Europe against Cancer:
Optimisation of the Use of Registries for Scientific Excellence in research

WP5 "Interface of cancer registries with cancer screening programmes"

D5.1 "Recommendations on screening related items in European data set"

Work group:
Ahti Anttila (chair)
Antonio Ponti
Guglielmo Ronco
Stefan Lönnberg (rapporteur)
Nea Malila
Arkadiusz Chil
Jacques Fracheboud
Sven Törnberg
Maja Zakelj
Lawrence von Karsa

Content

Content 2
1. Introduction 3
2. Evaluation of cancer screening 4
2.1 Evaluation methods 4
3. Registration procedures 5
3.1 Screening registration 5
3.2 Linkage procedures 6
4. Data items and coding structures for cancer screening registers 6
5. A minimum set of performance indicators for the European data 7
6. Dissemination within the European level 11
7. References 12
Appendix 1. Example of individual-level coding structure for breast cancer screening records .. 13
Appendix 2. Example of individual-level coding structure for cervical cancer screening records 27
Appendix 3. Example of individual-level coding structure for colorectal cancer screening records 41

Recommendations on screening related items in European data set

1. Introduction

The purpose of screening for cancer is to prevent mortality from the disease. In addition, cancer incidence and quality-of-life will be affected. It is essential that when providing screening for cancer, a well-organised population-based approach is utilised with systematic quality assurance at all appropriate levels [1].

According to the Council Recommendation [1], systematic implementation requires an organisation with a call/recall system and with quality assurance at all levels, and an effective and appropriate diagnostic, treatment and after-care service following evidence-based guidelines. Centralised data systems, including a list of all categories of persons to be targeted by the screening programme and data on all screening tests, assessment and final diagnoses, are needed to run organised screening programmes. Quality screening includes analysis of the process and outcome of the screening programme and rapid reporting of these results to the population and screening providers.

The purpose of the present recommendations on information on cancer screening is to outline procedures, data items and coding structures for a systematic individual-level registration of cancer screening programmes, provide a set of aggregated key performance indicators for the European level based on the European quality assurance guidelines for cancer screening, and illustrate how to compute the key performance indicators. Dissemination of aggregated information at the national and European levels is also dealt with. The recommendations are developed in the context of monitoring and evaluation which are essential to quality assurance of cancer screening [1-4]. Strictly speaking the "European data set" is a set of parameters or indicators and will be referred to as such in the present document.

There is a clear need to promote availability of standardised screening registration and respective data classification systems in the population-based cancer screening programmes across Europe. Effective utilisation of screening registers includes, but is not limited to systematic and comprehensive linkages with cancer, cause-of-death and other relevant registers in the health care system. Basic requirements for these linkages in quality assurance and evaluation of cancer screening programmes are also included in the presently proposed data descriptions. These recommendations have importance also in developing accreditation of cancer screening programmes.

The present document is based on key aspects of screening registration, and monitoring of the current European quality assurance guidelines for breast, cervical and colorectal cancer screening [2-4], and on activities of the work groups on registration of cancer screening in the former EU-funded project 'European Network for Information on Cancer' (EUNICE), and the current work group on "Interface of cancer registries with cancer screening programmes" of EUROCOURSE.

The present recommendations, including the data specifications and descriptions will be made available through the appropriate web-site.

2. Evaluation of cancer screening

Evaluation of cancer screening programmes involves analyses of process and outcome. Reduction in disease-specific mortality, being the primary purpose of screening, is the outcome of choice for studies of effectiveness. Impact on cancer incidence and overall mortality also need to be included in effectiveness studies. Process analyses include statistics of key monitoring data of cancer screening. These must be made publicly available on a regular basis, i.e., annually, and over longer periods of time at the local/regional, national and European level.

Evaluation and monitoring must also deal with cost-effectiveness and the adverse effects of screening. Screening can decrease quality of life, for example, through over-diagnosis, overtreatment, serious complications, anxiety due to false positive test results or through prolonged cancer morbidity due to diagnosis in the preclinical phase. Continuous evaluation of the balance between mortality outcome, life-years gained, potential adverse effects, and quality of life is essential.

2.1 Evaluation methods

Randomised controlled trials on the outcome and balance between benefit and harm should be performed whenever a new programme or a new screening technology is being planned or implemented. Experimental studies can be embedded also as randomised public health trials within established, well-organised programmes or in the roll-out of new programmes with a random allocation of a modality [5,6]. This approach both reduces costs compared to separate trials and provides data on actual performance and outcome in the routine health-care environment. When investigating process performance or e.g. diagnostic accuracy of methods, cross-sectional studies can also be embedded within screening programmes. In order to utilise these designs, information must be collected from the screening register at an individual level. Respective information from the control population is also required.

In the absence of a randomised setting, observational cohort studies with exposure to screening invitation or screening participation linked to incidence and mortality outcomes are recommended [2-4,7,8]. Expected rates can be estimated from the period before screening was implemented, or, if relevant, using a reference population not targeted for screening. If baseline risk has changed during a prolonged screening period and no reference population exists (the whole general population invited), modelling or simulation studies can be used to describe the expectation without screening.

Case-control studies compare risk between groups with different screening histories. The absolute risks remain unknown. This complicates correction for self-selection bias in attendance and can result in over-estimation of the screening effect [7,8]. A specific case-control setting is required for systematic audit of screening, based on cases observed in the population. These studies can assess screening policy aspects and screening validity, by reviewing screening tests and histological samples [2,3]. The systematic audit can identify shortcomings in the screening process, such as barriers to participation or suboptimal professional performance; and feed-back is valuable in order to enable the programme to deal with them effectively.

Trends of cause-specific incidence and mortality in the overall target population can also be informative. Comparison of trends sometimes necessitates transformation of the screening-register-based data to aggregated data in small geographical units and/or various time-windows.

The mode of detection, see D5.2 of the Eurocourse WP5, also gives important feed-back on the impact of the programme.

3. Registration procedures

3.1 Screening registration

As pointed out in the European cancer screening guidelines [2-4] the information in cancer screening registers should cover the following key conditions, components and activities:

- target population
- unique personal identifiers
- relevant background and anamnestic data
- invitations
- allocated screening method
- screening visit
- test results
- recommendations based on the result
- referral for assessment
- diagnosis, treatment and management.

A minimum set of the above data items and their coding structures that are recommended to be registered from each individual screening episode are presented in Chapter 4 and in related appendices below. The screening register database will consist of data from all the episodes in the programme.

Screening registers should include information on any diagnostic tests and treatments in participants, even if they are performed outside the programme [3]; if the test was performed in opportunistic screening or due to clinical indication or management that should also be recorded

The internal and external quality of the central screening registries needs to be checked and errors corrected. Unique personal identifiers are required to compile the full information of an individual over multistep screening episodes, and to link this information to other data sources in health-care.

Appropriate funding of screening registration and its utilisation should be included in the planning and quality assurance of screening programmes. An appropriate legal framework and related communication and training are required for registration of individual data and linkage between population databases, screening files, and cancer and mortality registers.

The screening register should provide information also on the basic descriptions of the data sources, coding structures & recommendations within the programmes, linkages, and other such basic data structures.

3.2 Linkage procedures

Registers used in monitoring and evaluation of screening programmes include screening registers, population registers, cancer registers, cause of death registers, and registers of treatment and diagnostic services such as hospital/outpatient discharge registers. Vaccination registers and biomaterial archives in the health-care system also require linkage. The same unique personal identifier should be used in all of the registers to enable accurate linkage procedures. Appropriate quality control of the registers is required and will involve linkages between the data in the registers.

Cause of death statistics may be less accurate concerning the specific cancer site than the cancer registry data, as cancer registries can utilise multiple data sources. For example, "uterus, NOS," may be listed as the cause of death in death statistics, while the cancer registry may have more information on the original cancer diagnosis, such as "cervix uteri". Thus, regular linkages between the two registers are required.

It is equally important to check that the information from the screening registry has reached the cancer registry because linkages between these data sources permit detection and correction of deficiencies in the cancer registry data. Since cancer registries should have as complete and accurate data as possible with several notifications per case, the cancer registry should decide which case is an invasive cancer case and which is pre-invasive, such as CIN3 or in situ. This information should then be taken into account in the final information within the screening register.

Information on less severe findings than those included in the cancer registry − e.g. the screening test result, assessment and/or treatment − can vary in different time points of the diagnostic and management process. This information in the screening register can therefore be less reproducible than the final data in the cancer registry. It is important to collect information on these findings from all sources (registers and patient files) and to systematically define the final information for the screening register based on linkages.

4. Data items and coding structures for cancer screening registers

It is essential to distinguish between the data input to screening registers, and the information needed to generate the aggregated monitoring data which programmes should provide to the data portal for key performance indicators at the European level. The data input to the screening registers should utilise as far as possible electronic data with standard coding practice within the health-care system. This data can be condensed and processed further in order to provide information required for the standard performance indicators. The data to be provided to the European data portal should be generated from the standard individual data of the screening register in such a manner that elaboration of the performance indicators also follows the standard definitions.

Descriptions and examples of the recommended standard coding structures for the input data for cancer screening registers required to produce the minimum set of standard performance indicators are shown separately for the three cancer screening programmes (breast, cervix uteri, and colorectal cancers) in the Appendices 1-3.

Further specifications must be developed for the central national or regional screening registers mentioned above in order to permit quality-controlled input and processing of individual data and tabulation of the minimum set of aggregate indicators proposed in Section 5 for monitoring implementation of screening at the European level.

5. Minimum set of performance indicators for European monitoring data

The requested aggregated indicators for breast cancer screening recommended by the experts in Work Package 5 are shown in Table 1.

The requested aggregated indicators for cervical cancer screening are shown in Table 2.

The requested aggregated indicators for colorectal cancer screening are shown in Table 3. :

Appendices 1-3 include definitions for the standard individual data input for screening registers. More detailed instructions and specifications will be required to test and validate the regular production of the the above standard key performance indicators at the European level.

Table 1. Description of the performance indicators to be generated for European monitoring data on breast cancer screening.

Indicator	Numerator	Denominator
Extension by screening programme	N target population within the area with the organised screening programme	N of population with corresponding age and gender within the whole country
Coverage by invitation	N women invited during time frame	N women in target population
Coverage by examination	N women screened during time frame	N women in target population
Participation rate	N women invited and screened in episode	N women invited in episode
Further assessment rate	N screened referred to further assessment	N screened
Technical repeat rate	N with a recall for technicaql reasons	N screened
Intermediate mammography rate	N recalled with symptoms	N screened
Missing (indicators required for various levels)	N screened but with the 1st level result missing	N screened
Referral to surgery rate	N referred to surgery or inoperable cancer	N screened
B/M ratio	N with benign histological diagnosis	N with histologically confirmed in situ or carcinoma
Breast cancer detection rate (in situ included)	N with histologically confirmede in situ or carcinoma	N screened
Breast cancer detection rate (DCIS)	N with DCIS	N screened
Breast cancer detection rate (invasive)	N with breast carcinoma	N screened
Benign biopsies rate	N with benign histology	N screened
Small invasive cancers as proportion of invasive cancers	N with carcinoma with pT 1A or 1B	N with carcinoma
Missing small invasive cancers as proportion of invasive cancers	N with carcinoma with pT missing	N with carcinoma
Node negative cancers / total cancers screen-detected	N with lymph nodal status negative	N with carcinoma
Missing node negative cancers / total cancers screen-detected	N with data missing on lymph nodal status	N with carcinoma
Stage II+ breast cancers / total cancers screen-detected	N with pTNM stage IIA to IV	N with carcinoma
Missing stage II+ breast cancers / total cancers screen-detected	N with missing data on pTNM stage	N with carcinoma
Stage II+ breast cancers / total screened women	N with pTNM stage IIA to IV	N screened
Missing stage II+ breast cancers / total screened women	N with missing data on pTNM stage	N screened
Conservative therapy (DCIS)	N with DCIS with breast conserving surgery	N with DCIS operated
Missing conservative therapy (DCIS)	N with DCIS operation code missing	N with DCIS
Conservative therapy (invasive)	N with carcinoma with breast conserving surgery	N with carcinoma
Missing conservative therapy (invasive)	N with carcinoma with operation code missing	N with carcinoma
Conservative therapy (pT1)	N with carcinoma with pT1 with breast conserving surgery	N with carcinoma with pT1
Missing conservative therapy (pT1)	N with carcinoma with pT1 with operation code missing	N with carcinoma with pT1

Table 2. Description of the performance indicators to be generated for European monitoring data on cervical cancer screening.

Indicator	Numerator	Denominator
Extension by screening programme	N target population within the area with the organised screening programme	N of population with corresponding age and gender within the whole country
Coverage by invitation	N women invited during time frame	N women in target population
Coverage by examination	N women screened during time frame	N women in target population
Compliance to invitation	N invited and screened women in episode	N invited women in episode
Incidence of fully invasive cancer in unscreened and underscreened women	N fully invasive cancers detected in women not screened within interval	N person-years of women not screened for interval
Distribution of screened women by the results of cytology	N of women with each cytological diagnosis	N women screened in programme
Referral rate for repeat cytology	N screened women recommended for repeat screening after shorter interval	N women screened in programme
Compliance with referral for repeat cytology	N women screened after shorter interval	N women recommended for shorter interval
Referral rate for colposcopy	N women referred for colposcopy	N women screened in programme
Positive predictive value of referral for colposcopy	N women with histologically confirmed CIN1+/CIN2+/CIN3+	N women with colposcopy
Test specificity	N screened women not referred for colposcopy	N screened women with no CIN1+/CIN2+/CIN3+
Detection rate by histological diagnosis	N screened women with each histological diagnosis	N women screened in programme
Cancer incidence after normal cytology (optional)	N screened women with fully invasive cancer within interval after normal test	N person-years of women with normal test for interval
Compliance to referral for colposcopy	N screened women with colposcopy	N women referred for colposcopy
Treatment of intraepithelial lesions	N women with treated screen-detected lesions CIN1/CIN2/CIN3	N women with screen-detected lesions CIN1/CIN2/CIN3
Proportion of women hysterectomised on screen-detected intraepithelial lesions	N women hysterectomised on histological CIN1/CIN2/CIN3	N women with histological CIN1/CIN2/CIN3
Incidence of non-screen-detected fully invasive cancer after abnormal cytology (optional)	N cases of invasive cancer after abnormal cytology	N person-years of screened women after abnormal cytology

Table 3. Description of the performance indicators to be generated for European monitoring data on colorectal cancer screening.

Indicator	Numerator	Denominator
Extension by screening programme	N target population within the area with the organised screening programme	N of population in corresponding age groups within the whole country
Invitational coverage	N invited during time frame	N eligible in target population
Coverage by examination	N screened or tested during time frame	N eligible in target population
Compliance to invitation (uptake rate)	Screened	Invited
Rate of inadequate tests	Inadequate	Screened
Rate of test positives	Positive test result	Screened
Referral rate to colonoscopy after positive test	Referred	N with a positive test result
Compliance to colonoscopy	Colonoscopied	Referred
Rate of complete colonoscopies	Complete colonoscopies	Total colonoscopied
Biopsy rate	Biopsy taken	Colonoscopied
Lesion detection rate	N with at least one lesion	Screened
Adenoma detection rate	N with at least one adenoma	Screened
Advanced adenoma detection rate	N with at least one advanced adenoma	Screened
Cancer detection rate	N with at least one cancer	Screened
PPV for detection of lesions	N with at least one lesion	N with colonoscopy
PPV for detection of adenoma	N with at least one adenoma	N with colonoscopy
PPV for detection of advanced adenoma	N with at least one advanced adenoma	N with colonoscopy
PPV for detection of cancer	N with at least one cancer	N with colonoscopy
Endoscopic complications	N with complication	N with colonoscopy
Interval cancer (optional)	Cancer in screen negatives or episode negatives during the interval	
Screen detected cancer	Cancer in screen positives during a specified time (e.g. 6 months)	

6. Dissemination within the European level

The assessment of the status and impact of cancer screening in Europe requires assessment of both short-term and long-term indicators. Standard sets of screening indicators and outcomes are provided by the European guidelines for quality assurance in cancer screening. The present document focuses on the specifications of data elements required in cancer screening registration, and descriptions of how this data can be used to produce key data for monitoring cancer screening in Europe. Collection of aggregated data from national or regional cancer screening programmes is feasible, as demonstrated for cervix and breast cancer screening by the EUNICE project. Such regular monitoring systems for cancer screening are not yet available at the European level, however. We propose here that they be made available because regular monitoring activity is needed within the European Union to recognize best practices which could improve performance and outcome through more effective dissemination across the EU and to recognize areas in need of improvement.

We have defined for this purpose a comprehensive, minimum data matrix, i.e., minimum set of individual variables, including descriptions of the characteristics or events recorded and relevant data coding standards when available. Based on these documents, a web-based data portal for monitoring cancer screening in Europe can be further planned. The portal would consist ideally of background documents on the implementation of national or regional cancer screening programmes, further specifications used in their screening registers, standard input data from the national and/or regional cancer screening registers, and the standard reporting of the aggregated performance indicators for the European-level monitoring on cancer screening.

Given the current absence of regular monitoring activity at the European level, design and piloting of a model data warehouse for screening monitoring and evaluation is essential. This would provide the technical and organizational infrastructure to make the information matrix operational and to support the individual screening programmes in implementing the recommended standards.

An official reference group to develop standards of data integration in cancer screening is also needed at the European level. The activities of the group should be included in efforts to develop standards of data integration for other chronic disease. Setting up a continuous activity, co-ordinated at the European level, would also facilitate preparation of periodic status reports on screening in Europe based initially on standardized data collection and analysis. These activities should be coordinated with the national or regional cancer screening registers and could be lead by the Quality Assurance Group (QAS) at the IARC, Lyon which has coordinated the production of the first report on implementation of cancer screening in the EU [9].

Piloting the collection and validation of the aggregate data for European-level monitoring will require specific project funding. The impact of this funding could be enhanced by combining activities with projects using the screening data for prioritised research on cancer screening (D5.3 of the Eurocourse). The pilot funding is proposed to be obtained through a new ERANET application for cancer screening programmes from EU/FP7 during the course of 2012. In addition, sustainable funding is required to permit regular use of the European monitoring data.

7. References

[1] Council of the European Union (2003), Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC), Off J Eur Union no. L 327, pp. 34-38.

[2] Perry N, Broeders M, de Wolf D, Törnberg S, Holland R, von Karsa L. European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. Luxembourg: Office for official publications of the European Communities; 2006.

[3] Arbyn M, Anttila A, Jordan J, Ronco G, Schenck U, Segnan N, et al. European guidelines for quality assurance in cervical cancer screening. 2 ed. Luxembourg: Office for Official Publications of the European Communities; 2008.

[4] Segnan N, Patnick J, von Karsa L. European guidelines for quality assurance in colorectal cancer screening and diagnosis. Luxembourg: Office for official publications of the European Communities; 2010.

[5] Anttila A, Hakama M, Kotaniemi-Talonen L, Nieminen P. Alternative technologies in cervical cancer screening: a randomised evaluation trial. BMC public health 2006; 6:252.

[6] Malila N, Oivanen T, Malminiemi O, Hakama M. Test, episode, and programme sensitivities of screening for colorectal cancer as a public health policy in Finland: experimental design. BMJ (Clinical research ed 2008; 337:a2261.

[7] IARC. Breast Cancer Screening. International Agency for Research on Cancer (IARC) Handbooks of Cancer Prevention. Lyon: IARC Press; 2002. p. 229.

[8] IARC. Cervix Cancer Screening. International Agency for Research on Cancer (IARC) Handbooks of Cancer Prevention. Lyon: IARC Press; 2005. p. 302.

[9] von Karsa L, Anttila A, Ronco G, Ponti A, Malila N, Arbyn M, Segnan N, Castillo-Beltran M, Boniol M, Ferlay J, Hery C, Sauvaget C, Voti L & Autier P (2008), Cancer Screening in the European Union. Report on the implementation of the Council Recommendation on Cancer Screening - First Report European Commission, Luxembourg.

[10] Solomon D, Davey D, Kurman R, Moriarty A, O'Connor D, Prey M, et al. The 2001 Bethesda System: terminology for reporting results of cervical cytology. Jama 2002; 287(16):2114-9.

[11] Fritz A, Percy C, Jack A, Shanmugaratnam K, Sobin L, Parkin D, et al. International Classification of Diseases for Oncology. 3rd ed. (ICD-O-3). Geneva: World Health Organization; 2000.

[12] The International Health Terminology Standards Development Organisation.

[13] Sobin L, Gospodarowicz M, Wittekind C. TNM Classification of Malignant Tumours. 7th ed ed. Oxford: Wiley-Blackwell; 2009.

[14] Bay-Nielsen H, Niinimäki T, Magnússon J, Birkeland S, Thorsen G, van Paaschen H. NOMESCO Classification of Surgical Procedures, version 1.15 no. 93 Copenhagen: Nordic Medico-Statistical Committee (NOMESCO); 2010.

[15] L.H. Sobin, C. Wittekind C (eds.): TNM classification of malignant tumours. Fifth edition 1997, John Wiley & Sons.

[16] L.H. Sobin, C. Wittekind C (eds.): TNM Classification of malignant tumours, Sixth edition 2002, John Wiley & Sons.

[17] The Paris Classification (2003), The Paris endoscopic classification of superficial neoplastic lesions: esophagus, stomach, and colon: November 30 to December 1, 2002, Gastrointest.Endosc., vol. 58, no. 6 Suppl, pp. S3-43.

Appendix 1. Example of individual-level coding structure for breast cancer screening records

Var#	Variable name	Format	Length	Values	Description	Coding standard	Note
					ID		
01	Personal ID	STR					
02	Date of birth	DATE	10		DD/MM/YYYY		

		INVITATION		
03	Regional ID	STR		
04	Screening program ID	STR		
05	Number of episode for this patient	INT	2	1…N
06	Date of first invitation in this episode	DATE	10	DD/MM/YYYY
07	Date of reminder	DATE	10	DD/MM/YYYY

1ST LEVEL MAMMOGRAM					
08	Screening attendance	INT	1	0	No
				1	Yes
09	Reason for mammogram	INT	1	0	Programme invitation
				1	Self referral
				2	Clinical first level mammogram
10	Date of 1st level examination	DATE	10		DD/MM/YYYY
11	Screening centre code	STR			
12	Type of unit	INT	1	1	Fixed
				2	Mobile
13	Rank	INT	2		1…N
14	1st level mammogram result	INT	1	0	No 1st level, sent to 2nd level
				1	Normal
				2	Benign
				3	Maybe malignant
				4	Suspicion of malignancy
				5	Obvious malignancy
15	Reason for further assessment	INT	1	0	No further assessment
				1	Radiological findings
				2	Subjective breast symptoms
				3	Other

2ND LEVEL RADIOLOGICAL EXAMINATION					
16	Date of 2nd level examination	DATE	10		DD/MM/YYYY
17	Result of 2nd level examination	INT	1	0	None performed
				1	Normal
				2	Benign
				3	Maybe malignant
				4	Suspicion of malignancy
				5	Obvious malignancy
18	Woman refuses examination	INT	1	0	No
				1	Yes

CLINICAL ASSESSMENT					
19	Number of assessment in episode	INT	2		1…N
20	Assessment centre code	STR			
21	Assessment date	DATE	10		DD/MM/YYYY
22	Result of the assessment	INT	1	0	None performed
				1	Normal
				2	Benign
				3	Maybe malignant
				4	Suspicion of malignancy
				5	Obvious malignancy
23	Woman refuses examination	INT	1	0	No
				1	Yes

CYTOLOGICAL EXAMINATION					
24	Date for fine needle biopsy	DATE	10		DD/MM/YYYY
25	Biopsy guidance	INT	1	0	Manual
				1	ultrasound
				2	x-ray
26	FNA result	INT	2	0	None performed
				1	Normal
				2	Benign
				3	Atypical
				4	Suspicion of malignancy
				5	Malignant
				9	Not possible to assess
27	Refusal of cytological examination	INT	1	0	No
				1	Yes

CORE NEEDLE BIOPSY AT SCREENING CENTRE							
28	Date for core biopsy	DATE	10		DD/MM/YYYY		
29	Biopsy guidance	INT	1	0	Manual		
				1	ultrasound		
				2	x-ray		
30	Core Biopsy result	STR	5			SNOMED/ICDO-3*	Morphology + behaviour sometimes classified to: normal, benign, atypical, suspicion of malignancy, malignant
31	Woman refuses core biopsy	INT	1	0	No		
				1	Yes		

REFERRAL TO SURGERY					
32	Referral to surgery	INT	1	0	No
				1	Yes
33	Date of referral	DATE	10		DD/MM/YYYY

MULTIDISCIPLINARY CONFERENCE/DECISION FOR TREATMENT					
34	Date for treatment decision	DATE	10		DD/MM/YYYY
35	Type of decision	INT	1	0	No treatment
				1	Control (intensified screening)
					CNB
				2	Surgical biopsy
				3	Definitive treatment
				4	Declines treatment
36	Neoadjuvant chemotherapy	INT	1	0	No
				1	Yes
37	Tumor size before neoadjuvant	INT	3		mm

					SURGERY		
38	Date of first breast intervention	DATE	10		DD/MM/YYYY		
39	Date of final surgical procedure	DATE	10		DD/MM/YYYY		
40	Type of final intervention	STR	5			NOMESCO†	Can be condensed to: Not operable partial mastectomy partial mastectomy + ax. Resection mastectomy mastectomy + ax.
41	Sentinel node	INT	1	0	Negative		
				1	Positive		
				9	Not assessed		

PATHOLOGICAL REPORT						
42	Histological diagnosis	STR	5		SNOMED/ICDO-3*	Morphology + behaviour
43	Pathological size (mm)	INT	3	0-999 mm.		
44	Hormonal receptor status					
45	Number of removed lymph nodes	INT	2	1…N		
46	Number of positive lymph nodes	INT	2	1…N		

STAGE/GRADE					
47	pT - primary tumour	STR	3	Tx	TNM‡
				T0	
				Tis	
				T1	
				T1a	
				T1b	
				T1c	
				T2	
				T3	
				T4	
				T4a	
				T4b	
				T4c	
				T4d	
48	pN - regional lymph nodes	STR	3	Nx	TNM‡
				N0	
				N1	
				N1a	
				N1b	
				N1c	
				N2	
				N2a	
				N2b	
				N3	
				N3a	
				N3b	
				N3c	

49	M - distant metastasis	STR	2	M0		TNM‡
				M1		
50	pTNM stage	INT	2	0		TNM‡
				IA		
				IB		
				IIA		
				IIB		
				IIIA		
				IIIB		
				IIIC		
				IV		
51	Grade	INT	2	0	Not performed	
				1	Grade 1	
				2	Grade 2	
				3	Grade 3	

					SUMMARY
52	Result of the episode	INT	2	1	Returned letter
				2	Not respondent (screening)
				3	Not respondent (assessment)
				4	Incomplete assessment
				5	Negative
				6	Surgery or inoperable cancer
53	Episode classification	INT	2	1	Screen detected
				2	Screened NSD
				3	Never attending
54	Date of final report	DATE	10		DD/MM/YYYY

NOTE: all results variables are duplicated for the other breast

* SNOMED CT at http://www.ihtsdo.org/ and Fritz A, Percy C, Jack A, Shanmugaratnam K, Sobin LH, Parkin DM, Whelan S (2000). International Classification of Diseases for Oncology (ICD-O). 3rd ed. World Health Organization: Geneva.

†NOMESCO Classification of Surgical Procedures (http://www.nordcase.org/eng/ncsp/)

‡L.H. Sobin, M.K. Gospodarowicz and Ch. Wittekind (eds.):TNM Classification of Malignant Tumours. Seventh edition 2009, Wiley-Blackwell

Appendix 2. Example of individual-level coding structure for cervical cancer screening records

Var#	Variable name	Format	Length	Values	Description	Coding standard	Note
					ID		
01	Personal ID	STR					
02	Date of birth	DATE	10		DD/MM/YYYY		

INVITATION					
03	Regional ID	STR			
04	Screening program ID	STR			
05	Number of episode for woman	INT	2		1…N
06	First appointment date	DATE	10		DD/MM/YYYY
07	Reminder appointment date	DATE	10		DD/MM/YYYY
08	Reason for invitation/sample	INT	1	1	invitation by age
				2	repeat cytology
				3	repeat HPV
				4	opportunistic
				5	diagnostic smear
				6	follow-up after treatment

		SAMPLING		
09	Sampling date	DATE	10	DD/MM/YYYY
10	Randomisation group			
11	Type of sampling unit			
12	Sampling unit			

				TEST RESULTS		
13	Analysis date	DATE	10		DD/MM/YYYY	
14	Analysis technique	INT	1	1	conventional	
				2	liquid-based (specify type)	
				3	other (specified)	
15	Specimen adequacy	INT	1	1	satisfactory	TBS2001*
				2	satisf. but no endocerv. cells	
				3	satisfactory but limited	
				4	unsatisfactory sample	
16	General category	INT	1	1	negative for intraepithelial lesion	TBS2001*
				2	intraepithelial lesion	
				3	other abnormality	
17	Squamous cell abnormality	INT	1	0	no squamous cell abnormality	TBS2001*
				1	ASC-US	
				2	ASC-H	
				3	LSIL	
				4	HSIL	
				5	squamous carcinoma	
18	Glandular cell abnormality	INT	1	0	no glandular cell abnormality	TBS2001*
				1	AGC, atypical endocervical cells	
				2	AGC, atypical endometrial cells	
				3	AGC-NOS, atypical glandular cells	
				4	AGC-FN, favor neoplastic, endocerv.	
				5	AGC-FN, favor neoplastic	
				6	AIS, endocervical adenoca in situ	
				7	adenocarcinoma	
19	Pathological organisms	INT	1	0	no	TBS2001*
				1	yes	
20	Reactive changes	INT	1	0	no	TBS2001*
				1	yes	
21	Other non-neoplastic changes	INT	1	0	no	TBS2001*
				1	yes	

22	Papanicolaou classification	INT	5	0	unsatisfactory
				1-5	Pap 1-5
23	HPV sampling date	DATE	10		DD/MM/YYYY
24	HPV laboratory	STR			
25	HPV method	STR			
26	HPV analysis date	DATE	10		DD/MM/YYYY
27	HPV result	INT	1	0	not performed
				1	negative
				2	positive

RECOMMENDATION					
28	Recommendation	INT	1	0	negative test result
				1	Control sample / shorter interval
				2	Referral for colposcopy
29	Referral date	DATE	10		DD/MM/YYYY

SECONDARY ASSESSMENT						
30	Colposcopy compliance	INT	1	0	no	
				1	yes	
31	Date of colposcopy	DATE	10		DD/MM/YYYY	
32	Date of histopathology	DATE	10		DD/MM/YYYY	
33	Diagnosing care provider	STR				
34	Diagnosis topography	STR	3	C51	Vulva	ICD-0-3†
				C52	Vagina	
				C53	Cervix uteri	
				C54	Corpus uteri	
				C55	Uterus, NOS	
35	Diagnosis morphology	INT	5	00100	Normal or benign	
				74006	Dysplasia levis	SNOMED‡
				74007	Dysplasia moderata	SNOMED‡
				74008	Dysplasia gravis	SNOMED‡
				80702	Squamous cell carcinoma in situ	ICD-0-3†
				80703	Squamous cell carcinoma	ICD-0-3†
				80763	Squamous cell carcinoma, microinv	ICD-0-3†
				80772	Squamous intaepith. neopl, gradeIII	ICD-0-3†
				81402	Adenocarcinoma in situ	ICD-0-3†
				81403	Adenocarcinoma	ICD-0-3†

36	Clinical class of primary	STR	4	cTx	Primary tumour cannot be assessed	TNM§
				cT0	No evidence of primary tumour	
				cTis	Carcinoma in situ	
				cT1	Cercvical carcinoma confined to uterus	
				cT1a	Invasive carcinoma diagnosed only by microscopy	
				cT1a1	Stromal invasion no greater than 3.0 mm in depth and 7.0 mm or less in horizontal spread	
				cT1a2	Stromal invasion more than 3.0 mm and not more than 5.0 mm with horizontal spread 7.0 mm or less	
				cT1b	Clinically visible lesion confined to the cervix or microscopic lesion greater than T1a	
				cT1b1	Clinically visible lesion 4.0 cm or less in greatest dimension	
				cT1b2	Clinically visible lesion more than 4.0 cm in greatest dimension	
				cT2	Tumour invades beyond uterus but not to pelvic wall or to lower third of vagina	
				cT2a	Without parametrial invasion	
				cT2b	With parametrial invasion	
				cT3	Tumour extends to pelvic wall, involves lower third of vagina, or causes hydronephrosis or non-functioning kidney	
				cT3a	Tumour involves lower third of vagina, no extension to pelvic wall	

cT3b	Tumour extends to pelvic wall or causes hydronephrosis or non-functioning kidney
cT4	Tumour invades mucosa of bladder or rectum or extends beyond true pelvis

37	Pathological class of primary	STR	5	pTx	Primary tumour cannot be assessed	TNM§
				pT0	No evidence of primary tumour	
				pTis	Carcinoma in situ	
				pT1	Cercvical carcinoma confined to uterus	
				pT1a	Invasive carcinoma diagnosed only by microscopy	
				pT1a1	Stromal invasion no greater than 3.0 mm in depth and 7.0 mm or less in horizontal spread	
				pT1a2	Stromal invasion more than 3.0 mm and not more than 5.0 mm with horizontal spread 7.0 mm or less	
				pT1b	Clinically visible lesion confined to the cervix or microscopic lesion greater than T1a	
				pT1b1	Clinically visible lesion 4.0 cm or less in greatest dimension	
				pT1b2	Clinically visible lesion more than 4.0 cm in greatest dimension	
				pT2	Tumour invades beyond uterus but not to pelvic wall or to lower third of vagina	
				pT2a	Without parametrial invasion	
				pT2b	With parametrial invasion	
				pT3	Tumour extends to pelvic wall, involves lower third of vagina, or causes hydronephrosis or non-functioning kidney	
				pT3a	Tumour involves lower third of vagina, no extension to pelvic wall	

pT3b	Tumour extends to pelvic wall or causes hydronephrosis or non-functioning kidney
pT4	Tumour invades mucosa of bladder or rectum or extends beyond true pelvis

38	Regional lymph nodes	STR	2	Nx Regional lymph nodes cannot be assessed N0 No regional lymph node metastasis N1 Regional lymph node metastasis
39	Distant metastasis	STR	2	Mx Distant metastasis cannot be assessed M0 No distant metastasis M1 Distant metastasis (includes inguinal lymph nodes and intraperitoneal disease except metastasis to pelvic serosa, excludes metastasis to vagina, pelvic serosa and adnexa)

40	Treatment	STR	5	00000	No treatment	NOMESCO¤
				LCC00	Partial excision of uterus	
				LCD00	Hysterectomy	
				LDB00	Exscision of lesion of cervix uteri	
				LDB10	Cryotherapy of cervix uteri	
				LDB20	Electrocoagulation or laser therapy of cervix uteri	
				LDC00	Conisation of cervix uteri using knife	
				LDC03	Conisation of cervix uteri using diathermy or laser	
				LDC10	Partial excision of cervix uteri	
41	Biopsy performed	INT	1	0	No biopsy performed	
				1	Yes, biopsy performed	

EPISODE RESULT					
42	Result of episode	INT	1	1	returned letter
				2	did not attend
				3	negative screening result
				4	intensified follow-up
				5	referral, did not comply
				6	referral, negative histology
				7	referral, precancerous lesion
				8	referral, invasive cancer

REFERENCES

*Solomon D, Davey D, Kurman R, et al., for the Forum Group Members and the Bethesda 2001 Workshop. The 2001 Bethesda system: terminology for reporting results of cervical cytology. JAMA 2002;287:2114-9.
†Fritz A, Percy C, Jack A, Shanmugaratnam K, Sobin LH, Parkin DM, Whelan S (2000). International Classification of Diseases for Oncology (ICD-O). 3rd ed. World Health Organization: Geneva.
‡
§L.H. Sobin, M.K. Gospodarowicz and Ch. Wittekind (eds.):TNM Classification of Malignant Tumours. Seventh edition 2009, Wiley-Blackwell
¤NOMESCO Classification of Surgical Procedures (http://www.nordcase.org/eng/ncsp/)

Appendix 3. Example of individual-level coding structure for colorectal cancer screening records[1]

Var#	Variable name	Format	Length	Values	Description	Coding standard	Note
					ID		
01	Personal ID	STR	11		Personal identifier		
02	Randomisation date	DATE	10		DD/MM/YYYY		
03	Randomisation group	STR	2				
04	Date of birth	DATE	10		DD/MM/YYYY		

					INVITATION
05	Municipality name	STR	50		
06	Birth cohort	INT	4	YYYY	
07	Gender	STR	1	F/M	
08	Screening center	STR	50		Name
09	Screening center code	STR	4		Short name - code
10	Invitation date	DATE	10		DD/MM/YYYY
11	Testnumber	INT	12		
12	Repeated test	INT	1	0/1	0 if first in same round, renewals 1

				SCREENING TEST
13	Testnumber	INT	12	unique identifier, link to invitation
14	Date of sample1	DATE	10	DD/MM/YYYY
15	Date of sample2	DATE	10	DD/MM/YYYY
16	Date of sample3	DATE	10	DD/MM/YYYY
17	Date of examination	DATE	10	for endoscopy
18	Date of 1st level examination	DATE	10	DD/MM/YYYY
19	Testresult1A	STR	3	"-", " ", +/-, +, ++
20	Testresult1B	STR	3	"-", " ", +/-, +, ++
21	Testresult2A	STR	3	"-", " ", +/-, +, ++
22	Testresult2B	STR	3	"-", " ", +/-, +, ++
23	Testresult3A	STR	3	"-", " ", +/-, +, ++
24	Testresult3B	STR	3	"-", " ", +/-, +, ++
25	Testresult (FOBT)	STR	3	POS, NEG, REP, or " "
26	Testresult (endoscopy)	STR	6	INADEQ, INCOMP, POS, NEG
27	Testresult comment (endoscopy)	STR	100	Details of positive test
28	Date of answering	DATE	10	DD/MM/YYYY
29	Referral date	DATE	10	DD/MM/YYYY

			COLONOSCOPY			
30	Personal ID	STR	11			
31	Testnumber	INT	12			
32	Date of Colonoscopy	DATE	10		DD/MM/YYYY	
33	Colonoscopist	STR	50		optional	
34	Reason	STR	50		First colonoscopy, repeated, other	
35	Reason not done	STR	2		Only if not colonoscopy, coded	see supplement
36	Cecal intubation	INT		0/1	NO/YES	
37	Biopsy taken	STR			removal,biopsy,no	
38	Finding	STR	3		coded values	see supplement
39	Diagnosis code	STR	10		ICD10 codes	ICD10*
40	Recommendation	STR	3		treat, surveillance, return to screening	
41	Complications	STR	3		coded values	see supplement

				HISTOLOGY	
42	Testnumber	INT	12		
43	Date of colonoscopy	DATE	10	DD/MM/YYYY	
44	Site1	STR	5	Topography code_ICDO-3	ICD-O-3†
45	Morphology1	INT	5	Morpho_code_ICDO-3	ICD-O-3†
46	Grade1	INT	1	1 mild, 2 moderate, 3 severe	
47	Size_col1	INT	3	size in mm, by colonoscopist	
48	Size_path1	INT	3	size in mm, by pathologist	
49	Site2	STR	5	Topography code_ICDO-3	ICD-O-3†
50	Morphology2	INT	5	Morpho_code_ICDO-3	ICD-O-3†
51	Grade2	INT	1	1 mild, 2 moderate, 3 severe	
52	Size_col2	INT	3	size in mm, by colonoscopist	
53	Size_path2	INT	3	size in mm, by pathologist	
54	Site3	STR	5	Topography code_ICDO-3	ICD-O-3†
55	Morphology3	INT	5	Morpho_code_ICDO-3	ICD-O-3†
56	Grade3	INT	1	1 mild, 2 moderate, 3 severe	
57	Size_col3	INT	3	size in mm, by colonoscopist	
58	Size_path3	INT	3	size in mm, by pathologist	
59	Site4	STR	5	Topography code_ICDO-3	ICD-O-3†
60	Morphology4	INT	5	Morpho_code_ICDO-3	ICD-O-3†
61	Grade4	INT	1	1 mild, 2 moderate, 3 severe	
62	Size_col4	INT	3	size in mm, by colonoscopist	
63	Size_path4	INT	3	size in mm, by pathologist	

COLORECTAL CANCER					
64	Testnumber	INT	12		
65	Topography	STR	5	Topography code_ICDO-3	ICD-O-3†
66	Morphology	INT	4	Morpho_code_ICDO-3	ICD-O-3†
67	Behavior	INT	1	3 = malignant, 2= in situ	ICD-O-3†
68	T-code	STR	2	T Tumor according to the WHO	TNM‡
69	N-code	STR	2	N Nodus according to WHO	TNM‡
70	M-code	STR	1	M Metastases according to WHO	TNM‡
71	Date diagnosis	DATE	10	DD/MM/YYYY	

REFERENCES:

*Available from www.who.int/classifications/icd/en/

†Fritz A, Percy C, Jack A, Shanmugaratnam K, Sobin LH, Parkin DM, Whelan S (2000). International Classification of Diseases for Oncology (ICD-O). 3rd ed. World Health Organization: Geneva.

‡L.H. Sobin, M.K. Gospodarowicz and Ch. Wittekind (eds.):TNM Classification of Malignant Tumours. Seventh edition 2009, Wiley-Blackwell

[1] Note: EU CRC Screening Guidelines[α] allow use of TNM edition 5,[β] 6,[μ] or 7,[‡] but recommend reporting which TNM edition is used. Only two grades of neoplasia (dysplasia) are recommended, and morphology of endoscopically removed lesions should be reported according to modified version of the [q]Paris Classification ("polypoid or nonpolypoid").

[α]Segnan N, Patnick J, von Karsa L. European guidelines for quality assurance in colorectal cancer screening and diagnosis. Luxembourg: Office for official publications of the European Communities; 2010. [4]

[β]L.H. Sobin, C. Wittekind C (eds.): TNM classification of malignant tumours. Fifth edition 1997, John Wiley & Sons

[μ]L.H. Sobin, C. Wittekind C (eds.): TNM Classification of malignant tumours, Sixth edition 2002, John Wiley & Sons

[q]The Paris Classification (2003), The Paris endoscopic classification of superficial neoplastic lesions: esophagus, stomach, and colon: November 30 to December 1, 2002, Gastrointest.Endosc., vol. 58, no. 6 Suppl, pp. S3-43.