Requirements for the evidence base for implementing colorectal cancer screening programmes

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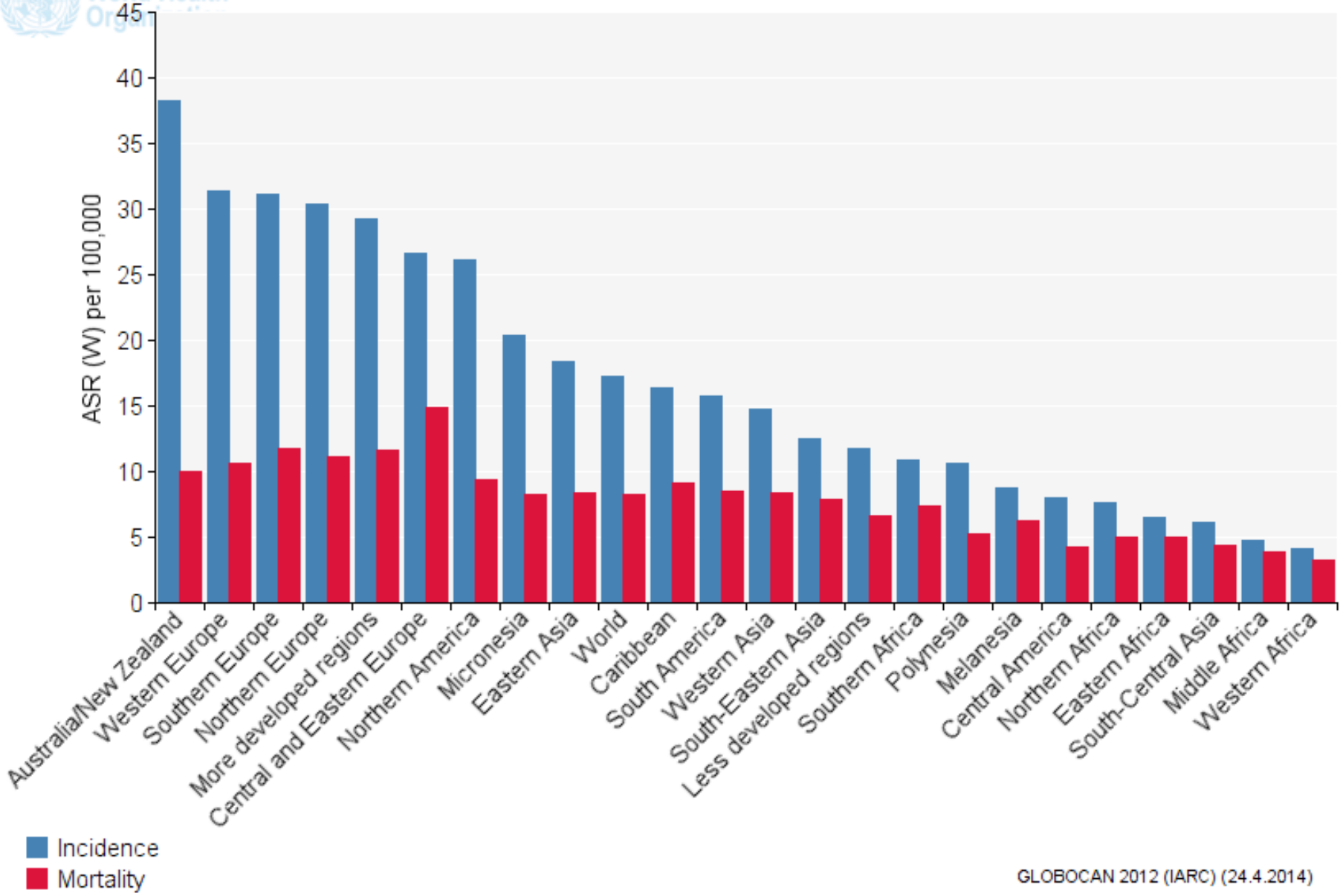
Colorectum: both sexes, all ages



GLOBOCAN 2012 (IARC) (24.4.2014)

Purposes of cancer screening

- Prevent mortality from invasive cancers, for some cancers also incidence can be prevented
- Improve quality of life: Less invasive treatment if cancer treated early or in a precancer phase
- Improve availability of quality-assured services; a platform for sustainable development on health planning, education & training, enhancing social development (LMIC)
- Control adverse aspects the earlier diagnosis of cancer may bring to the QoL, maintain balance
  - Diagnosis at an earlier age, longer lifetime with cancer
  - Cancer treatments have long-term adverse outcomes
  - Whether overdiagnosis and/or overtreatment?

Information needs for implementing population-based cancer screening

Evidence base and communication of it must be accurate at every step and element in the screening programme:

- Decisions about screening
- Information and communication with target population and medical professionals
- Identifying and inviting the target population
- Screening tests, and related diagnostic confirmation and management of screen-detected lesions
- Monitoring and evaluation of the programme

➢ Evidence need to be acquired, reviewed and interpreted on each of the above components with comprehensive standard protocols

Examples of information needs for decision-making on cancer screening

- Benefits, mainly mortality and incidence outcomes in invited, screened, and unscreened (non-participants)
  - RCTs – always before new programmes efficacy
  - Ongoing programmes effectiveness
  - Impact on opulation-based (overall) cancer burden
- Adverse effects, costs and other issues on the QoL
- Balances between benefit and harm
- Social inequalities, cultural aspects, risk factors, disease burden, etc aspects in priorization
- Organizational, institutional and legal frameworks
- Resources

Need to put in the context of cancer control (CanCon /WP9)

Quality assurance involve evaluation and monitoring of routine services

Verify benefit and harm continuously

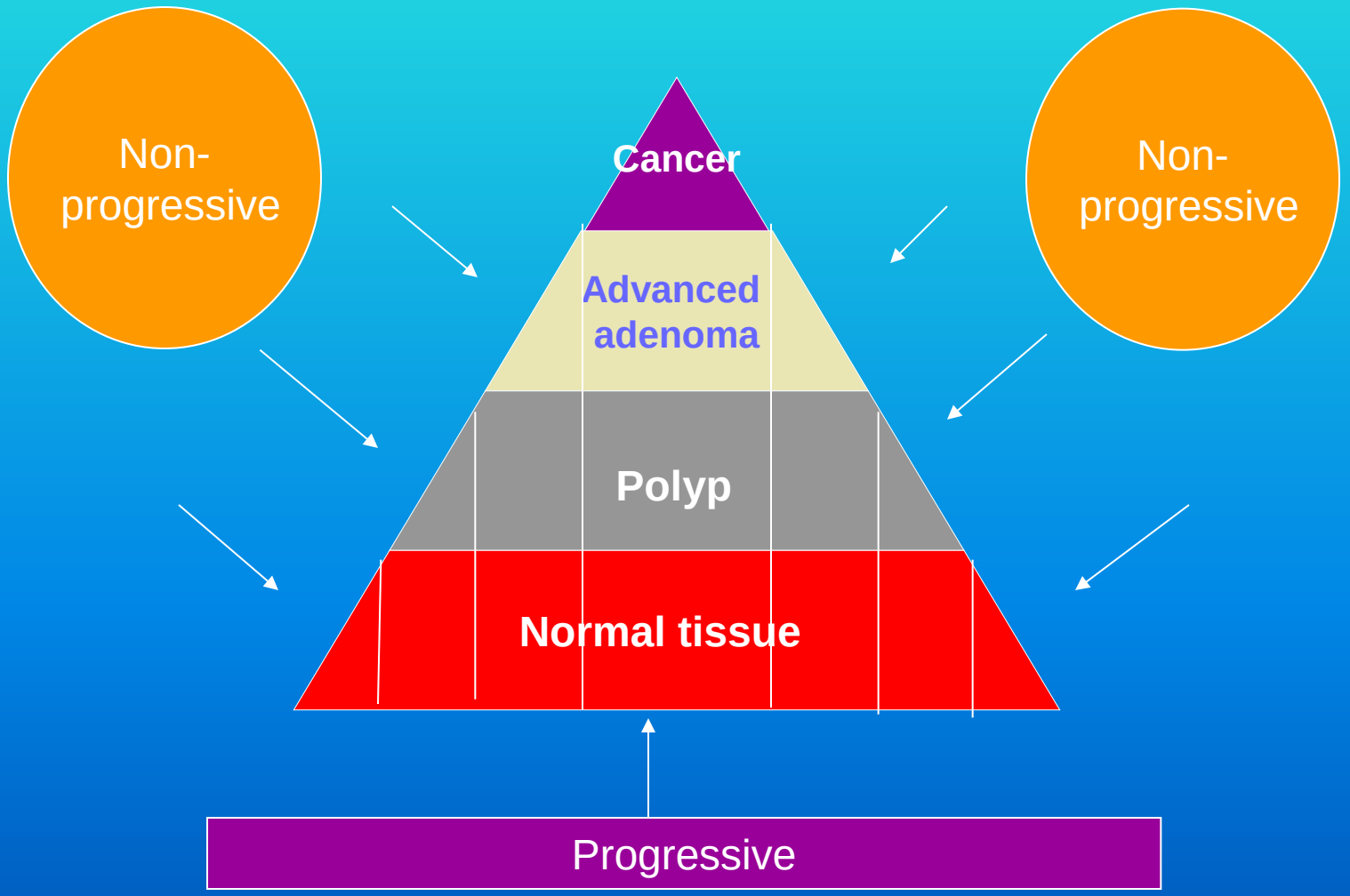
- Collect information about the programmes and their pilots and feasibility phase studies
- Link databases for monitoring and outcome evaluation
  - Cancer registries involved in the outcome evaluations
  - Evaluation of diagnosis and management outside the programme also in a focus, synergies
- Make basis for
  - Programme improvement and modification
  - Feed-back to service providers and for
  - Informing population and stakeholders

Levels of health-economical analyses

- Modeling studies
  - Simulation using intermediate or non-systematic data
- Cost-efficacy = minimum for a new cancer site to be targeted by screening programmes
  - Based on measurements in RCTs
- Cost-effectiveness on real conditions and results
  - Can be performed 10-15 years after start of programme
  - Need to be performed continuously
  - Strongest evidence assuring that working models are good and the programme is justified

Natural History of cancer with its precursors and stages, and of cancer screening = the key affecting balances on the benefits and harm

Only some precursor lesions progress to cancer



The physician who initiates screening procedure has a bigger responsibility for his/her patients: he/she must have *conclusive evidence* that screening could alter the natural history of the disease in a significant proportion of those screened (Cochrane & Holland, 1971)

Conclusive evidence?

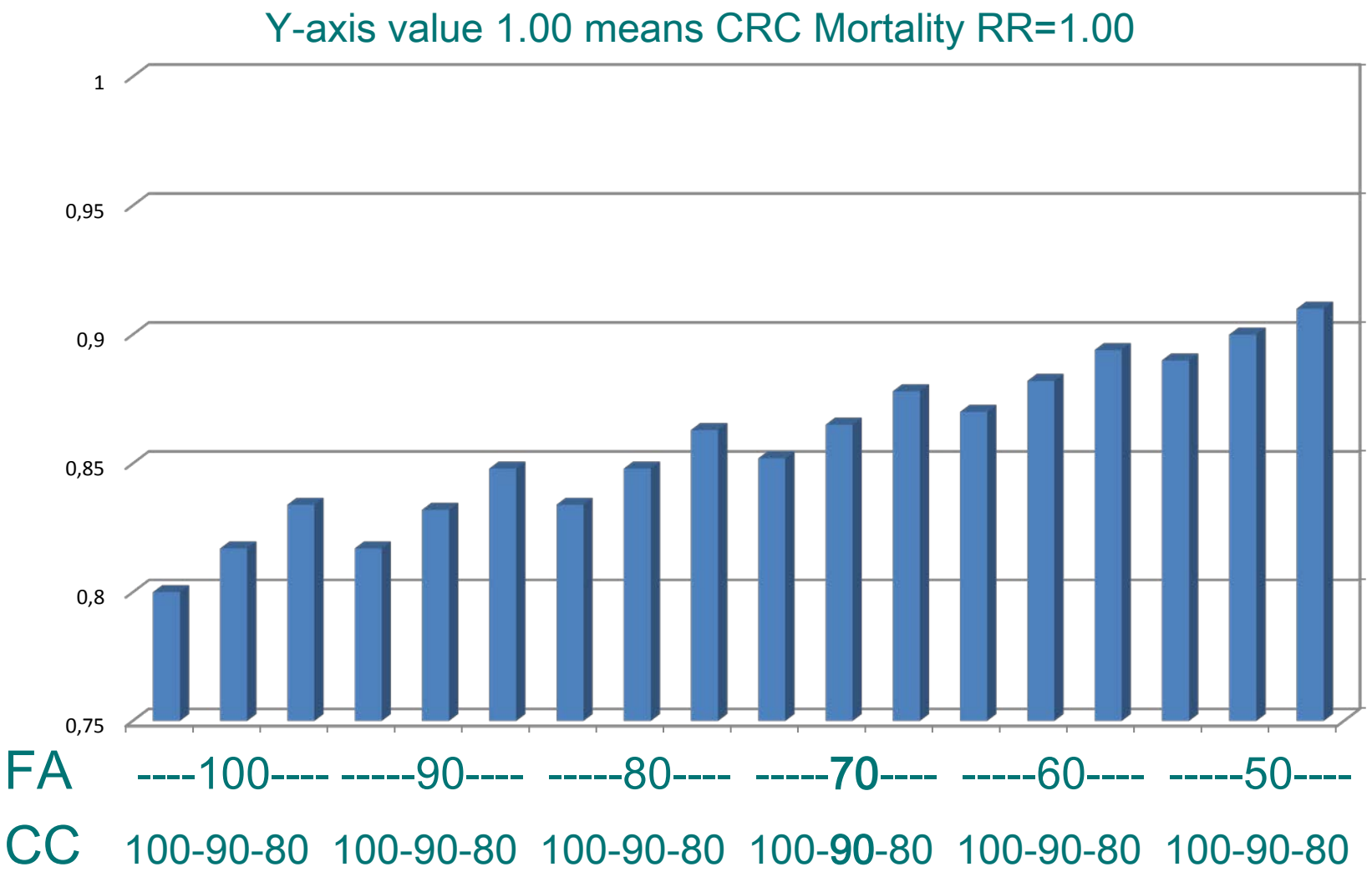
Efficacy of cancer screening

Anttila & Martin-Moreno, 2013

In: Successes and failures of health policies

Site, sex and test	*Target age (years)*	*Screening interval (years)*	*Expected mortality outcome among invited (% reduction)*	*Source*
Cervix, females, Pap smear	25 or 30 to 64	3–5	≥80	IARC 2005
Breast, females, mammography	50–69	2	25	IARC 2002
Colorectum, males and females, faecal occult blood tests	50–74	2	16	Hewitson et al. 2007

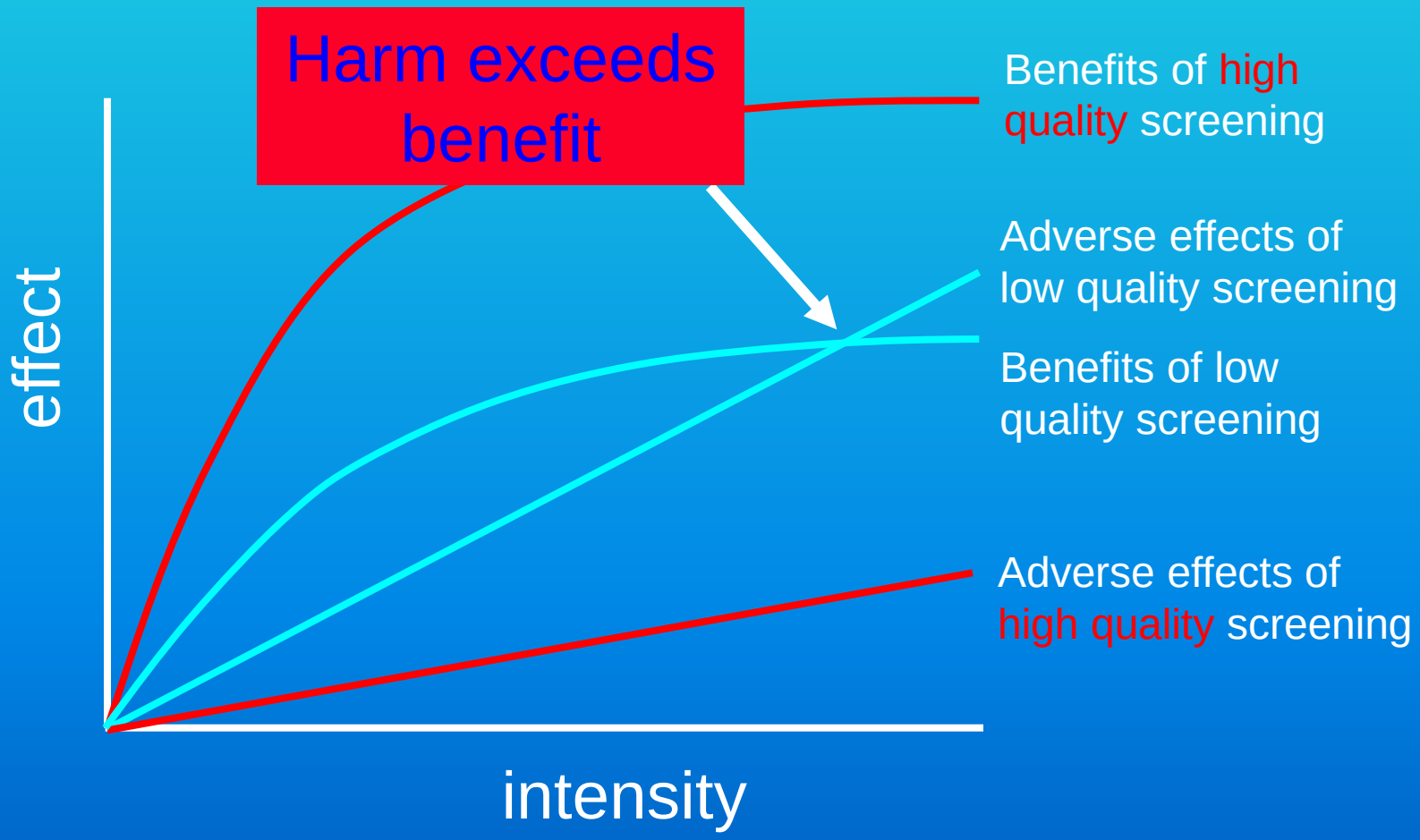
Modelled effectiveness of CRC screening in Finland by assumptions on gFOBT attendance (FA) and colonoscopy compliance (CC) (Chiu et al. 2010)



Effectiveness of colorectal cancer screening in the European dimension

- CRC screening programmes started in several EU countries using innovative designs after the EU Council recommendation (2003)
- There are different policies as to target ages and test methods, and effectiveness is expected to vary also by ethnic groups, gender; and by regional, social and cultural environments
- Outcome evaluations not yet available

Benefits and risks of high and low quality screening



What are harms (in relation to quality of service)?

- **False positive tests or assesments**: psychosocial harm, overuse of surveillance and other services and resources
- **False negative tests or assesments**: false reassurance, delay of diagnosis, errors reducing effectiveness
- **Complications and severe long-term consequences of cancer or precursor treatments** ; eg, complications after resection (bleeding, perforation) or cancer surgery, second cancer due to cytostatic drugs, physiological damage, social and psychosocial burden in cancer patients

Quality-assured management in colonoscopy service

Create **a patient centred environment and a personalised colonoscopy experience**

Ensure **a unit provides a high quality service *before* screening programme is introduced**

Use **the quality framework of screening programme to drive improvements across the service**

Measure **key performance indicators continuously from the outset at the service providers and programme levels**

Examples of barriers to organised screening among medical professionals and practitioners

- ”Culture” of opportunistic services; working models do not include systematic screening chain, strict/detailed enough national quality management system may be missing
- Properly trained staff is lacking and also available professionals need extensive re-training
- Insufficient communication and interaction with decision-making
- Insufficient knowledge regarding effectiveness
- Insufficient organisational models & financing

What are harms (in relation to programme policy and protocols)?

- **Overdiagnosis, overtreatment**
  - Overdiagnosis inherent in early diagnosis
  - Overtreatment depends upon management options; evidence on treatment outcomes often not yet available
  - ***Natural history differ by age***
- If not evidence-based policy (=target age, screening methods and intervals) and organisation, in addition use of **resources** to activity where those could be used better elsewhere

Implications in ethics

- Information on efficacy is not enough on decision on cancer screening programmes, proper evidence needed on acceptable balance with harm and a wide range of organisational aspects
- Primary prevention also in a priority. In high-risk areas and populations, screening for CRC is not enough but research on aspects for the risks and for developing effective primary prevention should also be in focus

Evidence-base for successful implementation of cancer screening

- The experience in Europe shows that successful implementation of population-based cancer screening programmes requires
  - long-term societal and political commitment,
  - a comprehensive quality management programme and
  - sustainable resources.
- In a fully established programme the proportion of the expenditure devoted to quality assurance should be no less than 10-20%, depending on the scale of the programme. This would enable producing and maintaining the necessary evidence base at all steps of the programme

Thank you for your attention!