

Policy recommendations on governance, organisation and evaluation of cancer screening

Cancer Control Joint Action



CanCon
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Introduction & background

- Council of the EU has recommended cancer screening with a systematic population-based approach and quality assurance at all appropriate levels and in accordance with European guidelines; valid for breast, cervix & colorectal cancer screening
- Most EU countries are planning, piloting or implementing population-based screening programmes for these cancer sites
- However, there are barriers; e.g. the required evaluation and monitoring capabilities lacking; and very low attendance rates documented in a remarkable number of programmes

Synthesis of emerging screening criteria proposed over the past 40 years (from Andermann et al. 2008)

- *The screening programme should respond to a recognized need.*
- *The objectives of screening should be defined at the outset.*
- *There should be a defined target population.*
- *There should be scientific evidence of screening programme effectiveness.*
- ***The programme should integrate education, testing, clinical services and programme management.***
- *There should be quality assurance, with mechanisms to minimize the potential risks of screening.*
- *The programme should ensure informed choice, confidentiality and respect for autonomy.*
- *The programme should promote equity and access to screening for the entire target population.*
- *Programme evaluation should be planned from the outset.*
- *The overall benefits of screening should outweigh the harm.*

5. Continue, modify or discontinue

- Long-term evaluation
- Accurate communication
- Ensure sustainability
- Continuous quality improvement
- Prospective evaluation of new methods
- Stopping if not any more effective

4. Rollout to national implementation

- Enlargement of programme organisation
- Early evaluation of outcome and adverse effects
- Training
- Reducing barriers and social inequalities
- Continuous implementation, modification or stopping if indicated

3. Piloting

- Testing all programme components
- Early evaluation of outcome and adverse effects
- Training
- Reducing barriers and social inequalities
- Rollout, modification or stopping if indicated

1. Consensus building and pre-planning

- Active acquirement of evidence
- Evidence synthesis
- Assessment of baseline conditions
- Health-economical aspects
- Prioritization
- Setting policy objectives and targets
- Communication strategy

2. Planning & feasibility studies

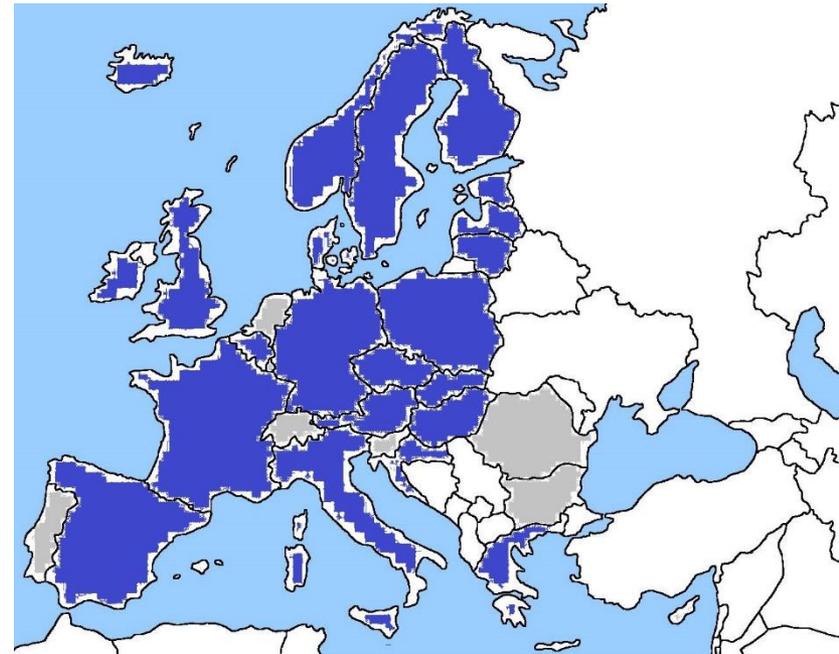
- Coordination, evaluation, QA teams
- Governance structure and legal support
- Feasibility testing, screening policy and protocols, manuals & key indicators
- Developing IT and information systems
- Contracting local and regional teams
- Training staff and reference centers

Survey of governance and legal frameworks for quality assurance

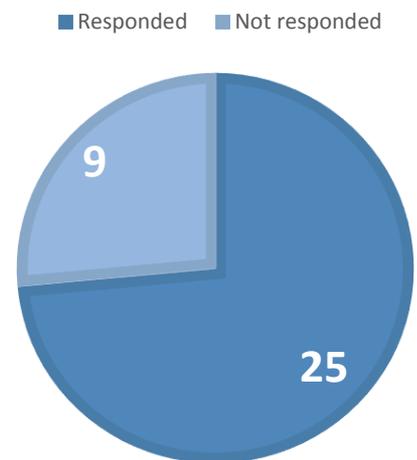
- WP9 Screening in Cancer Control Joint Action

<http://cancercontrol.eu/>

- 34 EU and EFTA countries/nations
- Lead by O.Majek and S.Lönnberg

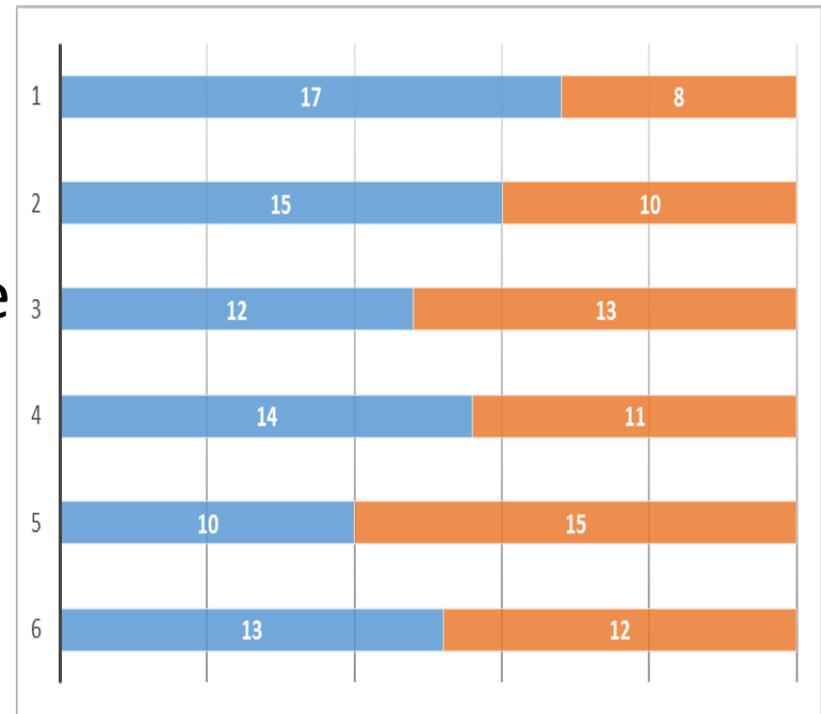


SURVEY RESPONDENTS BY 10 JUNE 2016



Governance - cervical cancer screening programme

- National screening board
- Structured decision-making
- Steering board for programme
- Management team
- Advisory board
- Quality manual



Legal framework for invitation, registration and linkage in Cx screening programmes

1) allow **personal invitation** of individuals based on their age and gender?

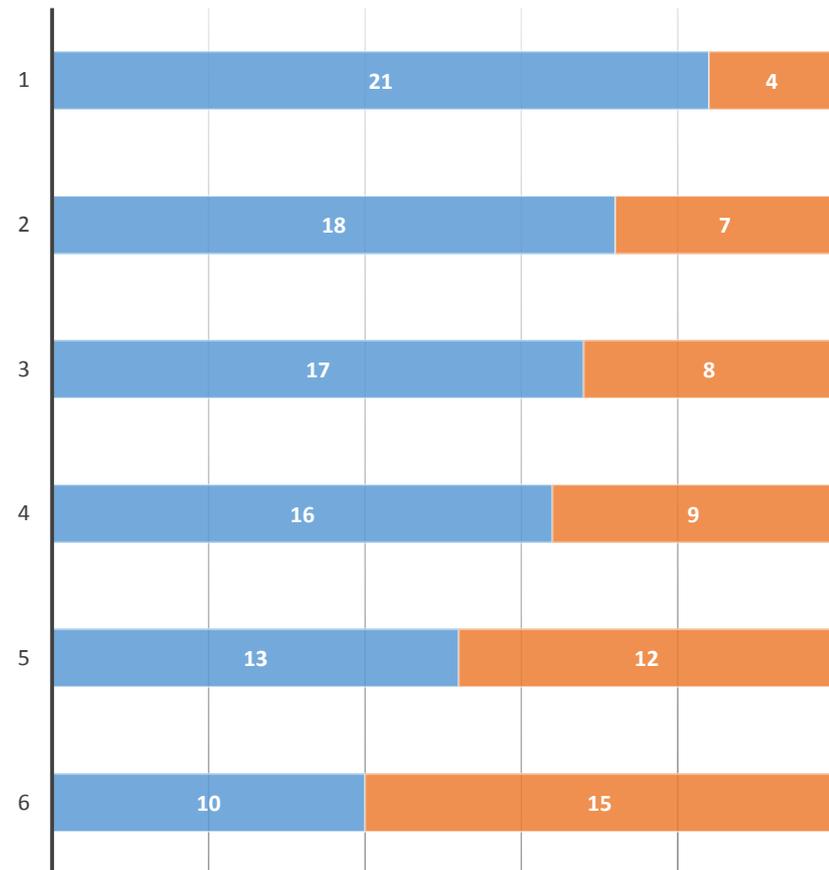
2) allow personal **invitation** of individuals based on their **screening history**?

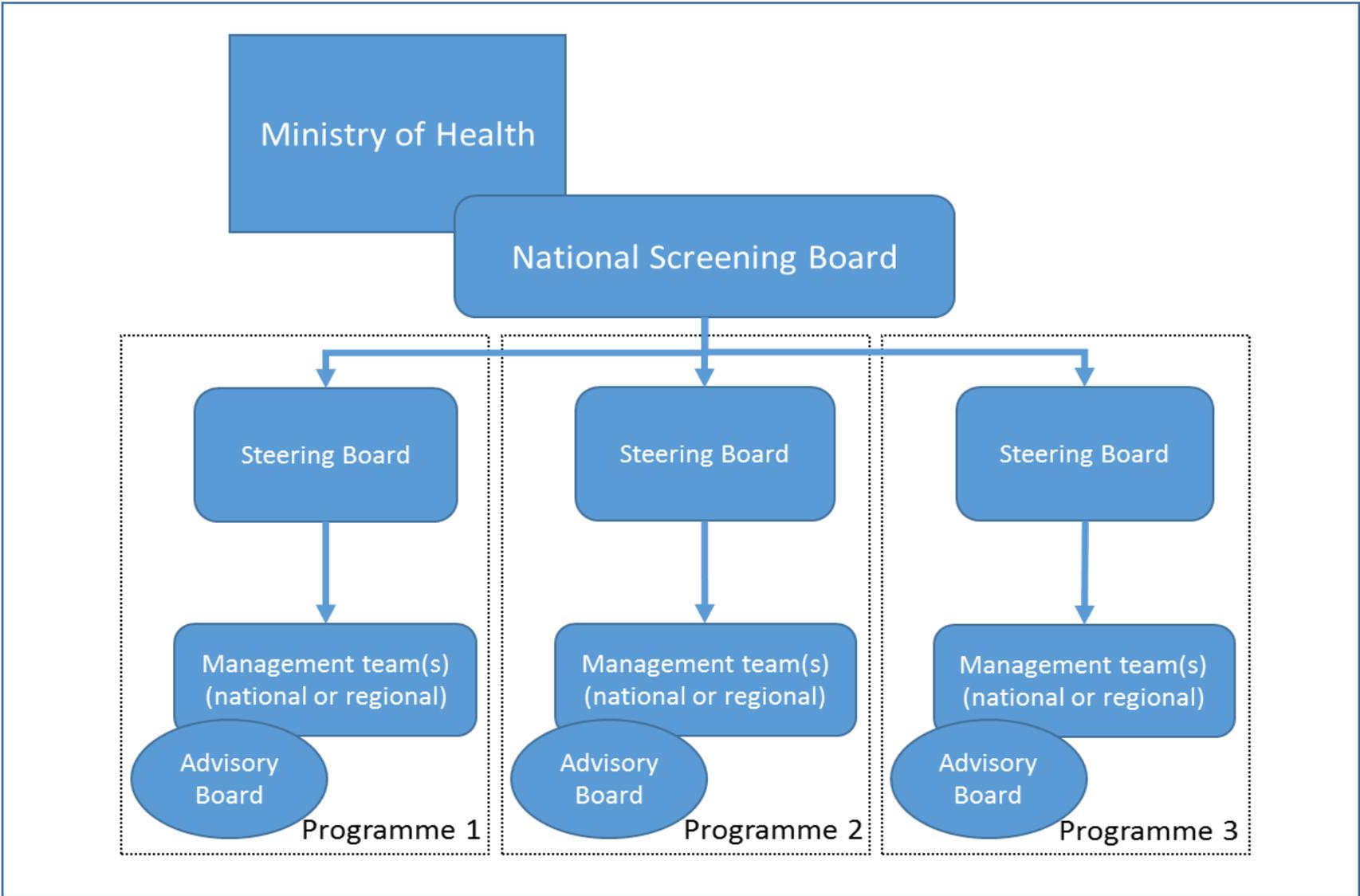
3) prescribe **systematic screening registration** in an electronic screening registry?

4) allow **individual linkage** of records between **screening and cancer** registries?

5) allow individual linkage of records between **screening, cancer and cause of death** registries?

6) allow central coordination of routine quality assurance by **re-reading** of potential false negative tests and their controls?





GOVERNANCE RECOMMENDATIONS

- Successful evidence-based cancer screening needs a competent, multidisciplinary governance structure for sustainable implementation of new screening programmes, and for significant modifications, including possible cessation, of existing programmes
- The legal code for cancer screening should specifically enable as a minimum these basic functions: mandatory notification and central registration of complete screening and outcome data, individual linkage to cancer and cause of death, and quality assurance including clinical and programme audits
- Implementation of effective cancer screening programmes requires significant resources for quality assurance i.e. 10–20% of total expenditure

Functions covered by the quality assurance allocation of 10-20% of total screening programme expenditures, in accordance with the European guidelines for quality assurance in cancer screening

- *Development and maintenance of well-organised information systems*
- *Clinical and diagnostic quality management*
- *Development of population-based cancer registration*
- *Development, implementation and enforcement of a Quality Manual based on the European and national standards*
- *Reporting of key performance indicators based on European and national standards*
- *Retrospective evaluation of the effectiveness of the programme and its components*
- *Prospective evaluation of new screening methods, policies and organisational models*

ORGANISATION RECOMMENDATIONS

- Implementation of population-based screening should be a carefully managed multi-step process through the phases of coordinated planning, piloting, and rollout
- The mandate and resources for screening coordination and training, and for the electronic information systems necessary for quality assurance and incremental improvement, must be secured before starting the population-based screening service

INTEGRATED EVALUATION RECS

- To maximize the benefits of a screening programme, proper linkage with all the relevant registries is essential; while the indicators for quality and effectiveness based on most recent evidence-based reviews should be monitored and acted upon regularly
- Benefits and harms of screening need to be presented and clearly communicated to the general public; a scientific consensus on the appropriate method and estimate would be of great value
- The cost-effectiveness of a programme or a specific modification of it should be evaluated prior to making any substantial changes/modifications

INTEGRATED EVALUATION RECS EQUITY

- Evaluation and regular monitoring of cancer screening should involve social inequalities and research on improved equity in health
- Transition research in the specific programmes where poor attendance or other serious barriers have been identified, e.g. on reasons and how to optimize attendance; and on balanced, appropriate information of screening
- *Research collaboration has an added value to develop interventions and solutions in the local settings where social barriers and social inequalities in cancer have prevailed*

POTENTIAL NEW CANCER SCREENING PROGRAMMES

- Three key policy-making criteria:

- *Effectiveness*
- *Benefits outweigh harms*
- *Health-economic evaluation*

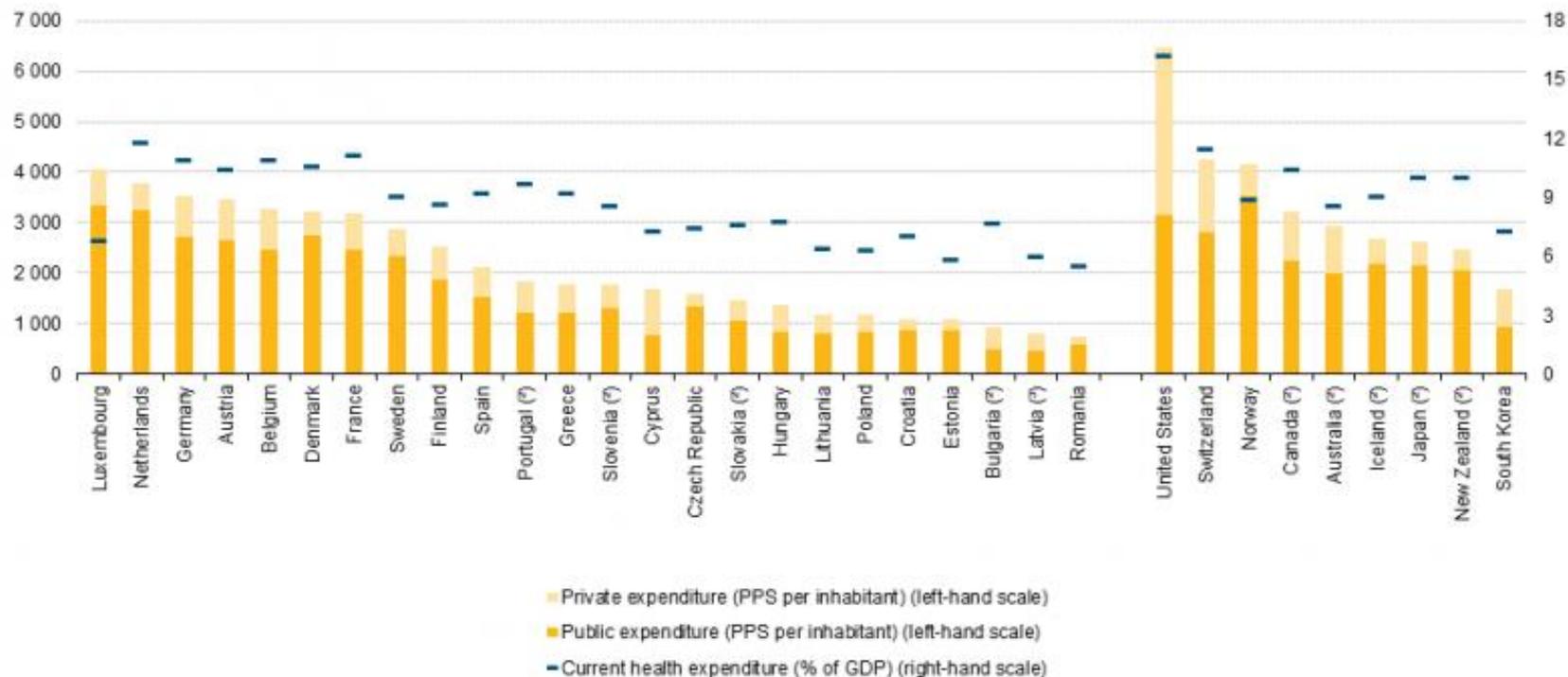
based on efficacy and adverse effects data from RCTs

- Examples on available evidence and assessments from: prostate, gastric, lung, ovary cancer screening research

ISSUES IN HEALTH-ECONOMICAL DECISIONS

- No detailed criteria for health-economical methods and relevant thresholds with a given methodology have been included in the recommendations (Wilson & Jungner 1968; Andermann et al. 2008; 2003/878/EC)
- In some (high-resource) MSs, screening is regarded cost-effective if the costs per QALY gained are lower than a threshold of €20,000 or €30,000. National values vary and there are countries, particularly within the middle-income settings, where national values have not been formally decided
- Also financial and human resources in the healthcare vary very remarkably between the MSs of the EU, affecting life expectancy, healthy life-years, affordability, etc

CURRENT HEALTHCARE EXPENDITURE, 2012 (PPS) IN EU MEMBER STATES



(*) Countries are ranked on total (public + private) healthcare expenditure in PPS per inhabitant. Denmark, Cyprus, Portugal, Iceland, Norway and Switzerland: provisional. Ireland, Italy, Malta and the United Kingdom: not available.

(*) 2011.

(*) 2010.

Source: Eurostat (online data code: h1th_sha_hf)

EUROSTAT Health 2015

POTENTIAL NEW SCREENING PROGRAMMES

Prostate cancer screening

- The ERSPC has showed that PSA-based screening resulted in a 21% prostate cancer mortality reduction (Schröder et al. 2009, 2012 and 2014)
- The point estimates varied between participating countries, due to differences in length of follow-up, underlying incidence and mortality, screening interval, and PSA testing contamination in the control arm
- No mortality difference was found after a median follow-up of 11 years in the US trial, failure to do so likely attributable to contamination of the control arm (Andriole et al., 2009)
- Concerns on the harms of overdiagnosis and overtreatment

An example of current health-economical assessment on prostate cancer screening with PSA testing

Table 2. Predicted effects, costs, and cost-effectiveness for various screening scenarios per 1000 men*

Screening scenario	No screen	One screen at age 55 y	Screening at age 55–59 y at 2-y intervals	Screening at age 55–67 y at 4-y intervals	Screening at age 55–69 y at 2-y intervals	Screening at age 55–75 y at 1-y intervals
Screening tests	-	800	2342	2944	5706	13610
Men screened at least once	-	800	935	955	989	997
Effects						
Cancers diagnosed	120	124	132	156	169	207
Screen-detected cancers	-	12	34	86	115	180
Overdiagnosed cancers (as % of screen-detected men)	-	4 (30)	11 (32)	35 (41)	49 (43)	87 (48)
Prostate cancer deaths (% reduction)	32	31 (5)	28 (13)	25 (24)	23 (30)	20 (40)
Life-years gained	-	18	41	66	83	102
QALYs gained	-	17	36	50	61	64
Costs x \$1000						
Screening	-	32	94	118	228	542
Diagnosis and treatment	1882	2003	2229	2842	3161	3909
Palliative care	649	616	568	496	452	390
Total costs	2531	2652	2890	3456	3841	4842
Cost-effectiveness†						
Net costs per QALY gained (3.5% discounted)	-	31467	45615	92031	120185	320042

* Effects and costs are shown without discount. The cost-effectiveness is calculated at 3.5% discount rate for effects as well as costs. In 2008 US dollars. QALY = quality adjusted life year.

Heijnsdijk JNCI 2015

POTENTIAL NEW SCREENING PROGRAMMES

Lung cancer screening in smokers/ex-smokers

- 15-20% decrease in lung cancer mortality reported in annual LDCT screening trial in the US (NLST 2011; Pinsky et al. 2013)
- No impact in a small-size Italian trial (Infante et al. 2015)
- Other European RCTs still in the follow-up phase, important to wait for their results
- QALY cost has been estimated to vary at about 57,000-81,000 USD from the US trials (Black, 2015; Goffin et al. 2015)

Ovary cancer screening

- No clear evidence yet on efficacy (Buyss et al. 2011, Jacobs et al. 2016)

POTENTIAL NEW SCREENING PROGRAMMES

Gastric cancer screening, three potential strategies

- Screening for gastric cancer by endoscopy or fluoroscopy
- Screening for precancerous lesions, by pepsinogen I and II or other biomarkers in the circulation
- Screening for *Helicobacter pylori* with the aim to eradicate it, if positive (“search-and-treat” strategy)
 - Evidence from RCTs suggest that *H. pylori* eradication lowers gastric cancer risk by 30–40% (IARC 2014; Ford et al. 2015). Potential of adverse effects not investigated sufficiently. Endoscopy screening has been suggested to be cost-effective only in high-risk areas of Asia
 - Investments in evaluation needed in order to run appropriate RCTs in Europe such as the GISTAR trial

NEW CANCER SCREENING PROGRAMMES

- Active European research collaboration is necessary in order to obtain evidence relevant for the different settings with potential variations in the burden of disease, health priorities, effectiveness, and resources and affordability, within the European countries

OPEN ISSUES

- Chapter contents ready for editing
- Several manuscripts for peer-reviewed papers on-going
 - Governance and legal frameworks
 - Organizational requirements and coordination
 - Potential new cancer screening programmes
 - Prostate screening: Pros (favour) and Cons (against) rather than consensus?
 - Gastric cancer screening(?)
- We are still awaiting results from the 2nd Implementation status report (EUSR)

OPEN ISSUES

- Further work required to develop health-economics assessments for policy-making
 - For breast, cervix and colorectal cancer screening possible in the EU-TOPIA project (H2020)
- Risk-stratified cancer screening (e.g. HPV positive, H.Pylori, tobacco smokers, risk families and breast or colorectal cancer screening programme, ...) largely covered by population-based screening
- C.f. 'genetic screening', 'genetic testing' or 'genetic counseling'
 - Genetic screening: Largely same criteria than for cancer screening (Andermann et al. 2008)
 - BRCA: counseling largely from clinical settings

Thank You