT outside the RI and subsequently undergo HT for recurrence of disease at RI do not come under this category of HT. Therefore this group of patients are not eligible to be entered in the item number 13.1. In fact the details of HT in this group of patients is entered in the treatment of recurrent lesion under the point no.13.1.
- (b) The item 13.1 should be entered,
  - i) If the patient undergoes HT afresh at RI
  - ii) If the patient undergoes part of the HT outside RI and part of Treatment at RI or vice versa
  - iii) Patients undergoing HT for residual disease, either treated outside the RI with initial HT or treated at RI from the beginning.

**13.1 If Yes, Type of HT**

Under item 13.1, one or more of the following codes has to be ticked.

- (1) Surgical :- Oophorectomy
- (2) RT:-Ovarian Ablation

- (3) Medical:- This could be Tamoxifen and/or Aromatase inhibitors
- (8) Others (*specify*).....

*Explanation:*

- (1) Surgical oophorectomy: When oophorectomy is done as a planned procedure during the initial therapy.
- (2) RT-ovarian ablation: When ovarian ablation is done using RT as a planned procedure during the initial therapy.
- (3) Medical: When drugs like anti-oestrogens / aromatase inhibitors are used as a planned procedure during the initial therapy.
- (8) Others (*specify*).....:When type of HT is other than given above this are to be ticked with reason.

**13.2 Details of HT**

Under item 13.2, the following details of HT have to be recorded.

Regimen specify .....

Date of start of of HT

Date of completion of HT

*Explanation:*

Regimen: Under this the type of regimen should be written. Name (if not well known)/acronym (if well known) of the drug if single, or names (if not well known)/acronym (when well known) of the combination HT schedule, should be entered here.

The dose of HT also must be recorded here.

Date of start of First regimen of HT: Here the date of first day of first regimen of HT is entered. The entry should be in date/ month / year format.

Date of completion of Last Cycle of CT: Here the date of last day of last regimen of HT is entered. The entry should be in date/ month / year format.

**13.3 Response of Disease (Adopted from WHO) to HT, when given alone.**

Under item 13.3, one of the following code is to be ticked when the HT treatment alone is given. This item applies to the response of the primary and axillary nodes together

- (0) HT not received
- (1) Complete response –



No Evidence of Disease

- (2) Partial response
- (3) No change
- (4) Progressive disease
- (5) NA / Adjuvant
- (9) Unknown

*Explanation:*

- (0) HT not received – when HT alone is not given.
- (1) Complete response –No Evidence of Disease: This code has to be ticked when there is complete disappearance of all known disease, determined by 2 observations not less than 4 weeks apart.
- (2) Partial response: This code has to be ticked when estimated decrease in tumour size is 50% or more, determined by 2 observations not less than 4 weeks apart.
- (3) No change: No significant change for at least 4 weeks. This includes estimated decrease of less than 50%, stable disease without any change in the size of the lesion or increase of <25% in size.
- (4) Progressive disease: This code has to be ticked when there is appearance of any new lesion not previously identified or estimated increase of 25% or more in existing lesions.
- (5) NA / Adjuvant: This code has to be ticked when HT is given with or without RT/CT in post-surgical situations and where the measurement of lesion is not applicable.
- (9) Unknown

*Conditions:*

In case of multiple lesions of primary or axillary/supraclavicular nodes, poorest of response designation shall prevail.

**13.4 Date (s) of assessment of response to HT alone:**

*Explanation:*

The two dates, recorded in the order of date/month/year, will show the interval between the two observations in the assessment of the response. To fulfil the WHO criteria of assessment of response the interval between the two dates should not be less than 1 month.

## 14. Complications During Treatment

Under item 14, the following details should be recorded.

- (0) No
- (2) Yes
- (9) Unknown

IF YES,

Nature of Complication(s)

Maximum Grade

Date of Onset (dd/mm/yy)

Resolved Yes No

Date last seen (if resolved) (dd/mm/yy)

*Explanation:*

- (0) No: To be ticked when no complications are seen
  - i. During surgery and within 28 days of surgery (the cut off day of 28 is arbitrary). Generally complications between 1<sup>st</sup> and 14<sup>th</sup> day are considered as acute complications and complications between 15<sup>th</sup> and 28<sup>th</sup> post-operative day are considered as subacute complications.  
AND
  - ii. During and within last day of Radiotherapy.  
AND
  - iii. During and within last day of last cycle of Chemotherapy.
- (2) Yes: To be ticked when complications are seen
  - i. During treatment or within 28 days of the surgery.  
OR
  - ii. When complications are seen during and within last day Radiotherapy.  
OR
  - iii. When complications are seen during or within last day of last cycle of Chemotherapy.
- (9) Unknown

*Conditions:*

For practical reasons no distinction is made between sequelae and complications. All radiation reactions, even the mild one (usually classified as grade I), should be documented. During analysis Grade I reactions can be analysed separately or can be excluded from analysis depending on the frequency of Grade II (complications of moderate severity responding to conservative management) and Grade III & IV (complications of serious nature requiring surgical intervention or death) complications.

IF YES,

**Nature of Complication(s):**

The type of complication is entered here. If more than one complications are present, entries are made in subsequent lines in chronological order.

**Maximum Grade:**

RTOG criteria for radiotherapy complications and CTC criteria are applied for chemotherapy complications.

**Date of Onset:**

Here the date of first observation of reaction/complication is entered.

**Resolved: Yes / No**

Here whether the documented complication is resolved or not is recorded.

**Date last seen:**

When the complication is considered as resolved YES, the date of last manifestation of complication is entered in this column.

Here the last date of reaction or complications observed is recorded

*Conditions:*

If the complication is persisting beyond the end of treatment, then complication is considered as not resolved. The subsequent entry of the presence of complication is continued in - item number 16.7 late complications of CDT and is recorded as resolved with date or as not resolved as the case may be.

In case there is a recurrence of complication after some time, once it has been assessed as resolved, then the recurrent complication should be considered as a fresh complication.

## 15. Performance Status at 6-12 weeks of completion of all of CDT

Under item 15, one of the following codes has to be ticked.

- (0) Able to carry out all normal activity without restriction
- (1) Restricted in physically strenuous activity but ambulatory and able to carry out light work
- (2) Ambulatory and capable of all self-care but unable to carry out any work; up and about 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
- (9) Unknown

*Explanation:*

Codes to be ticked are self-explanatory.

*Conditions:*

- (a) The treating clinician should ideally record this information. A social investigator or trained nurse could also record it under the guidance and supervision of the treating oncologist.
- (b) If in doubt, the performance status should be assigned a lower category i.e. a higher status so as to give the benefit of doubt and have scope for more aggressive therapy.

### 15.1 Date of Assessment of Performance Status:

*Explanation:*

The actual date of assessment is entered here in date/month/year format. (The assessment and recording of performance status is ideally at 6-12 weeks of completion of treatment).

## E. FOLLOW-UP INFORMATION

Items 16.1 to 16.7 deal with follow-up details and this is the most critical portion of this format.

**For the first follow-up the page in the main form is used. For subsequent follow-ups, every time different follow-up pages are used as a supplement.**

*Importance:*

Loco-regional recurrence: 1) Loco-regional recurrences are usually histologically verified. 2) A secondary cure after recurrence is possible. 3) The frequency

of loco-regional recurrence is an important indicator of quality of treatment (Bartelink et al., 2001). 4) Loco-regional recurrence is relevant to quality of life **even for patients with metastases** (Ref1. Relevance and feasibility of recording recurrence and metastases, Engel J et al., Chapter 15, p 77-79, 2003).

Metastases: Continuous recording of metastases enables description of the post metastases survival time. This is important because randomized trials regularly show improvements with innovative chemotherapy for highly selective cohorts. For 3215 patients, no improvement of survival after metastases was detected among breast cancer patients in the past 20 years (Engel J et al, 2003). The same was true for prostate and colo-rectal cancer; this is remarkable because metastasis surgery and chemo-embolization have been used more frequently in the last few years. These results remained metastases-free survival time (interval from M0 to M1) < 24 months, 24-48 months and >48 months. **Therefore, a) metastases is a proxy variable for cancer related death for most cancers; b)** further an evaluation of quality of death certificate declaration is possible. In a series, about 20% of all deaths certificates with breast cancer as the underlying cause of death were false positive – the diagnosis was real but at the time of death the patient was free of tumour (Heck et al., 1997; Pollock et al, 1995). For prostate cancer, the false positive rate was even higher. This phenomenon could explain why increasing incidence due to early detection by PSA did not lead to mortality reduction (Feuer et al., 1999). With a two-fold increase in incidence, the resulting artificial increase in mortality due to false positive death certification may have compensated for a true decrease in mortality (“Blame it on Cancer”) (Ref1. Relevance and feasibility of recording recurrence and metastases, Engel J et al., Chapter 15, p 77-79, 2003).

## **16 Date(s) of Follow-up**

## **Follow-up visit No.**

### *Explanation:*

Here date of follow-up along with follow-up visit number is entered.

### *Conditions:*

Regular follow-up is ensured, so as not to miss the findings or miss the cause of death. Prolonged interval between follow-ups may result in missing the clinical findings, which are dynamic in real life situations and there is a possibility of missing the real cause of death.

Therefore, a follow-up of at least once in three months has to be ensured, in order to fulfil data standards.

### **16.1 Method of follow-up**

- (0) No follow-up
- (1) Hospital visit

- (2) By post
- (3) Through telephone
- (4) Home visit
- (8) Other(s), specify.....

*Explanation:*

- (0) No Follow-up: This code is ticked when there is no follow-up of the registered patient.
- (1) Hospital visit: This is the ideal method of follow-up since it allows for proper clinical examination and investigations if necessary. Follow-up investigation would be symptom based. Ultrasonography abdomen can be done at regular intervals since it is non-invasive, has no side effect and probably gives maximum information about the disease status and abdominal structures with relatively less cost.

***When the patient has not made further visits to the hospital, then any or all of the following needs to be adopted:***

- (2) By post: Symptom(s) of the patient is given priority here and if necessary hospital visit is insisted.
- (3) Through telephone: Symptom(s) of the patient is given priority here and if necessary hospitals visit is insisted.
- (4) Home Visit: When both 2 and 3 above are not satisfactory and home visit is feasible, then home visit with patient's prior permission, is a viable option.
- (8) Other(s), Specify.....: This is ticked when any other method of follow-up other than the methods mentioned above is used. The method employed here should be specified.

***Conditions:***

**Partial period of follow-up will be censored during the survival analysis as per the method employed in the survival analysis. However, the total percent of no follow-up or partial follow-up at Five years should be no more than 15%. In fact, the all-important objective of this study is to have strategies of good follow-up in order to give proper national survival analysis results.**

**16.2 Vital status**

- (1) Alive
- (2) Dead
- (9) Unknown

*Explanation:*

The given codes are self-explanatory.

If the code (1) Alive in 16.2 is ticked then the following codes under various items should be entered

### **16.3. DISEASE STATUS (at Follow-up)**

- (1) No Evidence of Disease
- (2) Residual disease
- (3) Local recurrence
- (4) Regional/nodal recurrence
- (5) Distant metastasis: Specify site
- (9) Unknown

- (1) **No Evidence of Disease:** This has to be ticked for every follow-up period, only, if there is no evidence of disease detected either loco-regionally or systemically i.e. anywhere in the body.
- (2) **Residual disease only:** This has to be ticked if the patient had no complete response but the disease has remained same or if there is <25% increase in size during the specific period of follow-up.
- (3) **Local recurrence:** This has to be ticked if there is reappearance of the disease at the site of chest wall / ipsilateral breast tissue (when breast conservation therapy is done).
- (4) **Regional/nodal recurrence:** This has to be ticked if there is reappearance of disease in the axilla or supraclavicular region or internal mammary nodal area or in any combination.
- (5) **Distant metastasis:** Specify site – The anatomical site or sites of distant metastasi(e)s needs to be specified.
- (9) **Unknown**

#### *Conditions:*

- (a) The period of overall response lasts from the first day of the treatment to the first observation of progressive disease. The time to recurrence or death should be measured from the first day of the therapy [1].
- (b) There could be situations where there could be doubt regarding the presence/absence of disease with presence of symptoms/ clinical examination findings / investigation reports during the follow-up. In such situations, the disease status is considered as no evidence of disease and subsequently if the presence of disease is confirmed at later date, which matches with the earlier symptoms or findings, the date of recurrence or metastases of disease is considered from the date of development of first symptom or abnormal clinical/investigational findings i.e. backdated [1].

The date of recurrence or metastases should be revised and updated accordingly.

- (c) An independent reviewer if possible should confirm dates of first recurrence, metastases and death. Data based on suspicion alone should be verified in order to establish the accuracy. Case records of patients not reported as having recurrent disease should be scrutinized annually, by an independent reviewer [1].

16.4 If disease is present, indicate basis of diagnosis: Tick the following alone or in combination depending upon the procedures done to diagnose the recurrence/metastasis.

- (1) Histopathology
- (2) Cytopathology, other than FNAC
- (3) FNAC
- (4) Bone marrow
- (5) Peripheral smear
- (6) Radiological
- (7) Clinical
- (8) Other(s), Specify....:
- (9) Unknown

*Explanation:*

Codes 1-7 are self-explanatory.

- (8). Other(s), Specify...: Specify the basis of diagnosis if the method of diagnosis of recurrence/ metastases are none of the above. When the basis of diagnosis is based on communication (not in person) with the patient the same is mentioned in this column, along with the type of communication.

#### **16.5 Treatment if 16.3 above indicate presence of disease**

- (0) No treatment
- (1) Yes, treatment given
- (9) Unknown

*Explanation:*

- (0) No treatment: This has to be ticked when surgery / radiotherapy / chemotherapy/ hormone therapy/ any combination therapy is not contemplated/given for the recurrent / metastatic disease.
- (1) Yes, treatment given: This has to be ticked when surgery / radiotherapy /



chemotherapy/hormone therapy / any combination therapy is given for the recurrent / metastatic disease.

(9) Unknown

**16.6 If yes, Details of Treatment and Outcome:**

This item is left “free hand” to fill in as much details of treatment and subsequent outcome in a précis manner. In details of treatment, type of treatment is important. In outcome of treatment, the response of disease and disease status is important.

**16.7 Late Complications of Treatment**

Under item 16.7, the following details should be recorded.

(0) No

(2) Yes

(9) Unknown

The guidelines given under Item 14 may be used to complete this item and the other details there-of.

**17. Second Primary**

Under item number 19, one of the following has to be ticked.

(0) No evidence of second primary

(1) Yes, evidence of second primary

(9) Unknown

*Explanation:*

(0). No evidence of second primary.

(1). Yes, evidence of second primary: This is to be ticked if there is evidence of second primary

If Yes,

**17.1. Primary site of tumour (ICD-0-3)(Topography)**

**17.2. Primary Histology (ICD-0-3)(Morphology)**

**17.3. Secondary (metastatic) site of tumour (ICD-0-3)**

**17.4. Histology of Metastasis**

**17.5. Basis of Diagnosis:**

The above are completed as per the NCRP procedure manual.

Tick the following alone or in combination depending upon the procedures done to diagnose the recurrence/metastasis.

- (1) Histopathology
- (2) Cytopathology, other than FNAC
- (3) FNAC
- (4) Bone marrow
- (5) Peripheral smear
- (6) Radiological
- (7) Clinical
- (8) Other(s), Specify...:
- (9) Unknown

*Explanation:*

Codes 1-7 are self-explanatory

- (8) Other(s), Specify...: Specify the basis of diagnosis if the method of diagnosis of recurrence/ metastases are none of the above. When the basis of diagnosis is based on communication not in person with the patient the same is mentioned in this column, along with the type of communication.

### **17.6 Date of Diagnosis:**

*Explanation:*

If (1) of 17 is ticked, the date of diagnosis of second primary should be recorded here.

### **17.7 Details of Treatment and Outcome:**

*Explanation:*

This item is left “free hand” to fill in as much details of treatment and subsequent outcome in précis manner. In details of treatment, type of treatment is important. In outcome of the treatment, the response of disease and disease status is important.

## **18 If dead**

### **18.1 Cause of death:**

Under item 18.1 one of the following has to be ticked, if the patient had died

- (1) As a result of cancer
- (2) Most probably due to cancer
- (3) Intercurrent Death
- (4) Treatment related Death
- (8) Other(s), Specify.....
- (9) Unknown

*Explanation:*

When code (2) of item 16.2 is ticked, then one of the following must be ticked.

- (1) As a result of cancer:

When the cause of death is confirmed to be due to cancer e.g. Hospital death after investigations, this code should be ticked.

- (2) Most probably due to cancer: When death occurs in RI or a hospital, clinical findings indicating the presence of disease status but without confirmation through appropriate investigations, this code should be ticked. This code is also ticked if death occurs outside the hospital in a patient who is confirmed to have recurrent/metastatic or advanced disease by the investigations done earlier.
- (3) Intercurrent Death: When the patient is confirmed to have died of disease other than cancer, although cancer might have contributed to the cause of death, this code should be ticked.
- (4) Treatment related Death: This code is ticked when the patient dies of treatment related complications in the presence or absence of disease as confirmed by clinical examination or by investigations, even though disease might have contributed to the death.
- (8) Other(s), Specify.....: This code is to be ticked in a patient when death is reported without confirmed evidence of recurrence of cancer or any documentation of any other cause of death. The indicated or possible cause may be specified here.
- (9) Unknown: This code is to be ticked when the possible cause of death cannot be determined.

18.2 Date of death in dd/mm/yy  
Entered in day, month, year format.

**19. Remarks (add additional sheet(s) if necessary):**

*Explanation:*

This is left “free hand” for comments about any problems in filling **this** form or suggestions to improve the form and format of entry or any other feed back.

## 4. Appendix I

### **TNM staging UICC Clinical Classification, 2003**

Edited by LH Sobin and Ch. Wittekind

#### **Introductory notes**

Each site is described under the following headings:

- Rules for classification with the procedures for assessing T, N, and M categories; additional methods may be used when they enhance the accuracy of appraisal before treatment.
- Anatomical sites and subsites where appropriate.
- Definitions of regional lymph nodes
- TNM clinical classification
- pTNM pathological classification
- G histopathological grading
- Stage grouping
- Summary

#### **5. References**

- [1]. WHO handbook for reporting results of cancer treatment, WHO offset publication no. 48, page no. 7-37, World Health Organization, Geneva, 1979. (it is also published as) Reporting of results of cancer treatment, A.B. Miller, B. Hoogstraten, M. Staquet and A. Winkler, Cancer 47; 207-214, 1981.
- [2] Textbook of radiotherapy Perez et al.

## Regional Lymph Nodes

## Distant Metastases

The categories M1 and pM1 may be further specified according to the following notation:

Pulmonary	PUL	Bone Marrow	MAR
Osseous	OSS	Pleura	PLE
Hepatic	HEP	Peritoneum	PER
Brain	BRA	Adrenals	ADR
Lymph nodes	LYM	Skin	SKI
Others	OTH		

## G – Histopathological Grading

GX	Grade differentiation cannot be assessed
G1	Well differentiated
G2	Moderately differentiated
G3	Poorly differentiated
G4	Undifferentiated.

## R Classification

The absence or presence of residual tumour after treatment may be described by the symbol R. The definitions of R classification apply to all H&N sites. These are:

RX	Presence of residual tumour cannot be assessed
R0	No residual tumour
R1	Microscopic residual tumour
R2	Macroscopic residual tumour