Out of the blue: German skin cancer screening

- Initiated in 2003, in a pilot study, the SCREEN project, in Schleswig-Holstein, Germany
- Extended to the rest of Germany in 2008

German melanoma screening

- A two steps process:
  1. Full body skin examination performed by trained GPs
  2. Referral to dermatologists in case of suspicious lesion

Possibility to get a screen done directly by a dermatologist.
Initial evaluation

- The SCREEN programme was promising with 5 years of follow-up: increase in melanoma incidence with a strong decrease in mortality
- Some criticisms:
  - mortality starting to decline too early. In other cancer screening: latency of 3-6 years
  - low participation and already strong effect: not plausible
  - association from an ecological study (as compared to other screening which required randomised trials)

Extension to the rest of Germany since 2008

- In July 2008, the screening for skin cancer was extended to the rest of Germany
- Our research question:
  - With same follow-up as in SH, we investigated if similar declines in melanoma mortality could be observed.
  - In addition, did the mortality in SH continued to further decrease?
**Impact on melanoma incidence in Germany after 2008**

**Comparison of melanoma mortality trends with surrounding countries**

**Impact on melanoma Mortality in SH and Germany – updated trends**

**Bias: cause of death ascertainment**

- A well known bias, even in randomised trials (ex: breast cancer screening).
- The absence of blinding and the mobilisation of the medical community could impact the ascertainment of cause of death.
Bias: cause of death ascertainment (2)

- Is it likely in SCREEN project? Yes! Very likely:
  - GPs as the main entry point for screening
  - Receiving a financial incentive for each screen
  - Convinced of the utility of screening
  - In Germany, GPs from the locality where death occurs are in charge of assessing the cause of death

Discussion

- How does the melanoma screening program hold up against the WHO guidelines for screening?
- What are the lessons from German experiment?
- Should we stop melanoma screening in Germany?

Principles of screening

- Nearly half a century ago, WHO commissioned James Maxwell Glover Wilson and Gunner Jungner to issue a report on screening for disease.
  “In theory, screening is an admirable method of combating disease [...] in practice, there are snags”
WHO's 10 principles of screening-applied to melanoma

1. The condition sought should be an important health problem
2. There should be an accepted treatment for patients with recognized disease
3. Facilities for diagnosis and treatment should be available
4. There should be a recognizable latent or early symptomatic stage
5. There should be a suitable test or examination
6. The test should be acceptable to the population
7. The natural history of the condition, including development from latent to declared disease, should be adequately understood
8. There should be an agreed policy on whom to treat as patients
9. The cost of case findings (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole
10. Case finding should be a continuing process and not a ‘once and for all’ project


Additional criteria since 1968

- 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 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.


Conclusion

- Screening programme in Germany was promising, although “politically driven”
- Unfortunately not confirmed with longer follow-up
- Criteria for melanoma screening not yet fulfilled, in particular evidence of effectiveness

Conclusion (2)

- Should the screening programme in Germany be stopped? NO!
  Before it is important to:
  - Investigate adequately what occurred in Schleswig-Holstein
  - Set up a retrospective and prospective cohort of screened and non-screened individuals with linkage to registries and vital statistics
  - Identify impact of screening on the medical practice in Germany (modifications to the health system, burden if any of additional excisions...)
  - Identify if a benefit could at least be observed in a sub-population.
  => This requires a real commitment, with strong involvement of epidemiological expertise. Proper evaluation is lacking.
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Europe

Germany and surrounding countries
Definition of screening

Screening is the systematic testing of asymptomatic individuals for pre-clinical disease. The purpose of screening is to prevent or delay the development of advanced disease in the subset with preclinical disease through early detection and treatment. The primary goal of population-based screening is to decrease disease-specific mortality.

Morrison 1992

Ethics: screening is a special “health intervention”

“If a patient asks a medical practitioner for help, the doctor does the best he can. He is not responsible for defects in medical knowledge.

If, however, the practitioner initiates screening procedures, he is in a very different situation. He should have conclusive evidence that screening can alter the natural history of disease in a significant proportion of those screened.”

Archie Cochrane and Walter Holland, 1971

World Health Organization's 10 principles of screening

1. The condition sought should be an important health problem

Globocan 2012: 8th most frequent incidence from cancer, 17th most frequent death from cancer. Mortality declining.

2. There should be an accepted treatment for patients with recognized disease

The treatment is excision, performed before knowing the disease was there. Some promising new treatments

3. Facilities for diagnosis and treatment should be available

Availability of dermatology clinics and GPs as entry point if screening performed as in Germany
World Health Organization's 10 principles of screening

4. There should be a recognizable latent or early symptomatic stage
   Naevi excision. Unclear if fast growing tumors diagnosed at advanced stage could have been spotted earlier

5. There should be a suitable test or examination
   Visual examination, suitable, not invasive

6. The test should be acceptable to the population
   Easily acceptable, only visual examination

7. The natural history of the condition, including development from latent to declared disease, should be adequately understood
   Hypothesis that melanoma follow the pathway: melanocyte => naevi => displastic naevi => in situ melanoma => stage I => II => III => IV ... but this pathway is not well established

8. There should be an agreed policy on whom to treat as patients
   Histology confirmed melanoma become “patients”. Well admitted guidelines on surveillance only (in situ and stage I), further surveillance and treatment (stage II+)

9. The cost of case findings (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole
   Unclear, a clear benefit needs to be demonstrated in the first place

10. Case finding should be a continuing process and not a 'once and for all' project
    This should become the case if screening continued. In particular, take further actions to cover the whole eligible population.