Croatia and the EU:
Together
Against Cancer

IMPROVEMENT OF QUALITY OF THE NATIONAL CANCER SCREENING PROGRAMMES IMPLEMENTATION (CRO SCREENING)

MINISTRY OF HEALTH OF THE REPUBLIC OF LITHUANIA

NCI

LITHUANIAN UNIVERSITY OF HEALTH SCIENCES

CPVA

NIJZ Nacionalni institut za javno zdravje

Ministry of Health

HZJZ

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Quality Assurance And Quality Control In Breast Cancer Screening Programme

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“The greatest need we have today in the human cancer problem, except for a universal cure, is a method of detecting the presence of cancer before there are any clinical signs of symptoms.”

- *Sidney Farber, letter to Etta Rosensohn, November 1962 -*
(The Emperor of All Maladies, Siddhartha Mukherjee)

Sidney Farber (1903-1973)

Paediatric pathologist and “father” of modern chemotherapy.

The Dana-Farber Cancer Institute in Boston is partly named after him.

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Cancer screening

- = early diagnosis of non-symptomatic cancer
- aiming at the reduction of morbidity and mortality
- *Population-based screening*: offered systematically to all individuals in the defined target group within a framework of agreed policy, protocols, quality management, monitoring and evaluation
- *Opportunistic screening*: offered to an individual without symptoms of the disease when they present to a health care practitioner for reasons unrelated to that disease.

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When to screen – which cancer sites to screen?

- ❑ IMPORTANT DISEASE?
- ❑ TEST AVAILABLE?
- ❑ IMPACT ON DISEASE OUTCOME?
- ❑ COST-EFFECTIVE?
- ❑ CONSEQUENCES?

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When to screen – which cancer sites to screen?

❑ IMPORTANT DISEASE?

- Important health problem for the general population
- Natural history well known
- Accurate diagnostic assessment
- Effective treatment options
- Earlier treatment improves disease outcome/prognosis

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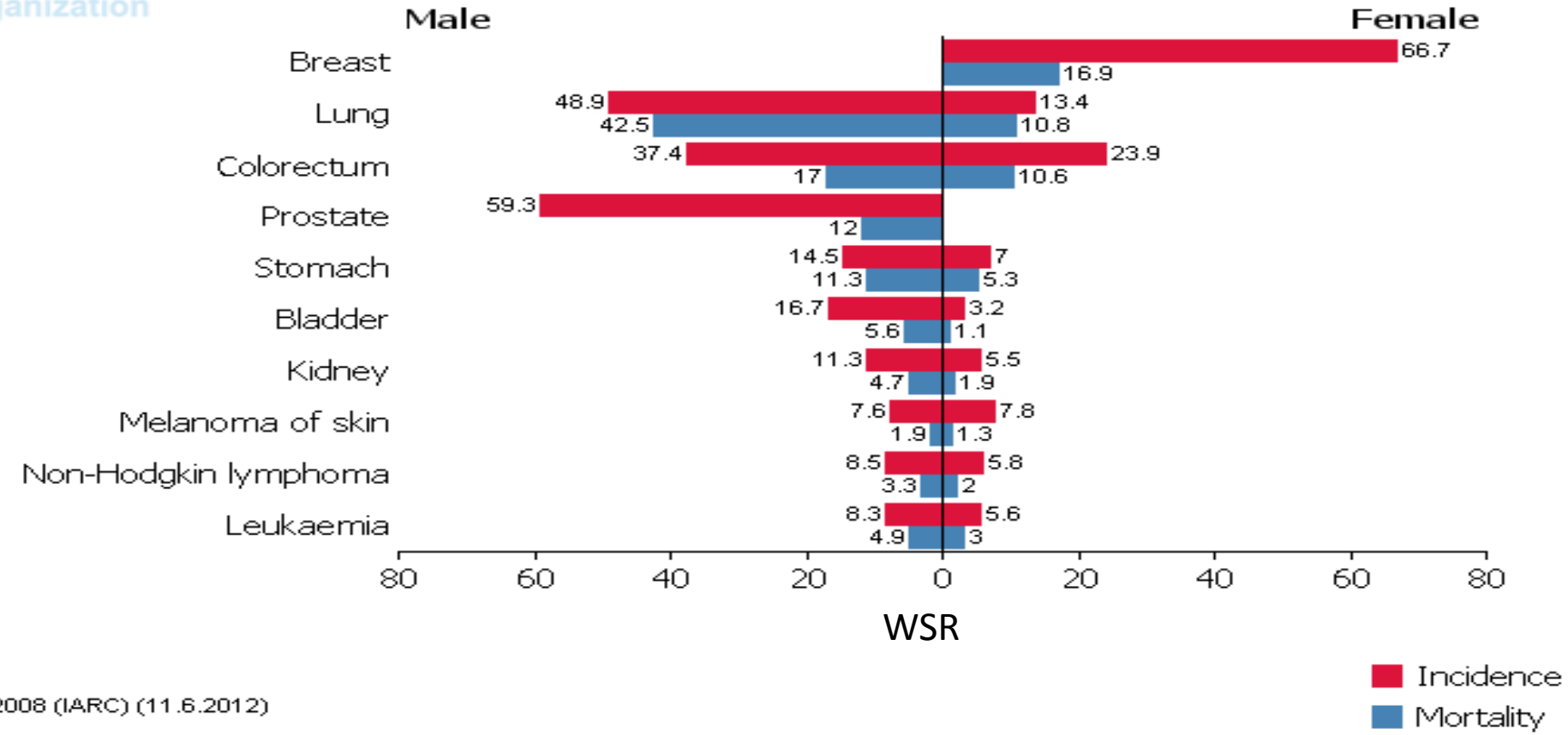
When to screen – which cancer sites to screen?

- **IMPORTANT DISEASE?**

International Agency for Research on Cancer
World Health Organization

Top 10 cancers
in European men and women



GLOBOCAN 2008 (IARC) (11.6.2012)

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When to screen – which cancer sites to screen?

- **SUITABLE TEST?**

  - Acceptable to the population
  - Test characteristics
  - Cancer process:
    - initation – promotion – abnormal growth – invasion – metastases
    - symptoms
    - diagnosis and treatment
    - long interim period - window for screening

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When to screen – which cancer sites to screen?

❑ TEST CHARACTERISTICS

Sensitivity:

- Ability of the test to identify positive results
- Proportion of actual positives which are correctly identified as such (i.e. the percentage of people with cancer who are correctly identified as having cancer)
- TRUE POSITIVE rate
- Never 100%

Specificity

- Ability of the test to identify negative results
- Proportion of negatives which are correctly identified (i.e. the percentage of healthy people who are correctly identified as not having cancer)
- TRUE NEGATIVE rate

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When to screen – which cancer sites to screen?

- **TEST CHARACTERISTICS**

Positive predictive value (PPV):

- The probability to have cancer following a positive test result
- Proportion of positive test results which are TRUE POSITIVE

Negative predictive value (NPV):

- The probability to be healthy following a negative test result
- Proportion of negative test results which are TRUE NEGATIVE

BUT: PPV and NPV vary with prevalence

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When to screen – which cancer sites to screen?

- **IMPACT OF EARLY DETECTION ON DISEASE OUTCOME?**
  - Lower disease-specific mortality
  - Less morbidity
  - Lower cancer incidence
    - E.g.: cervical and colorectal cancer – Detection + removal of pre-cancerous lesions => progression towards cancer is stopped
  - Higher cancer incidence – but shift towards lower stages = smaller tumours, not metastasised
    - E.g.: breast, prostate and lung cancer
  - Remark: at the start-up of a screening programme, prevalent tumours will be detected
    - Programme should be evaluated when it's running already for several years. Otherwise mortality rates will be biased by "old" = prevalent cases.

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When to screen – which cancer sites to screen?

❑ COST-EFFECTIVENESS OF SCREENING PROGRAMMES

Favourable versus unfavourable effects

Advantages

- Decrease of cancer mortality
- Healthy life-years gained (or Quality Adjusted LifeYears if in good quality (QUALY))
- Prevention of metastasis (more early stages, less advanced stages detected)

Disadvantages

- Earlier and additional diagnoses
- More years lived with disease and follow-up after treatment
- People worry about the risk that they might have a cancer
- Unpleasant test
- False positives and false negatives
- Financial costs, time loss

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When to screen – which cancer sites to screen?

❑ COST-EFFECTIVENESS OF SCREENING PROGRAMMES

- A large benefit for a few, and relatively small unfavourable effects for many
  - The main benefit - prevention of deaths, and the main harm - the over-detection, is not known to the individual participant
  - On the other hand, individual participants are confronted with less serious harms - false positive and false negative test results.
- Screening programmes will always cause harm
  - Physical harm: e.g. invasive interventions
  - Psychological harm: e.g. anxiety, additional years of living with a disease,…
  - Social harm: e.g. family relations, employment, insurance, financial implications,…

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When to screen – which cancer sites to screen?

❑ COST-EFFECTIVENESS OF SCREENING PROGRAMMES

- Well organised screening programme, with high quality and high participation ⇒ might be beneficial
    - Population
        - Lower cancer-specific mortality
        - Life-years saved
        - Less advanced disease stages
    - Individual
        - May be not dying from disease
        - Less severe diagnostics and treatment needed
        - May have a higher quality of life

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When to screen – which cancer sites to screen?

❑ CONSEQUENCES

When becomes screening acceptable?

- **Correct test**: proven effectivenes – preferably in well set-up randomised clinical trials
- **Positive balance** between favourable and unfavourable effects
- **Correct frequency**: periodical screening, but not too often (costs ↗)
- **Correct risk group**: broad age range, but not too young and not too old
- Optimal **quality of organisation and performance** of screening
- **Continual evaluation** is essential

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Summary

- Proven effectiveness and acceptable unfavourable side-effects
    - => population-based screening more efficient than *ad hoc* screening of individual patients
- Screening always implicates negative effects
    - => balanced information on both advantages and disadvantages is indispensable
- Population-based screening aims to improve public health.
    - => This can collide with interests of individual participants
- Organising a screening programme is complex.
- Effects only visible in a long period

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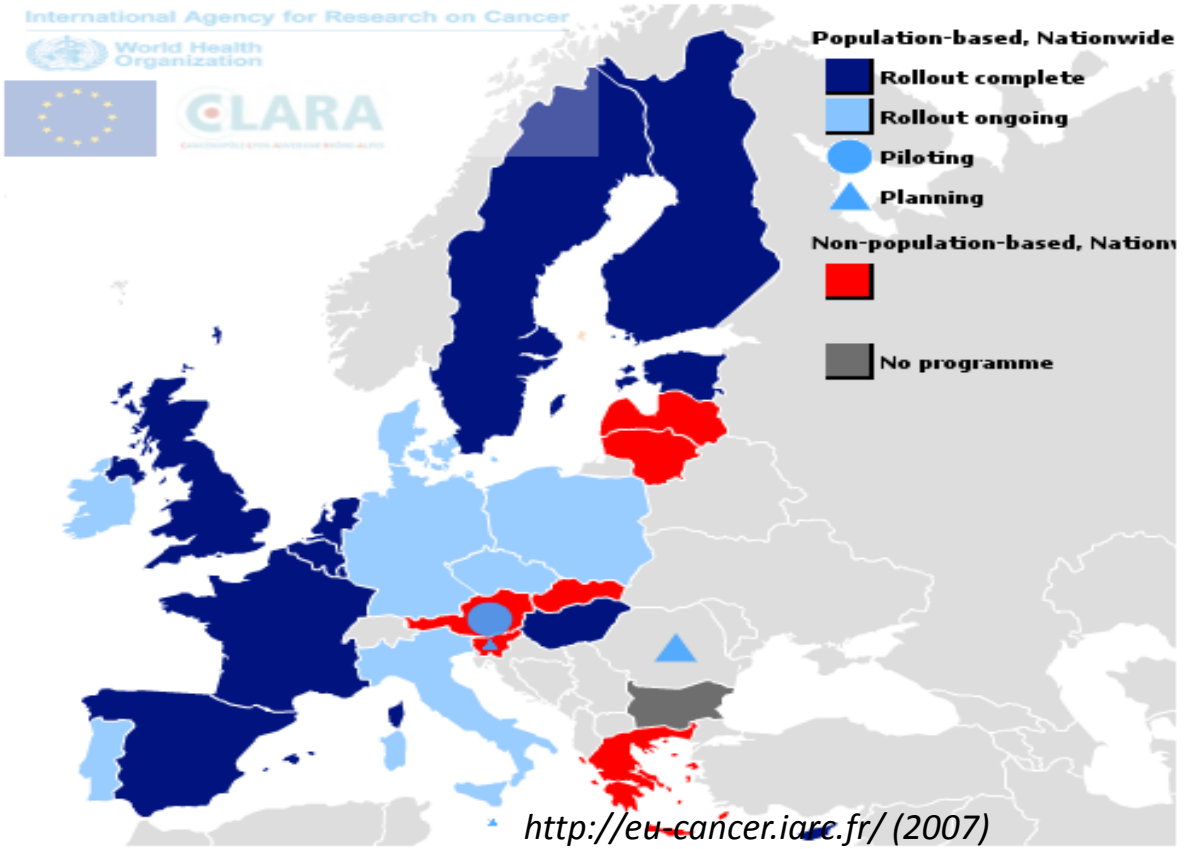
European recommendations

Breast cancer screening:

- 2-yearly Mammography screening for women aged 50 to 69 in accordance with European guidelines on quality assurance in mammography.
- Minimum participation rate of 70% recommended
- Current issues:
  - allowed rate of overdiagnosis (5%? 10%? 50%?)
  - lower age limit? (40? 45?)
  - upper age limit?
  - dense breast tissue: mmx -> ultrasound?



http://eu-cancer.iarc.fr/ (2007)

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Program goals

The main aim of breast cancer screening is to reduce mortality from the disease without adversely affecting the health status of participants.

The objectives :

- To decrease breast cancer mortality
- To detect breast cancer at an early stage of the disease in up to 70 percent of all cases
- To achieve compliance rate of at least 70 percent of target population
- To increase the quality of life of patients suffering from breast cancer by early diagnosis and complex treatment.

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Radiology screening units

- Mammography - the main method for population-based breast cancer screening
- Radiographer - the central player in producing high quality mammograms
- Radiologist - the prime responsible for mammographic image quality and diagnostic interpretation

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Screening test

High quality mammography

- Cancer detection 1 - 3 years before its clinical manifestation
- Quality of requisites required for its performance and interpretation determines balance of sensitivity and specificity.
- Full-field digital mammography has multiple advantages
  - image manipulation and transmission,
  - data display and other technological advantages.

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Risks of Mammography

- False positive results
  - 11% abnormal, 3% Ca
  - Increase anxiety, fear, healthcare visits
- Overdiagnosis (ductal carcinoma *in-situ*)
- Pain
- Radiation: 10 yrs x 10,000 women=1 breast Ca
- False negative results (more common in young women)

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Mammography examination

- Comparable high quality results for all centres participating in the mammography screening programme.

- Specific concern has to be paid on quality control of physical and technical aspects of mammography and the dosimetry:
  - images that have the best possible diagnostic information obtainable
  - image quality is stable and consistent with other screening centers
  - breast dose is As Low As Reasonably Achievable (ALARA)

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Quality of examination reporting

Double-reading (by two radiologists) and if possible - independent reading
BI-RADS lexicon

- **BI-RADS 0** – incomplete assessment – additional investigation is necessary in order to determine the nature of change
- **BI-RADS 1** – negative finding
- **BI-RADS 2** – benign finding
- **BI-RADS 3** – probably benign finding – risk of malignancy is lower than 2%, ultrasound imaging is necessary or a control mammography imaging and examination within 6 months
- **BI-RADS 4** – suspicious abnormality – risk of malignancy is 2-94%, it is necessary to conduct further cytology of pathohistology investigation right away to determine the nature of change
- **BI-RADS 5** – highly suspicious of malignancy – risk of malignancy is higher than 94%, a referral to a surgeon is necessary right away.

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Quality of examination reporting. Recomendations

- The conclusions BI-RADS 0, 3, 4 or 5 – further investigation is required.
- The conclusions BI-RADS 1 or 2 – next mammography screening test after two years.
- Women with BIRADS 4 or 5 have to be invited immediately to radiology unit not to delay the treatment in case of breast cancer diagnosis.

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General/family medicine practitioners

- Patient education
- Formation of positive preventive attitude
- Individual risk assessment
- Motivation of women
- Monitoring the response of invited women
- Determining reasons for non-response

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General/family medicine practitioners

- Close relations with Screening program coordination centre, Radiology screening unit
- Trained in communication
- Acquainted with the breast cancer screening organization scheme
- Introduced to IT system
- Have a deep knowledge in evaluation of screening mammography results (BIRADS system).
- Close relationship with breast cancer units timely addressing patients for necessary procedures.

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Patronage services

- Through a screening IT system obtain a list of non-responding women for a particular region
- Additionally motivate those women
- Schedule appointment at the mammography screening unit
- Record not responders

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Invitation of women

- Personalized letter
- Personal oral invitation
- Open non-personal invitation
- Combination of all three

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PROGRAMME MONITORING AND QUALITY CONTROL

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Epidemiological guidelines for quality assurance in breast cancer screening

- Determining and monitoring the indicators of Program implementation and efficacy.

- Implementation indicators are used during the implementation of the Program for monitoring Program quality.

- For assessing Program efficacy, long-term monitoring of target population is necessary along with monitoring efficacy indicators.

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Implementation

Complete and accurate recording of:

- individual data,
- the screening test, its result,
- the decisions made and their eventual outcome in terms of diagnosis and treatment.

A fundamental concern at each step is the quality of the data collected.

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Radiological quality control

- Setting of target standards and performance indicators, to comply with these wherever possible.
- Local quality assurance manuals based upon European or national documents.
- Regional and local organisations for QA, working at individual discipline level as well as in a multidisciplinary setting

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Radiological quality control

- Digital techniques will have a significant impact on practice, analysis and performance of screening programmes.

- Centralization of mammography reading could enable better radiologic services, training and auditing possibilities as the part of quality control and assurance system.

- Teleradiology service is as an option for quality control, higher effectiveness, and cost savings.

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Multidisciplinary aspects of QA in the diagnosis of breast disease

- Women with breast symptoms should be referred to a Breast cancer unit (the requirements for which have already been laid out by EUSOMA).

- Breast cancer unit need not necessarily be a geographically single entity, although the separate buildings must be within reasonable proximity, sufficient to allow multidisciplinary working.

- Specialists must be trained and certified in own discipline: surgery, radiology etc.

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Breast cancer units

- Teamwork involving a full range of specially trained professionals:
  - radiologist
  - radiographer
  - pathologist
  - surgeon
  - nurse counsellor
  - medical oncologist/radiotherapist
  - genetic
  - psychiatrist/psychologist

- No patients should undergo treatment without being evaluated by multidisciplinary breast manangement teams.

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Multidisciplinary aspects of QA in the diagnosis of breast disease

- Screening is predominantly a radiological procedure with particular emphasis placed on the optimal balance of sensitivity and specificity.
- The radiologist has the role of prime responsibility in screening.
- In symptomatic activity the clinician has the role of prime responsibility.
- The role of imaging, interpretation and cytological/histological sampling procedures is crucial in the cancer diagnostics.
- **Triple assessment**, i.e. clinical examination, imaging, and cytological / histological sampling is still regarded as the gold standard.

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Epidemiology group

- Quality assurance:
  - Coverage
  - Responce rate
  - BIRADS clasification
  - Time between exam and reporting
- Ensuring quality:
  - Communication with GP
  - Quality of promotional activity
- Obstacles
  - IT – upgrading needed, lack of buget
  - Data base for invitation – updating of data
  - Commnunication with GP and RTG units - ?
  - Not enough appointments for mammography – Lack o resources, investment urgently need
  - Lack of human and equipment resouces – PP should became priority in practice

Pathologist view

- 150 biopsies per year
- Training of pathologists
- Standart protocols, update of protocols
- External quality audit

- How can I ensure quality: good correlation MG-pathology, MDT meetings, interobserver variability
- Main obstacles: to be more involved in screening program, good IT data base

- 2 pathologists per unit
- At least 150 biopsies per year
- Standart procedures:

- Implementation: comunication among MDT members, working group for coordination