Załącznik nr 1 do OPZ

IPAAC – TASK 7.2: Piloting the integration of data on care pathways
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DRAFT PROTOCOL FOR INTEGRATING CANCER REGISTRY DATA ON CARE WITH ADMINISTRATIVE AND HEALTH INFORMATION SOURCES IN EUROPE

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INTRODUCTION and background

Describing the complete pathway of cancer patients from diagnosis to rehabilitation or terminal care provides us with useful information to understand factors that are lagging behind the remarkable survival differences in cancer survival across European regions, repeatedly documented by the EUROCARE (European Cancer Registry Based Study On Survival And Care Of Cancer Patients) project.

In the last 10 years, the population-based high resolution (HR) studies, collecting more detailed clinical data than those available in the routine cancer registry (CR) activity (such as stage at diagnosis, diagnostic procedures and main treatments), have been set up in several European countries on samples of cases representative of the whole cancer incidence population, in order to explain reasons of outcomes differences and to assess the adherence of treatments to standard guidelines in the participating countries. The HR are fully representative of the whole incident cases in the participating regions and provide a reliable picture of patterns of cancer care in their region/country. However, since these studies use individual level information collected by trained personnel by accessing the clinical records of each case included in the sample, they imply considerable workload and costs and are time consuming. Consequently, relatively small study populations are included, hampering robust results; also, a long delay occurs between collecting data and producing results. Access to automatic routine source of data would consent to reduce the personnel workload, enlarge the study samples and speed the production of results.

Aggiungere aggancio con IPAAC objectives

AIMS OF THE PILOT STUDY - TASK 7.2

This pilot study will evaluate the **feasibility of linking individual patient's data included in the participating population-based CRs, with administrative and health data,** in order to:

1) describe the complete pathway of cancer patients from diagnosis to rehabilitation or terminal care, including the use of health care resources at the end of life;
2) assess the adherence of the administered treatments to standard clinical guidelines.

Furthermore, taking into consideration the availability and type of administrative and health data, it will be also evaluated the feasibility of:

3) investigating pathological events occurring during the disease course;
4) investigating 1) and 2) taking co-morbidities and socio-economic status into account
5) integrating clinical data with patients' reported outcomes measures (PROMs)

The task leader and partners will derive procedures to reconstruct cancer–specific care pathways (and eventually presence of co-morbidities during the entire pathway), to be shared among MSs participating to this pilot (*list of countries*.).

TEAM OF THE PILOT STUDY - TASK 7.2

The pilot study will involve a multidisciplinary team that, besides CRs personnel, includes statisticians, epidemiologists and clinicians.

INCLUSION CRITERIA

Prevalence cohort

Invasive, primary, malignant neoplasms of **rectum (ICDO3 topography C19-20), colon (ICDO3 topography C18), pancreas (ICDO3 topography C25), and skin melanoma (ICDO3 topography C44, morphology 8720-8790) diagnosed in adult (aged ≥15 years) patients** are eligible for inclusion in the pilot study- task 7.2 (these are called **index tumours**).

The study cohort includes patients diagnosed with the index tumours during all years of activity of the CR and still alive at the prevalence year (**prevalence cohort**), thus including also the cases incident during the year. The prevalence year is the most recent one for which the CR database has been updated; an entire year of follow-up (life status) after the prevalence date must be available for the entire cohort.

In case of prevalent cases with multiple primaries, only the following cases will be included: a) patients with index tumours diagnosed as most recently as possible; **and** b) other primaries (any cancer type) that occurred 5 or more years before the index tumour diagnosis date.

The prevalence study cohort can be established by the participating Cancer Registry or it could be centrally selected by using the EUROCARE-6 database (if it included the last available and updated CR data).

Administrative/health care data sources

The type, number and contents of data sources considered for the linkage might vary according to the country-specific health care data system. The aim is to include as much information as possible to estimate the care pathway of the prevalence cohort, preferably in relation to their co-morbidities and socio-economic status. However, at least the following database is necessary:

- Hospital Admissions database, including hospitalisation for all diseases (related and not related to cancer)

DIAGNOSTIC CLASSIFICATION

Anatomic site, tumour morphology and behaviour must be coded according to the International Classification of Diseases for Oncology (ICD-O-3), published in 2000 and updated in 2011.

DATA SOURCES AND DATA LINKAGE

The pilot study-task 7.2 uses data **at individual level linked by the CR to different administrative/health care data sources and to the mortality file,** in order to reconstruct patterns of care of study cohort patients **in a 3-year period** spanning from 2 years before the prevalence date to one year after the prevalence date (**study period**).

All records identified from the record linkage as related to patients of the prevalence cohort **within the study period** are provided by the CR. The CR must provide **a code allowing the tracing of individual patients of the prevalent study cohort in all data sources provided (patient-ID properly anonymised)**.

A questionnaire investigating the availability and contents of data sources provided by the CR participating to the tasks included in the IPAAC-WP7 will be administered by the task 7.1 by September 2018 (according to the minutes of the WP7 Kick-off meeting held in Milan May 31st 2018).

A minimum number of data sources common to all participants as well as a common minimum set of variables collectable from automatic sources will be individuated through the common discussion among participants, also considering the task 7.1 results.

INFORMATION REQUIRED

From CR database: all variables included in the 2015 ENCR-JRC Call for Data study protocol. The dataset will include a record for each patient included in the prevalence cohort and for each tumour (i.e. patients with multiple tumours will have multiple records).
Information on stage at diagnosis is requested only for prevalent cases diagnosis up to 12 months before the prevalence date.
For each individuals all tumours occurred before the prevalence date should be provided.

From administrative/health care data sources:

- Patient-ID (the same one used in the CR database sent for the pilot study)
- Information on:
  - multiple diagnostic codes, including those not related to the cancer under study (main diagnosis, secondary diagnoses up to …)
  - multiple treatment codes (secondary treatments up to …)
  - type of treatments (e.g., type of chemotherapy)
  - Quantity of treatments (e.g., total dose and fractions of radiotherapy)
  - DRG code …
  - type of hospital

  and the main dates included in each data source, in order to investigate timing of treatments and pathological events occurring during the disease course, as well as the presence of co-morbidity

In addition to this basic information, we will examine and discuss the feasibility of also collecting information on:

- Type of procedure (diagnostic procedures, outpatient procedures and visits) classified according to the ICD9-CM (ICD10-CM ??), (please specify if you have suggestions)
- Date of procedure

- Quantity of procedure
- Socio-economic status (or information to estimate it)
- PROMs

The datasets (one for each health care source) will include a record per patient included in the prevalence cohort and per procedure (i.e., multiple procedures for the same patient correspond to multiple records).

From the mortality file:

- Patient-ID (the same one used in the CR database sent for the pilot study)
- Date of death;
- Cause of death

LIST OF INDICATORS

Each prevalent case is linked to the available administrative/health care databases in order to trace access to health services, drug prescription or pathological events of interest during the follow up time.

In addition, the data made available through the present pilot study will allow us to investigate the following indicators of standard care for specific cancers

Indicators of standard care for colon cancer *(Labianca R et al. Early colon cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. Ann Oncol 2013;24:vi64-72.; Van Cutsem E et al. Metastatic colorectal cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. Ann Oncol 2014;25:iii1-9.)*

At least one indicator among the following ones:

- Percentage of screened-detected colon cancer patients
- Percentage of colon cancer patients diagnosed by endoscopy (both sigmoidoscopy and total colonoscopy, excluded: Virtual colonoscopy or CT colonography)
- Percentage of stage III resected colon cancer patients treated with adjuvant chemotherapy (in common with WP10)
- Percentage of metastatic colon cancer patients treated with targeted therapy
- Percentage of resected colon cancer patients died within 30 days from surgery (in common with WP10)

Indicators of standard care for rectal cancer *(Glynne-Jones R et al. Rectal cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. Ann Oncol 2017;28:iv22-40.; Van Cutsem E et al. Metastatic colorectal cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. Ann Oncol 2014;25:iii1-9.)*

At least one indicator among the following ones:

- Percentage of screened-detected rectal cancer patients
- Percentage of rectal cancer patients diagnosed by digital rectal examination and endoscopy with biopsy
- Percentage of stage III resected rectal cancer patients treated with neo-adjuvant radiotherapy (in common with WP10)
- Percentage of metastatic rectal cancer patients treated with targeted therapy

- Percentage of resected rectal cancer patients died within 30 days from surgery (in common with WP10)

Indicators of standard care for skin melanoma *(Dummer R et al. Cutaneous melanoma: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. Ann Oncol 2015;26: v136-132.)*
At least one indicator among the following ones:

- Percentage of stage IV melanomas receiving mutation testing
- Percentage of melanomas with information on the maximum thickness in millimetres (Breslow)
- Percentage of melanoma patients with a tumour thickness of >1 mm receiving sentinel lymph node biopsy
- Percentage of metastatic melanoma patients treated with immunotherapy

Indicators of standard care for pancreatic cancer *(Ducreux M et al. Cancer of the pancreas: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. Ann Oncol 2015;26: v56-68.)*
At least one indicator among the following ones:

- Percentage of pancreatic patients receiving CT scan at diagnosis
- Percentage of localised pancreatic patients treated with surgery
- Percentage of metastatic pancreatic patients with information on performance status
- Percentage of resected pancreatic cancer patients died within 30 days from surgery (in common with AGENAS indicators)

For each tumour under study

- Type of hospital (oncological, general hospital, oncological department within general hospital) where patients received the main treatments

- Indicators of quality of care at the end of life: in this phase high hospitalisation or anticancer drugs use are considered indicator of inappropriate care *(Barbera et al. Quality of end-of-life cancer care in Canada: a retrospective four-province study using administrative health care data. Curr Oncol. 2015;22:341-55):*
At least one among

- a new hospital admission in the last 30 days of life,
- intensive care unit (ICU) admission in the last 30 days of life,
- chemotherapy use in the last 2 weeks of life,
- death in an acute care hospital

DATASETS FORMAT

The datasets (one for each data source) are required in CVS format with semicolon (;) separating the variables.