

Study protocol Task 3 WP 7

Piloting the integration of data on cancer costs

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Abbreviations

CR	Cancer registry
DB	Database
DRG	Diagnosis-related group
JRC	Joint Research Centre
ATC	Anatomical Therapeutic Chemical
ICDO3	International Classification Of Diseases For Oncology – Third revision
ICD9-CM	International Classification of Diseases, 9th revision - Clinical Modification

Executive summary

The present study protocol arises from the experience carried out within the framework of the EPICOST study [1]. EPICOST represents the first attempt in Italy to provide population-based estimates of direct cancer costs across the patient pathway (from diagnosis to possible recovery or death). The study uses information, obtained at individual level, merged from different data sources (cancer registries and administrative health care databases) to reconstruct patterns of care and cost profiles according to a three-phase disease pathway, from diagnosis to possible recovery or death. Results from the EPICOST study related to breast cancer in the female population and to rectal cancer are published in European Journal of Health Economics [2] and Int J of Environ Research and Public Health respectively [3].

Since 2011, European countries have been working to find a joint strategy to reduce cancer incidence and mortality, and improve survival and the quality of life of cancer patients, through systematic and equitable implementation of evidence based strategies for prevention, early detection, diagnosis, treatment and palliation, making the best use of available resources [European Commission 2017; European Commission 2018].

Information on demographic patients' data (including age, sex, geographic location, and socio-economic status), comorbid conditions, cancer burden, and the use or the efficacy of varying diagnostic and therapeutic methods are important information to achieve these goals [4]. Furthermore, describing and identifying costs related to access and use of health care services may provide useful information to better allocate health care resources and facilities, and to reduce possible inequalities among cancer patients within and between countries [5].

Population-based cancer registries (CRs) are key information sources, to effectively monitor and assess cancer control strategies, and to properly address clinically relevant issues. However, most population-based CRs routinely provide information on age, sex, and life status of cancer patients, and on date of cancer incidence, topography, morphology, and behaviour of the cancer diagnosed.

Pilot study proposed in the task 7.3 of the WP 7 of the Innovative Partnership Action Against Cancer (iPAAC) Joint Action (JA, [European Commission, 2018]) aims to enhance country-specific population-based cancer information systems to better support evidence-based comprehensive cancer care, with a focus on costs of care.

1 Introduction

In most developed countries, costs of cancer care are increasing [6], due to a growing cancer survivor population [7] and a rising cost of novel and more expensive treatments. As a consequence, the sustainability of cancer burden is a challenge for the welfare system and increasingly central in the policy makers debate.

Describing and identifying costs related to specific health care needs provide useful information to better allocate health care resources and facilities, and to reduce possible inequalities among cancer patients within and between countries.

The pilot 7.3 assesses the feasibility of extending to other European countries the procedures developed in the framework of the EPICOST Italian project in order to produce indicators on costs directly related to diagnosis, care and follow-up of cancer patients.

The integration of CR data with the other data sources is obtained by electronic linkage of individual based information. In the paragraphs here below details about the 7.3 pilot study protocol are provided in the following sections: aims, study design, study indicators and information required. Additional details about the methods implemented in the EPICOST study are in the references 2,3.

2 Aims

Specific aims of pilot 7.3 are:

- 1) To identify for each participating country a prevalence cohort stratified by phase of care according to the study design;
- 2) To assess the availability of the relevant information at individual level and the possibility for the participating country to link this information in order to reconstruct patterns of care and corresponding costs of the prevalence cohort;
- 3) To select for each data source/country a list of codes of cancer-related procedures according to the same methodology used in EPICOST and described in the following study indicators paragraph.

3 Study design

Invasive, primary, malignant neoplasms of colon (ICDO3 topography C18), rectum (ICDO3 topography C19-20), 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 (these are called index tumours).

The study cohort is cross-sectional and includes patients diagnosed with the index tumours during all years of activity of the CR and still alive at the prevalence date (prevalence cohort). The prevalence date is the most recent one for which the CR database has been updated; an entire year of follow-up (life status) after the prevalence year must be available for the entire cohort. We define 3 phases of care: initial (12 months after cancer diagnosis); continuing (time elapsed between initial and final); final (last 12 months before death due to cancer). In a cross-sectional study design phases of care are mutually exclusive.

On prevalence date, each patient of the prevalence cohort belongs to only one phase of care, depending on the interval between prevalence date and diagnosis date and on the occurrence of death for cancer during the following year. More details about phases of care definition are in [2,3]. Individual CR data will be linked to different administrative/health care data sources and to the mortality file, in a 3-year period spanning from 2 years before the prevalence date to one year after the prevalence date (study period). An example of the study design is provided in Figure 3.1.

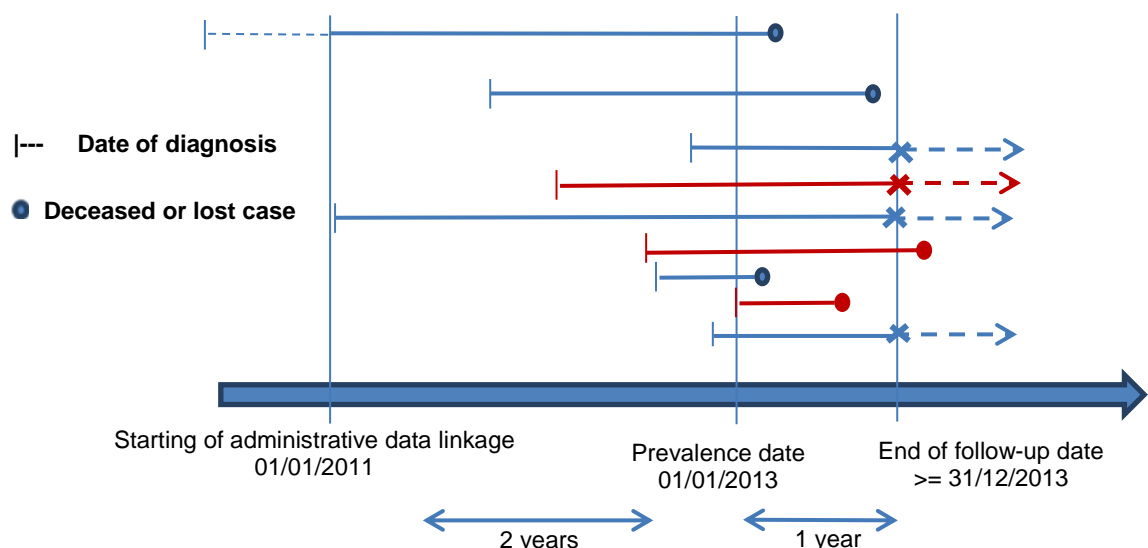


Figure 3.1: Pilot Study design, taking as prevalence date January 2013, 1st.

4 Study indicators

4.1 Cost indicators

Each patient of the prevalence cohort contributes to the study with a 12-month time interval and is linked to the available administrative/health care databases in order to trace every event of interest during the follow up time. In order to take into consideration only those events that are related to the index tumours, a list of events (specific for each index tumour) is utilised for each database. These lists were created by expert oncologists in the framework of the EPICOST Italian project and referred to diagnoses, interventions and procedures coded according to the ICD9-CM classification for Hospital Discharges DB and for outpatient services DB, and to the Anatomical Therapeutic Chemical Classification System (ATC code) for drug prescriptions DB. The lists are available within the EPICOST study for colon, rectum and breast cancers only. More details about the methodology and the lists for breast cancer are in [8].

Costs are expressed in Euros and are defined as the direct expenditure related to diagnosis, treatment, follow-up and end-of-life care provided to cancer patients.

We will identify homogeneous groups of patients according to clinical and demographic variables affecting the patterns of care: age, stage at diagnosis (for patients in the initial phase only), and we will compute costs as simple averages over patients belonging to the same homogeneous group.

The following indicators are considered for each of the three phases of care:

-Patient monthly average cost, C_i : all costs sustained on average for a patient in month i , obtained by dividing costs sustained for all patients in month i by the corresponding number of person-months.

A cost profile is a series of 36 patient monthly average costs C_i over the three phases of care.

-Patient annual average cost, C_A : all costs sustained on average for a patient in a year, obtained by summing up patient monthly average costs, i.e. $C_A = \sum_{i=1}^{12} C_i$

-Total annual cost: all costs sustained in 12 months for all patients, obtained by multiplying the patient annual average cost (C_A) by the total number of patients. These costs are computed by phase of care and/or by type of health care service.

4.2 Patterns of care indicators

In order to better describe and interpret results on costs in the initial phase of care, a list of patterns of care indicators is computed, the list is specific for each index tumour considered. Here an example of indicators computed by age at prevalence and stage at diagnosis, applicable to colon cancer:

- percentage of patients receiving at least one surgery treatment;
- percentage of patients receiving at least one chemotherapy over all patients in initial phase of care;
- time occurring between surgery and chemotherapy.

5 Information and data sources required

Cancer Registry data

For each cancer case, the CR will provide all variables included in the 2015 ENCR-JRC Call for Data study protocol [EUROCORE-6, 2015]. In particular,

- the information on stage at diagnosis is requested only for prevalent cases diagnosis up to 12 months before the prevalence date;
- all tumours occurred before the prevalence date should be provided;
- in case of prevalent cases with multiple primaries, all multiple primaries should be provided; patients with index tumours to be included in the study cohort will be defined centrally (by Task 7.3 coordination group) by selecting: 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.

To each cancer case, the CR will link the CR record with all the available administrative/health care data sources and to the mortality file.

Administrative/health care data

Number and contents of administrative/health care data sources considered for the linkage might vary according to the country health care data system. The aim is to include as much information as possible to estimate the total amount of health care expenditures directly related to diagnosis, treatment and monitoring of the prevalence cohort during the study period. However, at least cancer and not-cancer related hospitalisation data will be required.

From administrative/health care data sources, the following information will be analysed:

- Type of procedure (diagnostic procedures, treatments, outpatient procedures and visits) classified according to the ICD9-CM (or ICD10-CM), pharmaceutical prescriptions classified according to the ATC code;
- Date of procedure;
- Quantity of procedure;
- Cost per unit of procedure (in Euros) ;
- Total cost of procedure (in Euros);

Any other additional variable is data source- specific.

As an example, in the case of the Hospital Discharge database in Italy: regimen (with or without overnight stay in hospital), number of days of stay, multiple diagnostic codes (main diagnosis, secondary diagnoses up to five), multiple treatment codes (main treatment, secondary treatments up to ten), DRG code.

Table 5.1 includes an example of data from administrative/health care data sources used for EPICOST in Italy.

Data source	Data source variables
Hospital discharge file	<ul style="list-style-type: none"> -Patient ID (the same one used in the CR database) -Demographic variables (sex, place of residence, date of birth, civil status, education level) -Type of admission (ordinary, day hospital) -Dates of admission at the hospital and of discharge; -Diagnosis (principal diagnosis + the other secondary up to five); -Diagnostic and intervention procedures (principal intervention + the other secondary interventions up to ten); -Dates of diagnostic and intervention procedures; -Discharge modality (patient death, ordinary discharge, transfer to other unit same hospital, transfer to other hospital); DRG code -Total claim (in Euros)
Outpatient Services database	<ul style="list-style-type: none"> -Patient ID (the same one used in the CR database) -Dates of service; -Code of Diagnostic and intervention procedure; -Description of Diagnostic and intervention procedure; -Date of Diagnostic and intervention procedure; -Branch of the procedure (numerical code corresponding to homogeneous groups of interventions: diagnostic, visits, radiotherapy, genetic tests, ...) -Quantity: number of diagnostic or intervention procedure; -Tariff: unitary cost per single diagnostic or intervention procedure;

	-Total claim (in Euros): Quantity X Tariff, when quantity is >1
Drug Prescriptions database (DP) / Hospital Drugs (HDP) record track	-Patient ID (the same one used in the CR database) -Dates of pharmaceutical prescription; -ATC code; -AIC code; -Quantity: number of doses indicated in the prescription; -Tariff: unitary cost per single dose of drug; -Total claim (in Euros) corresponding to the total cost of the prescription (quantity X Tariff)

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).

Mortality data

As regards the information from the mortality file, the following will be analysed:

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

6 References

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