Policy and Procedures for Access to, and Disclosure of, Confidential Data from the Punjab Cancer Registry

1-Tracking

Amendment 2: July 23, 2013-Policy and Procedures for Access to, and Disclosure of, Confidential Data from the Punjab Cancer Registry

Amendment 1: Mar. 10, 2011-Policy and Procedures for Access to and Disclosure of Confidential Data from the Punjab Cancer Registry

First draft: Dec. 26, 2005-Policies and Procedures for Access to and Disclosure of Confidential Data from the Punjab Cancer Registry-Lahore Chapter

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2-Standard procedures for the Punjab Cancer Registry

- To define objectives of data collection:
  a) To record new cases of cancer in a specified population, in a defined geographic area, beginning with the residents of Lahore district, on an yearly basis; to collate information on incidence and types of cancers in Lahore district, so as to analyze data to study the distributions of cancers in the district, among others;
  b) To record mortality due to cancer in the residents of the district of Lahore;

- To announce the setting-up of the Registry in print and broadcast media;

- To identify the catchment population (*Appendix A*):
  The catchment population would be that group of individuals who are residents of the district of Lahore (1), who visit a facility for diagnosis, and who have either a histologically or clinically confirmed, diagnosis of cancer;

- To list reportable neoplasms (*Appendix B*):
  Any neoplasm with a behavior code (fifth digit in a complete six-digit morphology code) of '/2' (in situ) or '/3' (invasive) (2);

- To assign a unique identification number to each collaborating center (*Appendix C*), within the district of Lahore, at the assigned central data collection office;

- To update the aforementioned list periodically;

- To visit various collaborating centers to distribute the data capture forms and subsequently collect and bring the filled out forms to the central office;

- To use official transport for these visits, maintain a log of visits including dates, centers visited, and forms distributed/collected;

- To collect data on the data collection form designed specifically for this purpose (*Appendix D*);

- To assign an exclusive ID to each patient;

- To include residents of Lahore district diagnosed with cancer and/or treated for cancer on or after the Registry's reference date (February 01, 2005);

- To present year-wise aggregate data in the form of crude and standardized results when reporting is complete/nearly complete from all collaborating centers and information has been entered into the recommended software.

3-Check for duplicate records

- Perform checks for duplicate records by comparing the following variables:

  First name or initial and last name or initial, gender, date of birth, age range, telephone number, primary site, and histology.

- In case of non-availability of names, checks for absolute duplicates may be difficult though for probable duplicates may still be possible. The results may, thereby, be overestimated by 15-20%.

4-Check for multiple primaries

- Count two or more discrete tumors of different ("three-digit") sites in any individual separately for the purposes of incidence statistics. However, in accordance with international practice, count tumors arising in sites with the same first three digits (subsite) as one (3). This may be a recurrence of the disease;

- Group different histologies from the same subsite (same three-digit site) separately. In this way, for example, a squamous cell carcinoma of a lung and an adenocarcinoma of the same or other lung arising at any time will both be counted in incidence statistics-new case of cancer

- Tabulate lympho-hematopoietic malignancies (e.g. lymphomas and leukemias) by morphology;

- Treat renal tract as a special case of an "extended site", whereby consider multiple transitional cell carcinomas of non-bladder sites only once;

- Treat cancers of unknown primary sites as a distinct group. Attempt to determine the true primary site;

- A cancer diagnosed in a different organ from the one before will be considered a new case. However, a malignancy arising within the same organ and subsite (recurrence) will not be considered a new case.

5-Measures for confidentiality

- Sign a confidentiality pledge/declaration at the time of employment, which will remain in force after cessation of employment from the Hospital/Registry;
- Maintain a list, with Security, of all employees authorized to enter the Registry;
- Do not let anyone in the office you don't know;
- Escort visitors back and forth to the door;
- Provide proof of identification to Staff engaged in registration;
- Send Registry Staff on official transport to distribute and collect forms from various centers and to bring them back to the central data collection office;
- Mark the folders as "CONFIDENTIAL" and keep the forms locked in a cabinet in the central data office of the Registry;
- Lock the office at the end of the day, deposit the key with Security, and maintain a list of accessees;
- Allow Registry Staff to use the specific username (ID) and password to start the computer and another user-password controlled log on to access the Hospital information System and thus, the Punjab Cancer Registry software;
- Lock the computer by using CTL-ALT-DEL to bring up the Windows Security screen and click on the "Shut down" button when leaving the office;
- Pick up all the printouts pertaining to the Registry promptly;
- Refrain from discussing confidential data in the halls and from carrying them to break rooms or restrooms;
- Allow authorized individuals to examine collated results;
- Separate tumor-related data from key personal identifiers such as name, ID, and address, when reporting the results;
- Subject data on deceased persons to the same procedures for confidentiality as data on living persons;

- Treat all data in the Registry as confidential whether the data items are personal identifiers or not;

- Inform that confidentiality is the responsibility of all members involved in cancer registration;

- Define “data” as all information, documents, reports, and files;

- Avoid transmission of information on telephone;

- Dispose of paper-based forms once confirmed that there is no need to retain those forms; however, retain the entire information in the PCR software.

6-Release of Registry data

- All active members will be part of the authors' list for publications. If a journal requires a fixed number of authors, the largest contributors will be listed as authors and others will be acknowledged individually or collectively as the "Punjab Cancer Registry" in the acknowledgments

- Obtain written requests for release of Registry data for research or healthcare planning;

- Ensure that ethical aspects related to release of information are taken care of;

- Refuse requests for information on identifiable data concerning individuals (who may or may not have a cancer recorded at the Registry), from agencies dealing with pension schemes, healthcare cost re-imbursement, industrial disease compensation panels, and life insurance. Direct enquirer to obtain information directly from the subject or the subject’s treating physician;

- Ask nominated professionals to handle inquiries from the press about the Registry.

7-References

1. Population Census Organization, Statistics Division, Government of Pakistan. (2000). 1998 District Census Report of Lahore (Census Publication No. 125). Islamabad.

2. SEER Program Coding and Staging Manual 2010-REPORTABILITY http://www.seer.cancer.gov/manuals/2010/SPCSM_2010_maindoc.pdf. Accessed: Mar. 10, 2011.

3. The Western Australia Cancer Registry. http://www.health.wa.gov.au/wacr/home/whatis.cfm. Accessed: Mar. 10, 2011.

APPENDIX A

Table 1. Projected population of Lahore district in 2010-2011.

Total district land area	Population Census (1998) [1]			1981-1998 Average Annual Growth Rate for Lahore district	Estimated Population (2011)		
	Both sexes	Males	Females		Both sexes	Males	Females
1,772 sq. km.	6,318,745	3,328,502	2,990,243	3.46%	9,832,705	5,178,538	4,653,167

[1] Population Census Organization, Statistics Division, Government of Pakistan. (2000). 1998 District Census Report of Lahore (Census Publication No. 125). Islamabad.

APPENDIX B

Reportable diagnoses-SEER PROGRAM CODING AND STAGING MANUAL 2010.

1. In situ and malignant/invasive histologies

   All histologies with a behavior code of /2 or /3 in the International Classification of Diseases for Oncology, Third Edition (ICD-O-3).

   Exceptions:

   i Carcinoma in situ of cervix (/2) or cervical intraepithelial neoplasia (CIN III) of the cervix (C530-539)

   ii Prostatic intraepithelial neoplasia (PIN III) of the prostate (C619).

2. Benign/Non-Malignant Histologies

   a. Pilocytic/Juvenile astrocytomas are reportable; code the histology and behavior code 9421/3.
   b. Benign and borderline primary intracranial and CNS tumors with a behavior code of /0 or /1 in ICD-O-3 are collected for following sites. See table below for *required sites*.

Table 2. Required sites for benign and borderline primary intracranial and central nervous system tumors.

General term	Specific sites	ICD-O-3 Topography code
Meninges	Cerebral meninges	C 700
	Spinal meninges	C 701
	Meninges, NOS	C 709
Brain	Cerebrum	C 710
	Frontal lobe	C 711
	Temporal lobe	C 712
	Parietal lobe	C 713
	Occipital lobe	C 714
	Ventricle, NOS	C 715
	Cerebellum, NOS	C 716
	Brain stem	C 717
	Overlapping region of brain	C 718
	Brain, NOS	C 719
Spinal cord, cranial nerves, and other parts of the central nervous system	Spinal cord	C 720
	Cauda equine	C 721
	Olfactory nerve	C 722
	Optic nerve	C 723
	Acoustic nerve	C 724
	Cranial nerves, NOS	C 725
	Overlapping region of brain and central nervous system	C 728
	Nervous system, NOS	C 729
Pituitary, craniopharyngeal duct, and pineal gland	Pituitary gland	C 751
	Craniopharyngeal duct	C 752
	Pineal gland	C 753

3. *Note: Benign and borderline tumors of the cranial bones (C410) are not reportable.*

4. The ICD-O- is published by the World Health Organization and is the accepted reference for determining malignancy.

Table 3. ICD-O- Behavior Codes.

Code	Definition
0	Benign
1	Uncertain whether benign or malignant
2	Carcinoma in situ
3	Malignant, primary site
6	Malignant, metastatic site
9	Malignant, uncertain whether primary or metastatic site

5. Although the following malignant conditions with the ICD-O-3 behavior codes /2 and /3 are not required by the Commission on Cancer (COC), the PCR will include the following for incidence statistics:
Localized basal or squamous cell carcinoma of non-genital skin sites (C44.0-C44.9)

Table 4. Comparison of Cancer Reportability in ICD-O-3 [2].

Type of cancer	COC	SEER [3]
CIS & CIN III(Cervix)	No	No
PIN III (Prostate)	No	No
VIN III (Vulva)	No	Yes
VAIN III (Vagina)	No	Yes
AIN	No	Yes
Skin cancers	(C440_with morphology (8000-8110) and AJCC stage gp. 0 or 1 not reportable	(C44_ with morphology (8000-8110) not reportable

Basal and squamous cell carcinoma of the non-genital skin sites occur frequently. Most cancer registries do not collect them as basal and squamous cell carcinomas of the skin have a better prognosis than most other invasive cancers. The patients are often treated only in the physician's office, which makes it difficult to get complete and accurate information. *The COC requires that basal and squamous cell carcinoma of the non-genital skin sites be included when, at initial diagnosis, it has invaded regional tissue or lymph nodes, or metastasized.*

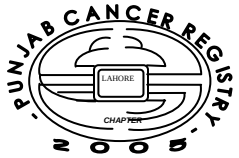
[2] North American Association of Central Cancer Registries. Guidelines for ICD-O-3 implementation: Prepared by the NAACCR ICD-O-3 Implementation Work Group: Nov. 27, 2000. www.facs.org/cancer/coc/naaccr.pdf. Accessed: Mar. 10, 2011.
[3] SEER in an acronym for: Surveillance Epidemiology and End Results.

APPENDIX C

Table 5. List of collaborating centers.

Center ID	Name of the Center
1	Allama Iqbal Medical College (AIMC)
2	King Edward Medical University (KEMU)
3	Lahore Medical and Dental College (LMDC)
4	Fatima Jinnah Medical College (FJMC)
5	Fatima Memorial Hospital (FMH)
6	Services Institute of Medical Sciences (SIMS)
7	Shaukat Khanum Memorial Cancer Hospital and Research Center (SKMCH & RC)
8	Institute of Nuclear Medicine and Oncology (INMOL)
9	Sheikh Zayed Hospital (SZH)
10	Jinnah Hospital
11	To be allotted
12	Chughtai's Lahore Lab.
13	Indus Lab.
14	Children's Hospital
15	Pride Lab.
16	Ittefaq Hospital
17	Shalimar Hospital
18.	Social Security Hospital
19	Post Graduate Medical Institute (PGMI)
20	Akhtar Saeed Medical College
21	Combined Military Hospital (CMH)

APPENDIX D



PUNJAB CANCER REGISTRY

DATA COLLECTION FORM

CENTER I.D. NO_____ PATIENT I.D NUMBER:
_____ (To be allocated by PCR Central Office)

HISTOLOGY NO._____ HISTOLOGY DATE: _____/_____/_____

PATIENT 'S NAME_____ _____ _____
FIRST MIDDLE LAST

SEX MALE ☐ FEMALE ☐ NEUTER (MUKHANNAS) ☐
FATHER'S NAME_____

BIRTH DATE _____ AGE _____

N.I.C. NUMBER (FOR CHILDREN ≤ 18 YEARS, ID OF MOTHER / FATHER) _____

PERMANENT ADDRESS-(NUMBER, STREET) _____
_____

CITY/TOWN _____ POSTAL CODE_____

HOME/CELL TELEPHONE WITH AREA CODE_____

↓RESIDENT OF LAHORE: YES ☐ NO ☐ IF YES, duration of stay in Lahore (Months/Year)
کیا آپ لاہور کے رہائشی ہیں.

↓COME TO LAHORE FOR TREATMENT/DIAGNOSIS ONLY_____ (YES / NO)
یا آپ لاہور بیماری کی تشخیص یا علاج کے لیے آئے ہیں.

Procedure/surgery done at (hospital).....
Name of surgeon.....
Cytology/histopathology done at (lab.) .....

PRIMARY SITE_____ DATE OF DIAGNOSIS _____

SITE OF BIOPSY_____ METASTATIC _____ (YES / NO)

LATERALITY (where applicable)_____ MORPHOLOGY _____

GRADING _____ STAGE (when available)_____

*MOST VALID BASIS OF DIAGNOSIS_____

FOR PCR CENTRAL OFFICE USE ONLYSTATUS AT LAST FOLLOW-UP - _____

DATE OF DEATH_____PLACE OF DEATH_____

***†PCR is an acronym for the Punjab Cancer Registry.**
***0. Death Certificate Only 1. Clinical; 2. Clinical investigation; 4. Specific tumor markers; 5. Cytology; 6. Histology of a metastasis; 7. Histology of primary tumor; and 9. Unknown.**

xx END xx

For some treating centers, where diagnostic facilities are not available, request additional information as follows (as written in the form):

Procedure/surgery done at (hospital)……..
Name of surgeon…….
Cytology/histopathology done at (lab.) ……

APPENDIX E

Definitions [4]

- "PCR data" means all information collected at any time by the Punjab Cancer Registry under the authority of Societies' Registration Act of Pakistan, XXI of 1860, whether or not such information identifies an individual or could be used to identify an individual. PCR data also means all documents, files or other records, regardless of format or medium, containing PCR data (whether alone or in combination with other data).

- "Access to data" means the right to examine data.

- "Disclosure of data" means the granting of the right to examine data and the right to create and retain a copy.

- "Research" means release of publications and presentations containing aggregate data and conclusions drawn from studying the PCR data, including journal articles, summary reports, special analyses, studies and other documents, and presentations to professional organizations, the news media and the public. These publications may contain case counts, rates, and survival analyses derived from the PCR incidence and mortality data. Individual cases or individual sources of information shall not be identified in any way.

- "Aggregate data" or "Collated results" mean statistical information derived from PCR data that does not include any individual item of data representing a person, whether identified, identifiable or anonymous, and from which no information about an identifiable or anonymous person can be obtained in any manner.

- "Reports and statistical information" mean reports, articles, special analyses, studies, and other publications and communications that contain aggregate PCR data.

- "Sources of information" or "collaborating centers" mean hospitals and other facilities or agencies, (be these private or government), providing diagnostic or treatment services to patients with cancer, and physicians, surgeons, dentists, podiatrists, and all other health care practitioners diagnosing or providing treatment for cancer patients, that have provided information contained in PCR data files.

---END OF DOCUMENT---

[4] Courtesy: Policies and Procedures for Access to and Disclosure of Confidential Data from the California Cancer Registry http://www.nccc.org/ResearchandTraining/docs/CCR_Data_Access_and_Disclosure_10: Accessed on Aug. 09, 2005.