Global surveillance of cancer survival (CONCORD programme)

Rationale and protocol **1 July 2016**

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1 Introduction

At the United Nations General Assembly High-Level Meeting in New York in September 2011, the governments of 113 countries set new strategic objectives for world-wide control of non-communicable diseases.[1] set new strategic objectives for world-wide control of non-communicable diseases. The UN declaration[2] emphasised the need for wider research and better policy for the prevention and control of all non-communicable diseases, including cancer, because of their rapidly growing impact on public health, especially in developing countries.

In 2012, the UN General Assembly endorsed the concept of universal health coverage, which means that everyone can access high-quality health services without financial hardship.[3] In 2016, the World Bank noted that universal health coverage is an inherently political goal, rooted in the human right to health, and that also makes economic sense.[a]

Following the World Health Assembly in 2012,[4] the governments of 119 countries agreed a set of 25 indicators and a voluntary global target to reduce premature deaths (defined as deaths in people aged 30-69 years) from all non-communicable diseases by 25% by 2025. This would represent a reduction of about 1.5 million from the predicted 6 million premature cancer deaths each year by 2025.

Achieving this target for cancer will require more effective prevention, to reduce incidence, and more effective health systems, to improve survival.

Only population-based cancer registries can tell us if those two requirements are being met. In 2010, the World Health Organisation assessed the capacity for prevention and control of non-communicable disease in 185 countries. Fewer than half the countries (48%) had national reporting of mortality. Population-based cancer registries were active in only 17% of low-income countries, compared with 79% of high-income countries, but only a third (36%) of registries had published a report in the previous 3 years.[5] Only 21% of the world's population was covered by cancer registration in 2006.[6]

At a global level, therefore, reliable and up-to-date information on cancer incidence, mortality and survival remains scarce.

Prevention will always be better than cure. However, even if every preventive measure known today were applied world-wide tomorrow, *and* were completely effective the next day, millions of patients would still be diagnosed with cancer every year for the foreseeable future. These patients all need access to good treatment to optimise their chances of survival, wherever they live, but there is huge global inequity in access to cancer care, including both surgery[7] and radiotherapy.[8]

The CONCORD programme will provide some of the information required to assess the effectiveness of health systems around the world in managing the cancer burden.

2 Global surveillance of cancer survival

Cancer survival varies very widely around the world.[9] Millions of cancer patients will continue to be diagnosed every year for the foreseeable future. All these patients will need access to optimal healthcare, which can be extremely expensive. Population-based cancer survival is a key measure of the overall effectiveness of health systems in managing cancer. Global surveillance of cancer

[a] http://universalhealthcoverageday.org/economists-declaration/

survival is required, because unless the avoidable inequalities in cancer survival are measured, and reported regularly, nothing will be done explicitly to reduce them.[10]

The aims of the CONCORD programme are to inform national and global policy for cancer control:

- To provide quantitative and directly comparable estimates of cancer survival in many countries world-wide, for 15 malignancies that are common in adults, and leukaemia, lymphoma and brain tumours in children, using individual data from population-based cancer registries, supplied to agreed standards and analysed centrally;

- To maintain systematic global surveillance of cancer survival, by documenting world-wide trends and inequalities in cancer survival from 1995 up to the latest possible year, currently 2014;

- To enable examination of the underlying causes of survival differences;

- To derive measures such as the population "cure" fraction and the number of avoidable premature deaths.

It has been estimated that about 14 million people were diagnosed with cancer around the world in 2012, and that more than 8 million people died from it.[11] More than half (56%) of those who were diagnosed in 2008 and almost two-thirds (64%) of those who died from it were living in low-income and middle-income countries.[12] Conservative projections suggest that more than 20 million people will be diagnosed with cancer every year by 2030, with more than 13 million cancer deaths.[13] The increase in the number of patients will arise mainly from population growth and ageing of the population, but in many countries, the risk of developing cancer at a given age (age-specific risks) will also rise. All three factors affect poorer countries more. Without global policy initiatives, the disparity between the growing cancer burden and the capacity of poorer countries to deal with it can be expected to widen.

Much of the global variation in survival is likely to be attributable to differences in access to diagnostic and treatment services, and lack of investment in health resources.[14] This is also true for children: about 80% of childhood cancers arise in resource-poor countries, where low survival is associated with failure to start or complete treatment in up to 60% of cases.[15] Variation in survival within Europe has been associated with gross domestic product, total national expenditure on health and the level of investment in health technology, such as CT scanners.[16] International differences in cancer survival may be seen as similar to the differences between rich and poor patients[17,18] or insured and under-insured[19] patients within a given country. Survival also varies widely between low- and middle-income countries,[20] and priorities for improving outcomes differ between these groups of countries.[21] Until publication of the first CONCORD study in 2008,[14] direct international comparisons of cancer survival between high-, middle- and low-income countries were not generally available.

Reliable information on global trends and disparities in cancer patient survival can therefore be expected to focus debate on health policy to reduce geographic, socio-economic and racial or ethnic inequalities.[21,22]

Long-term surveillance of world-wide trends in cancer incidence has provided information for aetiological research and the basis of prevention and screening since the 1960s.[23,24] We predict that continuous, global surveillance of cancer survival will in due course become equally valuable - a reliable source of information for cancer patient groups and researchers, a stimulus for change in health policy and healthcare systems, and one of the key metrics for global surveillance of cancer control.

Global surveillance of cancer survival (CONCORD programme)

The Organisation of Economic Co-operation and Development (OECD) noted that the first CONCORD study: *"has contributed to a sea-change in how national policymakers are using international comparisons to improve their health systems"* OECD also considers *"[the] proposals for a CONCORD-2 study, with its objective of producing data on cancer survival trends … for [15] major cancers, to be extremely important. We are excited by the prospect of being able to use your data to address the contribution of health system characteristics in explaining international differences in cancer survival. This is one of the tasks which our Member countries have given us for the next few years."*

From 2017, the Organisation for Economic Co-operation and Development[b] will include survival estimates from the CONCORD programme for 48 countries in its biennial publication *Health at a Glance*.[c] CONCORD will thus become the *de facto* standard for international cancer survival comparisons. This is formal recognition by an international agency of the global coverage, methodological rigour and international comparability of the CONCORD survival estimates, which will become crucial for the evaluation of health systems performance in all OECD Member States. The results will also help monitor progress toward the overarching goal of the 2013 World Cancer Declaration, to achieve major improvements in cancer survival by 2020.

Inequalities in cancer survival revealed by the EUROCARE studies[25-27] are partly responsible for the re-appearance of cancer control on the political agenda of the European Union.[28-30] The European Partnership Action Against Cancer[d] was set up in 2009 to coordinate the activity of EU organisations to improve cancer control. Survival trends have also provided an instructive backdrop for the evaluation of cancer control strategies in Europe and the USA.[31]

Survival is one of the measures of progress in cancer control. It is important to evaluate patterns and trends in incidence and mortality alongside those for survival.[32] World-wide trends in cancer incidence and mortality up to the late 1980s have been extensively analysed,[33] but this work has yet not been updated. Comparisons of incidence, survival and mortality have been published for many cancers in Europe,[34,35] and for Europe, Australia and Canada,[36] but not world-wide. Where possible, incidence, survival and mortality will be compared, to help interpretation of the survival comparisons.

2.1 National cancer control plans

National cancer plans are often focussed on improving survival, and others explicitly recognise its importance. International disparities in survival have underpinned the rationale and goals of cancer plans in many countries, such as Denmark (2005[37]), Northern Ireland (1996[38]), England (2000,[39] 2007,[40] 2011,[41] 2015[42]), Wales (2006[43]), Victoria (Australia) (2008[44]) and Sweden (2009[45]).

Secondary measures of the public health impact of disparities in cancer survival can also contribute to health strategy. Trends in the number of avoidable premature cancer deaths in Britain since the mid-1990s, derived from the persistent survival deficits identified in the EUROCARE studies,[46] were central to the National Awareness and Early Diagnosis Initiative (NAEDI) in the UK.[47]

Cancer survival trends are also being used to evaluate the effectiveness of national cancer plans, both in improving overall survival[48,49] and in reducing socio-economic inequalities.[50]

3 The CONCORD programme

CONCORD was the first world-wide study to provide direct comparisons of cancer survival between high-income and low-income countries, using standard quality control criteria and the same analytic

[b] http://www.oecd.org
[c] http://www.oecd.org/els/health-systems/health-at-a-glance-19991312.htm
[d] http://www.epaac.eu/

methods for all data sets[8]. It provided estimates of five-year survival for 1.9 million adults (aged 15–99 years) diagnosed during 1990–94 and followed up to 1999. It examined survival for four cancers of major public health importance: breast (women), colon, rectum and prostate. Individual tumour records were supplied by 101 population-based cancer registries in 31 countries on five continents. Sixteen of the 31 countries provided data with national coverage.

The CONCORD study found wide global variation in cancer survival: 5-year relative survival for breast, colorectal and prostate cancers was generally higher in North America, Australia and Japan, and in northern, western and southern Europe, and lower in Algeria, Brazil, and eastern Europe.

The study attracted widespread media coverage and significant scientific interest. It has been cited 900 times.[e]

CONCORD-2

In 2015, the CONCORD programme established global surveillance of cancer survival for the first time,[9] producing cancer survival trends over the 15 years 1995-2009 for 25,676,887 patients diagnosed with one of 10 common cancers that represented 63% of the global cancer burden in 2009. The 279 participating registries covered a total population of 896 million people, in 67 countries that were home to two-thirds (4.8 billion) of the world's population. In 40 countries, the data had 100% national population coverage. The Working Group included almost 500 collaborators.

More detailed studies of survival by stage at diagnosis and histologic type are in progress. They aim to explain the extent to which differences may be attributable to differences in definition, type or stage of disease at diagnosis, or in clinical investigation or treatment, or the effectiveness of health care systems. It will aim to provide evidence to support health policy.

The US National Cancer Institute pointed out that the global analyses of cancer survival in CONCORD-2 provided an opportunity for lessons from countries with successful cancer control initiatives to be applied to other regions.[22] They added that the availability of better data *"provides a clearer picture of the effect of cancer control programmes on the ultimate goal of improving survival and reducing the effect of cancer on the social and economic development of countries."*

The US Centers for Disease Control CDC described CONCORD-2 as the start of global surveillance of cancer survival,[f] with survival estimates *"that can be compared, so scientists can begin to determine why survival differs among countries. This could lead to improvements in cancer control programs."*

In September 2015, the International Atomic Energy Agency's Programme for Action on Cancer Therapy (PACT) used CONCORD-2 results to launch an ambitious world-wide campaign[g] to highlight the global divide in survival, and to raise awareness of persistent inequalities in access to life-saving cancer services.

CONCORD-2 was covered by TV, radio, press and wire services world-wide. The Altmetric score[h] of 780, reflecting social media impact, is higher than 99.98% of 6.5 million articles evaluated to date.

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[e] https://scholar.google.co.uk/citations?view_op=view_citation&hl=en&user=JeS_IMwAAAAJ&citation_for_view=JeS_IMwAAAAJ:u-x6o8ySG0sC

[f] http://www.cdc.gov/cancer/dcpc/research/articles/CONCORD-2.htm

[g] http://cancer.iaea.org/newsstory.asp?id=167

[h] https://elsevier.altmetric.com/details/2924704

Results have been incorporated into the American Cancer Society's on-line Cancer Atlas.[51] The article has been cited over 400 times since 2015 (Google Scholar[i]).

4 CONCORD-3

CONCORD-3 will update world-wide surveillance of cancer survival trends to include patients diagnosed up to 2014, with follow-up to 31 December 2014.

The results will be expected to have a substantial impact on the public, in the media and in the scientific and public health community.

In a global study of this scale, good communication is vital. The data specification for CONCORD-3 has been translated from English into Arabic, Chinese, French, Italian, Japanese, Portuguese, Russian and Spanish. The CONCORD team communicates with colleagues in six languages.

Many cancer registries told us that the data quality reports for CONCORD-2 helped them improve their data. We have extended these programs[52] and the quality control reports that we share with each registry. To control for background mortality by age and sex, we created a library of over 12,000 life tables by country, registry, race (selected countries), calendar year (1995-2010), and published it on-line,[53] with a statistical summary for each set of life tables. We will update the library to 2014.

4.1 Cancers to be studied

Research will focus on 15 common malignancies that represent 75% of the global cancer burden: oesophagus, stomach, colon, rectum, liver, pancreas, lung, melanoma, breast, cervix, ovary and prostate in adults (15-99 years), and brain tumours, lymphomas and leukaemias in both adults and children (0-14 years). We will examine geographic variation in cancer survival between 70 or more countries. Where adequate data are available, we will examine survival by stage at diagnosis, morphology, and race/ethnicity. We will also include information on the first course of treatment for each patient.

The additional cancers were suggested by epidemiologists in participating countries world-wide. This is reflected in the fact that the 15 cancers represent 75% of all new cancer cases and deaths, both in developed and developing regions of the world (Table 1).

4.2 Cancer registries

More than 300 population-based cancer registries in 70 countries have been invited to participate in CONCORD-3. At least 40 countries are expected to be able to provide national data with 100% population coverage.

4.3 Criteria for inclusion

4.3.1 Data quality

Population-based cancer registries that have recorded incident cases for all or part of the period 2000-2014 will be eligible to participate. Completeness and validity of the data for cancer survival analysis will be assessed on criteria such as the proportion of tumours that are morphologically verified (MV%), the proportion that are death-certificate-only (DCO%) and the proportion lost to follow-up. Extensive quality control procedures were developed for the first CONCORD study: most of the results were published on-line.[14] The procedures have been extended to improve the robustness of data preparation and the comparability of the survival estimates.

[i] https://scholar.google.co.uk/citations?view_op=view_citation&hl=en&user=JeS_IMwAAAAJ&citation_for_view=JeS_IMwAAAAJ:KbBQZpvPDL4C

Quality control is performed in three phases. First, each variable in each record in each file is checked for adherence to the coding specified in the protocol. A "protocol adherence" report is sent to each registry. Where compliance for any variable is less than 100%, the solution may be recoding by the Central Analytic canteen, or correction of the records in the source registry resubmission of an updated data file.

Second, each record in each file is checked for logical coherence, such as a plausible sequence of dates and plausible combinations of the patient's age and sex and the anatomic site and morphology of the tumour. An "exclusion report" is sent to each registry documenting the number percentage of patients in the data whose records have been excluded in one of 20 or more categories of error, in each calendar period, and the number and proportion of all eligible patients whose data can be included in survival analyses. Registries may be asked to resubmit data files after correction if a large proportion of definite or possible errors has been detected.

Third, standardised checks will be made on the distribution of major variables in every data file. These include the number and proportion of cases by age, sex, cancer site and registry for which microscopic confirmation of the diagnosis was available, and those reported by a death certificate only (DCO).

4.3.2 Completeness of follow-up

The first CONCORD study showed that in some countries, achieving complete follow-up for the vital status of all registered cancer patients can be very challenging. The three main problems are:

- patients who migrate outside the territory of the source registry after diagnosis, and who may become permanently lost to follow-up in that registry ("immortals")
- patients who emigrate to another country and will almost certainly be lost to follow-up
- the accuracy, efficiency and timeliness of the processes used to link incidence and mortality records at provincial or national level. This also applies to other sources of information that registries in some countries can use to follow up registered cancer patients for their vital status, such as social security or residence registers

Techniques developed in the EUROCARE study will be used to assess the completeness of follow-up in selected registries.[54] Completeness of follow-up will be assessed on random samples of apparent long-term survivors who were diagnosed with metastatic carcinoma in 2000 (or the earliest data year for that registry), and who appear from the registry's data still to be alive at the time of data extraction, up to 15 years after diagnosis with advanced disease. Special investigations will be carried out by these registries to document the current vital status of each sampled patient by tracing them through hospital or primary care records, administrative services (driving licence files, electoral rolls, birthplace registers, vital statistics files, etc.), using the data sources that are ethically approved for cancer patient follow-up in that territory.

The impact of loss to follow-up on five-year survival estimates will be quantified. Experience from the EUROCARE study suggests that errors of up to 4-5% in the diagnosis (not cancer) or vital status (dead, not alive) at 7 or 8 years may be expected, but that these will have a very small (less than 1%) impact on five-year survival estimates,[55] especially for cancers with relatively high survival,[56] such as those of breast and prostate.

4.3.3 Age range and calendar period

The study will focus on adults (15-99 years at diagnosis). Survival will also be examined for children (0-14 years) with acute lymphoblastic leukaemia, the most common malignancy in childhood, and for children with brain tumours and lymphomas.

The first CONCORD study produced survival estimates from 31 countries for adults diagnosed with cancers of the breast, colon, rectum and prostate during 1990-94 and followed up to 31 December 1999.

CONCORD-3 will provide data on patients with up to 15 index cancers diagnosed during 2000-2014, or as much of that period as possible, and for all of whom the registry has complete follow-up for vital status. It will not be a requirement that participating registries provide data for the entire period since 2000. The end of follow-up will be 31 December 2014, or a later year if adequate data are available from most registries.

Some cancer registries have been operational for over 50 years, while others have become fully operational only as recently as 2000 or 2005. Registries vary widely in the timeliness with which cancer incidence data for a given year are available, and in the methods by which they follow up their registered patients. As a consequence, the calendar periods for which registries can supply cancer incidence data with complete follow-up will vary.

4.3.4 Multiple primary cancer

In the first CONCORD study, as in most population-based cancer survival studies until recently, only the *first* invasive, malignant primary tumour in each patient was included in the analyses. Many patients (up to 10% or more in some registries[57]) have had more than one invasive cancer.[58] We will include both first and higher-order primary cancers diagnosed at index sites during 2000-2014. A patient diagnosed with colon cancer in 2003, then breast cancer in 2009, will be included in the separate survival analyses for each malignancy, but a subsequent tumour occurring in the same patient at the same site will be ignored for this purpose. Survival will be taken from the date of diagnosis until death or censoring.

If a person is registered with two or more invasive primary malignancies of the same index organ or site during the qualifying period, only the first will be included in analyses. Rarely, two or more invasive, primary, malignant tumours may be reported in the same person, in the same organ, and on the same date of diagnosis: in that case, the cancer with the most advanced stage will be included in survival analyses. If the stage at diagnosis is only known for one tumour, that tumour will be included. If the stage at diagnosis is not known for any of the tumours, the first tumour listed in the database will be included. Patients with synchronous, bilateral cancers in paired organs (e.g. simultaneous invasive, primary cancers of both breasts) and those with multiple, synchronous, invasive, primary cancers of the colon or rectum will be included. They will be treated as a single case in the analyses. If synchronous cancers in paired organs are discordant for stage, the record with the most advanced stage will be included in analysis.

The rationale for this change in approach for international survival comparisons follows:

- Long-established registries are able to identify most patients whose index tumour is their second (third, etc.) tumour. Newly established registries do not generally have the information to do this. If survival from a second tumour at a given site and age is different from survival after a first tumour, comparison of survival estimates that are restricted to first primary cancers could be subject to bias
- For cancers with a relatively good prognosis, adjustment for the occurrence of second cancers is required in order to obtain unbiased estimates of site-specific prevalence[59]
- Different rules for determining the existence of multiple primary malignancy are used by contributing registries. North American registries generally use the SEER (Surveillance Epidemiology and End Results) criteria,[60] while registries in the European Network of Cancer Registries generally use the criteria set by IACR (International Association of Cancer

Registries),[61] which are more conservative. Inclusion of all index primaries, regardless of rank order in a given patient, will reduce the impact of such differences on survival comparisons

- Cancer patients need treatment regardless of the rank of their tumour: survival estimates are required for those patients too
- The effect of including second and higher-order cancers is usually a small reduction in overall survival.[58] Recent trends in prostate cancer may have an opposite effect, however. The rapid increase in the incidence of prostate cancers, many of which have a benign clinical picture, has created a large prevalent pool of elderly male survivors who remain at high risk of developing a different cancer. If survival estimation were restricted to men with a *first* invasive cancer, men diagnosed with a colon cancer (say) who had already had a very early prostate cancer would not be included.

4.4 Data items

Given the global scale of this surveillance programme, and the fact that many registries - in both rich and poor countries - have not previously been involved in cancer survival analyses or international collaborative programmes, we have restricted the number of data items to the minimum required for quality control, the estimation of survival and patterns of stage at diagnosis and treatment. The specification of data variables is given in Annex 1.

Recent experience[36] has shown that even long-established registries may not have adequate data on stage at diagnosis for all cancer patients at the level of detail required for population-based comparison of stage-specific survival. Some registries use the UICC Tumour-Nodes-Metastasis (TNM) staging system,[62,63] others use SEER Summary Stage 2000,[64] others use Collaborative Stage,[j] and others use locally developed staging systems.

No bridging system currently offers a universal translation that is valid for each stage and all cancers.

We have developed an algorithm that enables component stage data in individual tumour records held by population-based cancer registries to be converted from TNM 5th and 6th editions (which covers the period 1995-2009 in most registries), into SEER Summary Stage 2000.[65] Deployment of this algorithm has enabled international comparison of stage-specific survival for cancers of the colorectum, lung, breast and ovary in the International Cancer Benchmarking Partnership.[k] The results for ovarian cancer are in press.[66,67] Results for colorectal, liver, lung and breast cancer are under review. It may be possible to adapt the algorithm for other epithelial neoplasms.

Despite these difficulties, many registries want to supply data on tumour stage for population-based comparisons. For the reasons given above, however, stage variables will be optional. They will include pathological and/or clinical T, N and M. We have also included the option to supply specialist staging classifications such as FIGO for gynaecological tumours, Dukes' for colorectal tumours and Ann Arbor for lymphomas.

4.5 Full dates of birth, diagnosis and death

Survival time between the dates of diagnosis and death (or emigration, loss to follow-up, end of study) will be computed in days and converted to years: this requires full dates (day, month, year). An accurate age at diagnosis also requires a full date of birth.

We hold statutory and ethical approvals for survival analysis using individual tumour records with full dates of birth, diagnosis and death.

[j] http://www.cancerstaging.org/cstage/manuals/
[k] http://info.cancerresearchuk.org/spotcancerearly/ICBP/

Most registries collect the full dates of birth, diagnosis and death, but some only collect the month and the year of one or more of these dates. For some registries that do collect full dates, providing individual records containing full dates for survival analysis by external researchers may be complicated by regulatory or legal concerns, usually on the grounds that those data items could enable the identification of persons. If full dates of birth, diagnosis and death are not available, however:

- some data quality control tests are disabled
- estimates of survival within the first month cannot be made
- survival comparisons are affected by biases that do not arise with full dates

It is impossible to calculate correctly the probability of survival in the first month or two after diagnosis if the data only contain the dates of diagnosis and death at the level of month and year. A person who is diagnosed and dies in July 2005 will be recorded as "diagnosis 07-2005, death 07-2005". The duration of survival will be computed as zero months, but the true survival time could be anything from 1 day (e.g. 7 July 2005 to 8 July 2005) to 30 days (1 July 2005 to 31 July 2005). Similarly, for a patient diagnosed in July 2005 who dies in August 2005 (diagnosis 07-2005, death 08-2005), the duration of survival will be recorded as 1 month, but the true survival time could be anything from 1 day (31 July 2005 to 1 August 2005) to 61 days (1 July 2005 to 31 August 2005).

This gives rise to an avoidable loss of precision at the most crucial point of the survival curve. The first month after diagnosis is usually when the probability of death is changing most rapidly: survival curves typically decay most steeply in the period immediately after diagnosis. That is also when the greatest differences in survival often arise, both between countries and between population groups within a country.[26,36,68,69] Survival in the first month affects the cumulative probability of survival for all subsequent durations, although the impact is smaller at longer intervals.[70]

We have analysed the biases in survival estimation and comparison that arise if full dates cannot be obtained. This is the evidence base for arguing that full dates should be used, especially in international comparisons of survival.[71]

4.6 Transmission of data files

Secure procedures are in place for the transmission and download of files (Annex 3).

4.7 Statistical analyses

The main analyses will follow this sequence:

- Distribution of variables that can affect survival (age, sub-site, morphology, stage)
- Estimation of survival by age and sex
- Standardisation for age with the appropriate set of weights for each cancer from the International Cancer Survival Standard (ICSS) weights[72]
- Multivariable regression to compare survival and the excess hazard of death between populations and over time, while adjusting for age, sex and race

Secondary analyses based on the survival estimates:

- Modelling of the population cure fraction
- Estimation of prevalence
- Estimation of the numbers of avoidable premature deaths

Global surveillance of cancer survival (CONCORD programme)

Incidence and mortality trends

Interpretation of survival trends and international differences can be improved by conjoint presentation of incidence and mortality.[34,36,73] Their combined utility in evaluating progress in cancer control is well known.[32]

Incidence data will be obtained from public databases at IARC[74] or directly from the cancer registries, and mortality data from the WHO database. We will examine regional or national incidence and mortality trends for the index cancers in each participating country.

Net survival

Net survival is what we wish to know: survival when the cancer can be considered as the only possible cause of death. It cannot be estimated directly from death certificates in population studies because the underlying cause of death is not consistently reliable by age, between countries or over time. In some countries, only the fact and date of death are available, while the cause of death is not.

Classical approaches to estimating population-based survival rely on a theoretical partitioning of the overall risk of death of cancer patients into two components. These are the background mortality (or baseline hazard of death), which is assumed to affect everyone whether they have cancer or not, and the cancer-related mortality (or excess hazard of death), which only affects cancer patients. The two hazards are assumed to be independent. The overall survival that can be directly observed reflects the sum of both hazards, while the expected survival reflects only the baseline hazard. Relative survival is the ratio of the observed and expected survival, and it reflects the excess hazard of death in cancer patients. It is interpretable as survival from the cancer after adjustment for other causes of death.

Relative survival has until very recently been considered as the best estimator for net survival[71-73], but net survival can now be directly estimated.[75,76] This is desirable for international comparisons of survival because it removes differences in the survival of cancer patients that are not related to their cancer. The excess hazard usually depends on demographic variables such as age, and in this situation relative survival may be a biased estimator of net survival, because the time to death from the cancer may not be independent of the time to death from other causes, and this bias tends to increase with time since diagnosis. The differences between net and relative survival estimates at 5 years after diagnosis are small, but the theoretical advantage is important.

Net survival will be estimated with an approach in which the total hazard of death is modelled as the sum of the cancer-related mortality hazard (the excess hazard), and the background mortality (the hazard of death from other causes). Age is the strongest factor in informative censoring, and unbiased estimates of net survival will be obtained by the inclusion of age as a continuous variable in all models. The background mortality will be derived from life tables for the general population from which the cancer patients are registered (see below).

Net survival will be estimated with the Pohar Perme estimator[76] at one and five years, and at five years, conditional on one-year survival, by registry, cancer, period of diagnosis, sex and age group, and where possible, race/ethnicity and stage at diagnosis.

Where five or more years of follow-up are available for all patients, we will use the classical cohort approach to estimate survival up to five years, since patients will have been followed up for at least that long. This should be viable for patients diagnosed up to 2008 or 2009, depending on the last year of follow-up (2013 or 2014) available for most registries (see Figure 1).

For patients diagnosed more recently, we will use the period approach[77] to estimate survival up to five years based on the latest calendar years for which adequate follow-up data for all patients are available, probably 2011-2013. Period survival estimates combine the conditional probabilities of survival in each successive year since diagnosis that were observed during the most recent period for which adequate follow-up data are available (probably 2011-13: shaded area in Figure 1). This approach is similar to the calculation of (period) life expectancy at birth from death rates at each age in the most recent year for which data are available. Period survival estimates represent a short-term prediction of five-year survival for patients diagnosed in 2011–13, if the most recently observed conditional probabilities of survival were to remain constant during the follow-up period of interest (here, up to the end of 2018). In most registries, survival probabilities will actually rise, so the period survival estimates for 2011–13 will be inherently conservative predictions of the (cohort) survival that will eventually be recorded, when the required data become available around 2021.

Where the follow-up data on deaths in the cancer patients are more recent (2014) than the incidence data (2013), we will use the hybrid approach[78] to obtain short-term predictions of survival based on follow-up during 2012-2014 (dashed outline in Figure 1).

Analyses will be performed in the latest version of Stata (StataCorp LP, College Station, TX).

4.8 Life tables

Some registries will supply complete life tables, but experience suggests that most will either submit the raw data on deaths and populations, or indicate the sources where we can obtain those data.[79]

For the first CONCORD study, we constructed 2,800 life tables of all-cause mortality rates single year of age (0-99 years) at death in the general population, by sex, cancer registry area, calendar year (1990-99) and (in the USA) race.[80] For CONCORD-2, we constructed a library of over 12,000 complete life tables of all-cause death rates by sex, race/ethnicity, registry and calendar year, to enable compensation for the wide differences and time trends in background mortality between national and regional populations in the estimation of net survival. These life tables are available from our web-site.[53]

For CONCORD-3, we will request the raw data on the numbers of deaths and the populations for selected years (death and population counts), either from the cancer registries or from national vital statistics offices. We will construct abridged (5-year) life tables and smooth them to single-year-of-age life tables up to age 99 years, using Poisson regression with flexible link functions to model the death rates.[81] Traditional methods of constructing complete life tables tend to fail when the data on deaths by age are relatively sparse. This prevented reliable estimation of relative survival in the first CONCORD study for blacks in five US states with relatively small black populations.[14] The new approach enables more robust life tables to be produced from sparse data, and it will enable reliable estimation of survival in smaller populations.

We will use linear interpolation between period life tables constructed from the available raw data to produce life tables for each year covered by the cancer data for each registry, to capture year-to-year changes in background mortality in all participating countries and regions up to 2014.

4.9 Inequalities in cancer survival

Racial and ethnic inequalities in survival can reflect differential effectiveness of health services for population groups within a country.[82,83] We will examine racial or ethnic differences in survival in

Israel (Jews, non-Jews), New Zealand (Maori, non-Maori), Singapore (Indian, Malay, Chinese) and the USA (Blacks, Whites).

4.10 Avoidable premature deaths

Equal treatment for a given cancer should yield equal outcome, regardless of race,[84] geography or socio-economic status.[85] Racial differences in survival in the USA have been known since the 1970s.[86] It can be shown that international, regional and socio-economic disparities in survival represent large numbers of avoidable premature deaths.[46,87] In Britain, some 11,000 more cancer patients a year died within five years of diagnosis up to 1999 than if five-year survival had been as high as the highest levels among 13 other countries in Europe: cancers of the breast, colorectum and lung accounted for half the avoidable deaths.[46] The survival deficit in England alone, representing about 10,000 (7%) avoidable premature cancer deaths every year, provided the evidence base for the 2011 national cancer strategy,[41] which aimed to halve that number to 5,000 by 2014. In Europe more widely, it has been estimated that disparities in five-year survival between the Nordic countries and other European countries may have represented up to 150,000 avoidable premature deaths a year during 1995-99, or 12% of the 1.3 million cancer deaths a year that occur within five years of diagnosis.[55]

CONCORD-3 will provide estimates of the number of deaths within five years of a cancer diagnosis that would be avoidable among black patients in the USA if their survival deficit in comparison with white patients were eliminated. It will identify any trends in these disparities among women diagnosed during the successive five-year periods 2000-2004, 2005-2009 and 2010-2014.

4.11 Population “cure” fraction

Identifying individual cancer patients who may be considered clinically cured is problematic, but the proportion of cancer patients who may be considered “cured” can be estimated from the level at which a curve of relative or net survival by time since diagnosis reaches a plateau, indicating that survivors to that point after diagnosis no longer have any significant excess mortality over that of the general population from which they are drawn.[88-90]

Mixture models[91] and other models[92] will be applied to the survival distributions to estimate the proportion of patients who may be considered cured, and the mean survival time of patients who die before the point of cure is reached. Estimates of cure have been made for patients with cancers of the bowel, breast and cervix in Europe.[93] The evidence of population cure for breast cancer is weak, even 20 years after diagnosis,[94,95] and cure is not likely to be estimable for cancers of the lung or liver. Levels of cure should be estimable in many populations, however, at least for cancers of the bowel and cervix, and for childhood leukaemia.[96] The cure fraction is not affected by lead-time bias.

4.12 Lead time, over-diagnosis and length bias

Diagnostic intensity and the availability of mass screening programmes vary widely between countries. This may produce differential effects of lead time, over-diagnosis and length bias for cancers such as those of prostate, breast and stomach. In this context, survival comparisons are more complex, and joint analysis of incidence, mortality and survival becomes even more important. In investigating the origins of survival differences, we propose to take account of these biases, where possible. Because the cure fraction is not affected by lead-time bias, comparable estimates of both survival and cure will help the interpretation of its impact on survival comparisons. Recent methodological developments enable the potential effects of lead time, over-diagnosis and length bias to be quantified.[97,98] This will be feasible in low-resolution analyses when stage data are available.

4.13 High-resolution studies

Health policy-makers need to know the main causes of disparities in cancer survival, both between countries and between regions or population sub-groups within a country, as part of the evidence base for policy development.[21,36] Evidence can be obtained by modelling the impact on survival differences of detailed clinical data that are not usually captured at cancer registration, such as diagnostic investigations and the details of surgery. Such "high-resolution" studies can be done with clinical data abstracted directly from the medical records by specialist registrars in selected cancer registries. High-resolution studies can show the extent to which international differences in survival are due to differences in stage at diagnosis,[99-102] sub-site distribution within an organ,[103] morphology and hormone receptors,[66,104] survival in the very elderly[105,106] and survival in the first year after diagnosis.[55]

Racial differences in treatment between blacks and whites contribute to the survival deficit for black women with breast cancer in the USA,[107] but while breast cancer treatment varies widely in Europe,[108] the US-Europe differences in survival from breast cancer[9,101] and other cancers[109,110] are not fully explained.

As part of the first CONCORD study, three high-resolution studies were conducted to examine the reasons why survival is generally higher in the USA than Europe. We collected data for some 12,000 patients diagnosed with cancer of the breast[111] or colorectum[112] in seven US states and 25,000 patients with the same cancers from 30 cancer registries in 12 European countries, using a common protocol. Early, node-negative breast cancers remain more frequent in the US than Europe. The US-European differences in breast cancer survival are mainly attributable to lower survival in Eastern Europe, where the mean excess hazard of death in the first three years was higher than elsewhere, especially for women aged 70 or over, or with locally advanced or metastatic tumours.[111]

Further high-resolution studies may be planned when the main survival comparisons are available to focus on the cancers and populations to be studies. Cancers of the colorectum, lung, breast, cervix and ovary would be candidates: stage at diagnosis is a major determinant of outcome, there is broad consensus on treatment, and access to high-quality treatment can vary widely in both developed[115] and developing[2] countries.

High-resolution studies have generally been retrospective, but the rapid evolution of diagnostic and therapeutic techniques leads to concern about timeliness. One approach might be for registries to collect the relevant data on suitable samples of patients on a prospective basis. This would enable population-based assessment of the impact of diagnosis and treatment in more timely fashion.

5 CONCORD Working Group

The CONCORD Working Group comprises representatives of each participating cancer registry, usually the director and one other person. For CONCORD-2, the Working Group comprised 496 persons, including members of the Central Analytic Team in London, members of the Steering Committee (ex officio), and a small number of scientists from other collaborating institutions. No more than two persons may be Working Group members from any given cancer registry.

6 CONCORD Steering Committee

The programme will be advised by the CONCORD Steering Committee,[l] which includes scientists from all over the world with a wide range of expertise in cancer registration, epidemiology, survival analysis and public health. The role of the Steering Committee is:

- to maintain communication between CONCORD Working Group members and study centres

[l] http://csg.lshtm.ac.uk/wp-content/uploads/2016/05/concordsc.pdf

- to propose improvements in study design
- to maintain an explicit policy on publication and authorship (Annex 9)
- to consider requests for access to the data (Annex 9)
- to help coordinate joint activity between CONCORD and other research projects

The Steering Committee will conduct most exchanges by email or teleconference.

Data submitted to the CONCORD programme remain the property of the source registry. They can only be used for the purposes for which they were supplied, as set out in the protocol. The Steering Committee will examine requests for access to the data for purposes that are not included in the CONCORD protocol, under an explicit policy for data release (Annex 9). Requesters will submit a short protocol explaining the need for the data.

7 Statutory and ethical approvals

The legal conditions under which data are collected and under which they may be accessed for research vary from country to country. Data requested for the CONCORD study relate to individuals diagnosed with cancer, but no data or codes allowing the direct identification of patients are required. Cancer registries will provide anonymous patient and tumour identification numbers which relate solely to their own registration system, and which carry no external meaning or potential for the identification of individuals.

The Cancer Survival Group has obtained the approval required under UK statute law from the Ethics and Confidentiality Committee of the statutory National Information Governance Board (NIGB) to process patient-identifiable information for the CONCORD study, without patient consent, under the Health Service (Control of Patient Information) Regulations 2002.[113] The approval includes specific permission to hold full dates (day, month, year) of birth, diagnosis and death, without patient consent (Annex 4):

> *"In reviewing this detailed application in depth, members had agreed that consent would not be feasible due to the large numbers of patients involved. Members also assessed the requested identifiers and agreed that these were reasonable in order to achieve the purposes. In particular, it was acknowledged that it would be necessary to access full dates of birth, diagnosis and death, as accurate survival calculations would require precise dates."*

Ethical approval has been obtained from the National Health Service South-East Research Ethics Committee (Annex 5).

These approvals are maintained annually.

8 Data security and confidentiality

The System-Level Security Policy of the Cancer Survival Group has been approved by the IT security adviser to NIGB. The policy sets out the requirements and responsibilities for all staff authorised to handle sensitive data, and the precise arrangements for physical and electronic security that are maintained to ensure the confidentiality of the data. The data controller responsible for data security is Professor Michel Coleman.

LSHTM is registered under the Data Protection Act 1998[114] (Z7513362).

9 International collaborations

The importance attached to global surveillance of cancer survival by national and international agencies is underlined by the official agreements that they have established with the CONCORD programme.

Global surveillance of cancer survival (CONCORD programme)

Organisation for Economic Co-operation and Development, Paris

The Organisation for Economic Co-operation and Development (OECD) has endorsed the CONCORD programme as:

> *"proving to be hugely valuable in our own work in documenting the quality of health care across countries. ... [I]t has contributed to a sea-change in how national policymakers are using international comparisons to improve their health systems."*

From 2017, OECD will include survival estimates from the CONCORD programme for 35 OECD Member countries, three Accession countries, six Key Partner countries and 12 other countries in its biennial publication *Health at a Glance*. This is an important recognition of the global coverage, methodological rigour and international comparability of the CONCORD survival estimates, which will now be used in over 50 countries in the evaluation of health system performance for the quality of cancer care.

International Atomic Energy Agency (IAEA), Vienna

The Programme for Action on Cancer Therapy (PACT) at IAEA has established a Practical Arrangement with the London School of Hygiene to support training in the CONCORD programme.

International Agency for Research on Cancer (IARC), Lyon

In 2011, the Cancer Survival Group at LSHTM initiated a Memorandum of Understanding with IARC to create a framework for capacity-building for cancer control. A second Memorandum of Understanding to collaborate on the CONCORD programme was established in 2012, and renewed in 2015.

10 National and international endorsements

The CONCORD programme is endorsed by many other national and international agencies: see the CONCORD web-page.[m]

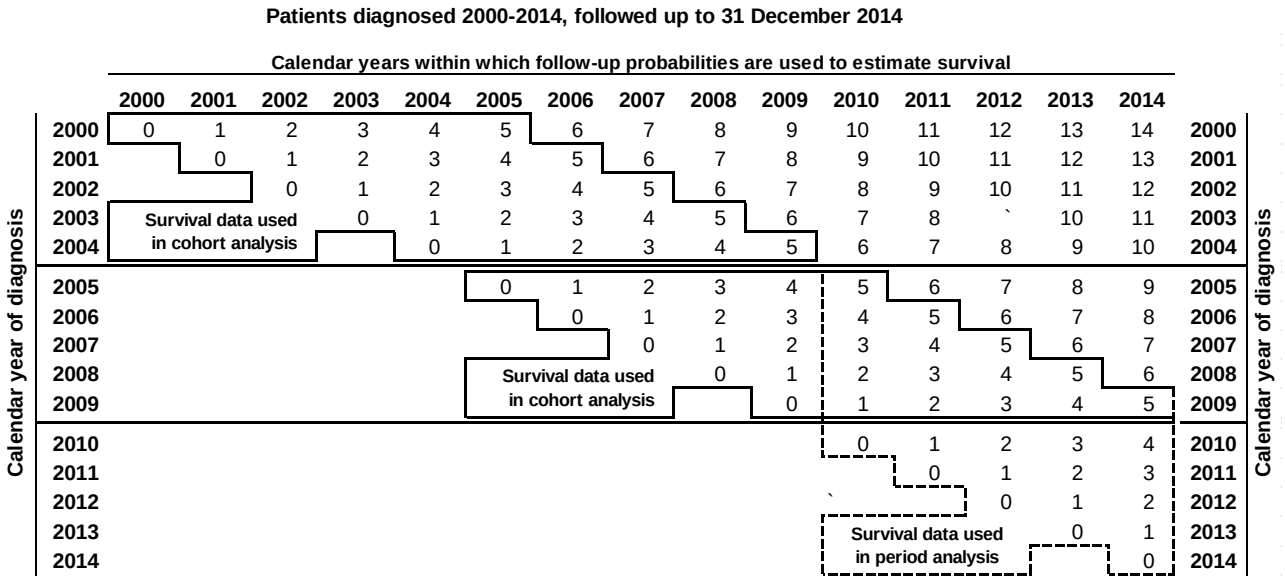
[m] http://csg.lshtm.ac.uk/research/themes/concord-programme/

Table 1: New diagnoses and deaths from cancer in 2012: number and proportion by sex and level of economic development

		Overall				Developed countries				Developing countries			
		Cases		Deaths		Cases		Deaths		Cases		Deaths	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Oesophagus	**Males**	323,008	**4.4**	281,217	**7.7**	67,748	**2.8**	56,099	**4.6**	255,260	**8.3**	225,118	**9.3**
	Females	132,776	**2.0**	118,952	**4.2**	18,396	**0.9**	15,249	**1.5**	114,380	**3.9**	103,703	**5.7**
	Persons	455,784	**3.2**	400,169	**6.2**	86,144	**1.9**	71,348	**3.2**	369,640	**6.2**	328,821	**7.8**
Stomach	**Males**	631,293	**8.5**	468,970	**10.1**	175,117	**5.4**	106,712	**6.7**	456,176	**10.9**	362,258	**11.8**
	Females	320,301	**4.8**	254,103	**7.2**	99,392	**3.5**	68,044	**5.3**	220,909	**5.8**	186,059	**8.2**
	Persons	951,594	**6.8**	723,073	**8.8**	274,509	**4.5**	174,756	**6.1**	677,085	**8.4**	548,317	**10.3**
Colorectum	**Males**	746,298	**10.1**	373,639	**8.0**	398,903	**12.4**	175,397	**11.0**	347,395	**8.3**	198,242	**6.5**
	Females	614,304	**9.2**	320,294	**9.0**	337,964	**12.0**	157,768	**12.3**	276,340	**7.2**	162,526	**7.2**
	Persons	1,360,602	**9.7**	693,933	**8.5**	736,867	**12.2**	333,165	**11.6**	623,735	**7.8**	360,768	**6.8**
Liver	**Males**	554,369	**7.5**	521,041	**11.2**	92,018	**2.9**	80,425	**5.1**	462,351	**11.1**	440,616	**14.4**
	Females	228,082	**3.4**	224,492	**6.3**	42,284	**1.5**	42,652	**3.3**	185,798	**4.9**	181,840	**8.0**
	Persons	782,451	**5.6**	745,533	**9.1**	134,302	**2.2**	123,077	**4.3**	648,149	**8.1**	622,456	**11.7**
Pancreas	**Males**	178,161	**2.4**	173,827	**4.8**	94,702	**3.9**	93,125	**7.6**	83,459	**2.7**	80,702	**3.3**
	Females	159,711	**2.4**	156,564	**5.6**	92,763	**4.4**	91,304	**9.1**	66,948	**2.3**	65,260	**3.6**
	Persons	337,872	**2.4**	330,391	**5.1**	187,465	**4.1**	184,429	**8.3**	150,407	**2.5**	145,962	**3.4**
Lung	**Males**	1,241,601	**16.8**	1,098,702	**23.6**	490,267	**15.2**	416,711	**26.2**	751,334	**18.0**	681,991	**22.3**
	Females	583,100	**8.8**	491,223	**13.8**	267,947	**9.5**	209,859	**16.3**	315,153	**8.2**	281,364	**12.4**
	Persons	1,824,701	**13.0**	1,589,925	**19.4**	758,214	**12.5**	626,570	**21.8**	1,066,487	**13.3**	963,355	**18.1**
Melanoma	**Males**	120,649	**1.6**	31,390	**0.7**	99,379	**3.1**	21,257	**1.3**	21,270	**0.5**	10,133	**0.3**
	Females	111,481	**1.7**	24,098	**0.7**	91,687	**3.2**	15,007	**1.2**	19,794	**0.5**	9,091	**0.4**
	Persons	232,130	**1.7**	55,488	**0.7**	191,066	**3.2**	36,264	**1.3**	41,064	**0.5**	19,224	**0.4**
Breast (F)	**Females**	1,671,149	**25.1**	521,907	**14.7**	788,200	**27.9**	197,618	**15.4**	882,949	**23.0**	324,289	**14.3**
Cervix	**Females**	527,624	**7.9**	265,672	**7.5**	83,078	**2.9**	35,514	**2.8**	444,546	**11.6**	230,158	**10.2**
Ovary	**Females**	238,719	**3.6**	151,917	**4.3**	99,752	**3.5**	65,904	**5.1**	138,967	**3.6**	86,013	**3.8**
Prostate	**Males**	1,094,916	**14.8**	307,481	**6.6**	741,966	**23.0**	142,014	**8.9**	352,950	**8.4**	165,467	**5.4**
Brain and CNS	**Males**	139,608	**1.9**	106,376	**2.3**	48,224	**1.5**	36,826	**2.3**	91,384	**2.2**	69,550	**2.3**
	Females	116,605	**1.8**	83,006	**2.3**	40,743	**1.4**	29,765	**2.3**	75,862	**2.0**	53,241	**2.4**
	Persons	256,213	**1.8**	189,382	**2.3**	88,967	**1.5**	66,591	**2.3**	167,246	**2.1**	122,791	**2.3**
Lymphomas	**Males**	256,163	**3.5**	130,867	**2.8**	117,434	**3.6**	44,429	**2.8**	138,729	**3.3**	86,438	**2.8**
	Females	195,528	**2.9**	94,272	**2.7**	101,821	**3.6**	36,992	**2.9**	93,707	**2.4**	57,280	**2.5**
	Persons	451,691	**3.2**	225,139	**2.7**	219,255	**3.6**	81,421	**2.8**	232,436	**2.9**	143,718	**2.7**
Leukaemias	**Males**	200,676	**2.7**	151,321	**3.3**	80,283	**2.5**	51,318	**3.2**	120,393	**2.9**	100,003	**3.3**
	Females	151,289	**2.3**	114,150	**3.2**	60,991	**2.2**	40,309	**3.1**	90,298	**2.4**	73,841	**3.3**
	Persons	351,965	**2.5**	265,471	**3.2**	141,274	**2.3**	91,627	**3.2**	210,691	**2.6**	173,844	**3.3**
Cancers included in CONCORD-3	**Males**	5,486,742	**74.0**	3,644,831	**78.3**	2,406,041	**74.6**	1,224,313	**76.9**	3,080,701	**73.6**	2,420,518	**79.1**
	Females	5,050,669	**75.9**	2,820,650	**79.5**	2,125,018	**75.2**	1,005,985	**78.2**	2,925,651	**76.4**	1,814,665	**80.3**
	Persons	10,537,411	**74.9**	6,465,481	**78.8**	4,531,059	**74.8**	2,230,298	**77.5**	6,006,352	**74.9**	4,235,183	**79.6**
All cancers except non-melanoma skin	**Males**	7,410,376	**100.0**	4,653,385	**100.0**	3,226,739	**100.0**	1,591,501	**100.0**	4,183,637	**100.0**	3,061,884	**100.0**
	Females	6,657,518	**100.0**	3,548,190	**100.0**	2,826,882	**100.0**	1,286,961	**100.0**	3,830,636	**100.0**	2,261,229	**100.0**
	Persons	14,067,894	**100.0**	8,201,575	**100.0**	6,053,621	**100.0**	2,878,462	**100.0**	8,014,273	**100.0**	5,323,113	**100.0**

Source:
Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F.
GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet].
Lyon, France: International Agency for Research on Cancer; 2013. Available from: http://globocan.iarc.fr, accessed on 25/11/2015.

Figure 1 Structure of survival analyses up to 2014



This graphic shows the structure of data to be used in the survival analyses. Patients diagnosed in a given year between 2000 and 2014 (rows) may be followed up in successive years (columns) until the end of 2014. Numbers in the cells indicate ***the minimum number of complete years of follow-up*** available for patients who were diagnosed in a given year (row) and survived to the end of a given year (column).

Three calendar periods of diagnosis may be defined for the analyses. Patients diagnosed during 2000-2004 all have a potential duration of follow-up of at least 5 years (and at least 10 years up to the end of 2009). Their survival can be estimated in classical **cohort** fashion (see text). The conditional probabilities of survival to the end of each successive year for each cohort are combined along the row (during successive calendar years) to obtain a cumulative probability of survival up to five years or 10 years.

Patients diagnosed during 2005-2009 also have five years of potential follow-up to the end of 2014.

A **period** estimate of survival can be made for patients who were alive and under follow-up for all or part of the period 2011-2014, by combining the conditional probabilities of survival within a given column (calendar period of observation) for patients diagnosed during 2006-2014 (shaded area).

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