Individual Health Assessment

Primum non nocere
First, do no harm!

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Considerations

• Up to 75% of patients who complete an initial test will have small, non-cancerous nodules detected in their lungs. However, it is necessary to have repeat tests at regular intervals to monitor the size and condition of the nodules. (~ $500 CAD for 1st baseline screen, ~ $300 thereafter)

Individual Health Assessment

• “...investigations for asymptomatic individuals have been made available to those who may consider they are at risk of a disease.”
• Consumer or Provider driven “Screening” at the individual level?
• Personalized, consumer driven, testing?
Screening

- Screening – the application of tests to asymptomatic individuals to risk stratify them into high or low risk with an aim to inform further definitive testing. The goal is to detect the pathology very early and provide an opportunity for radical intervention. Screening can be applied en masse or to targeted “at risk” groups.
parameters

Screening ←--------→ Diagnostic

- Asymptomatic ←-------→ Symptomatic
- Population ←----------------→ Individual
- Population risk ←-------------→ Individual Risk
- Population registry ←-------→ Individual records
- Screening technology ←--------→ Dx technology
- HC System driven ←------------→ Consumer/Provider
- Public facility ←--------------→ Private facility
- Systems driven f/u ←------------→ Provider driven f/u

IHA
Frameworks for IHA Review

• Screening (e.g. WHO, JAMA criteria)
• Radiation (e.g. ICRP)
• Physician duties
• Professional organizations (e.g. US Prev Task Force, Physician Regulatory bodies)
• Ethics
Harm versus Benefit IHA

• **System issues**
  ▫ Difficult to evaluate
  ▫ No coordinated infrastructure to follow patients with positive or negative results
  ▫ Continuity of care gaps
    • E.g. patient receives IHA test results directly from the imaging facility – who is putting the test results in context relative to the patient’s health status
Harm versus Benefit IHA

• **False positive**
  ▫ Risk of follow up investigations including interventional procedures
  ▫ Patient anxiety
  ▫ Cost – especially related to serial longer term follow up
Harm versus Benefit IHA

• **False Negative**
  ▫ Impaired prognosis
  ▫ False sense of safety
    • May be no standard follow up or or interval to the next test compared to standard screening interventions like breast, colon or cervical cancer screening
  ▫ Potential legal implications
Harm versus Benefit IHA

- Lead time bias

- Length time bias
Harm versus Benefit IHA

- Over diagnosis
- Selection Bias
Harm versus Benefit IHA

• **Radiation**
  ▫ ICRP System of Radiological Protection (ICPR 103)
  ▫ The use of radiation in medicine must take into account:
    • Justification
    • Optimization
    • (application of dose limits) [diagnostic reference levels under discussion]
    • LNT model
Patient Rights and Physician Duties

- Duty of care
- Fiduciary duty
- Duty to obtain consent (duty to inform/disclose) – risks, benefits, alternate options
  - Duty to disclose, without being specifically questioned, on the nature of the proposed intervention
- Life and disability insurance associated impact.
- Patient autonomy versus professional paternalism – right to choose or direct care irrespective of risk/benefit? Duty to accommodate?
  - In a strange way, it seems to be the case that these two divergent principles act as important checks and balances on each other.¹

¹ Bioethical Inquiry (2014) 11:21–29
Screening in the Dark: Ethical Considerations of Providing Screening Tests to Individuals When Evidence is Insufficient to Support Screening Populations

During the past decade, screening tests using computed tomography (CT) have disseminated into practice and been marketed to patients despite neither conclusive evidence nor professional agreement about their efficacy and cost-effectiveness at the population level. This phenomenon raises questions about physicians’ professional roles and responsibilities within the setting of medical innovation, as well as the appropriate scope of patient autonomy and access to unproven screening technology.

Screening in the Dark: Ethical Considerations of Providing Screening Tests to Individuals When Evidence is Insufficient to Support Screening Populations

We shall argue that under most circumstances, physicians should discourage individual patient access to screening examinations prior to conclusive evidence and professional society endorsement of population-based screening.

Ethics Framework
Beauchamp and Childress

- Non-maleficence
  ▫ First do no harm
- Beneficence
  ▫ Act in the best interest of the patient
- Autonomy
  ▫ the patient has the right to refuse or choose their treatment (self determination)
- Justice
  ▫ concerns the distribution of scarce health resources, and the decision of who gets what treatment (fairness and equality)
Framework for Assessment

ASSESSMENT LENSES

PROPOSAL

FINAL IMAGE

epidemiology

efficacy

effectiveness

economics

ethics

legal

Public opinion

politics

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Additional information for reference
WHO criteria for screening: synthesis of screening criteria (aka Wilson’s criteria)

1. The screening programme should respond to a recognized need.
2. The objectives of screening should be defined at the outset.
3. There should be a defined target population.
4. There should be scientific evidence of screening programme effectiveness.
5. The programme should integrate education, testing, clinical services, and programme management.
WHO criteria for screening: synthesis of screening criteria (aka Wilson’s criteria)

6. There should be quality assurance, with mechanisms to minimize potential risks of screening.

7. The programme should ensure informed choice, confidentiality, and respect for autonomy.

8. The programme should promote equity and access to screening for the entire target population.

9. Programme evaluation should be planned from the outset.

10. The overall benefits of screening should outweigh the harm
Evaluating Evidence
Screening Tests

Are the recommendations valid?

- Is there RTC that earlier intervention works?
- Were the data identified, selected, and combined in an unbiased fashion?

What are the recommendations and Will they positively influence patient management?

- What are the benefits?
- What are the risks?
- How do the benefits and risks compare in different people and with different screening strategies?
- What is the impact on individuals’ value and preferences?
- What is the impact of uncertainty associated with the evidence?
- What is the cost-effectiveness?

- Adopted from JAMA Users Guide to the Medical Literature
Justification of Computed Tomography (CT) for Individual Health Assessment - UK Dept of Health - Expert Working Group - further considerations

a) The extent of provision of information for potential clients before appointments are made, including the significant likelihood of false positive findings where the probability of disease is low

b) The detail provided on possible findings (whether clinically significant or not), potential risks, possible further investigations and where and how these would be conducted,

c) The support provided to individuals when results of scans are positive or indeterminate,

d) The impact or otherwise of negative findings on those who have unhealthy lifestyles,

e) The logistical arrangements for transfer of data into the individual’s healthcare record,

f) The mechanisms in place to develop an evidence base for justification of CT examinations for asymptomatic individuals with varying risk factors,

g) The relationship between the healthcare professional acting as referrer for the procedure and the practitioner justifying that the scan should be undertaken.
Canadian Medical Protection Assoc.

Making the Best Decision

Patients rely on their physicians to recommend the right tests and procedures based on their specific clinical needs. Doctors should use their knowledge, clinical judgment, and the best available evidence to guide their decisions, and they should speak with their patients about the appropriateness of specific tests and treatments. Physicians are called upon to use health care resources prudently, exercise appropriate judgment, and help their patients make informed decisions about their medical care.

The Right Test at the Right Time – Striking the Proper Balance. CMPA Perspective. 6(3);2014:10
Self-referred individuals are defined as those individuals with no health care provider, who decline having a health care provider, or for whom the health care provider declines responsibility. It is at the discretion of the facility’s medical director whether or not to offer screening to the self-referred individual. However, screening facilities that elect to accept self-referred individuals must have procedures for referring them to a qualified health care provider if abnormal findings are present.
US Preventive Task Force

The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery. (B recommendation)
Risks of Lung Cancer Screening

Lung cancer screening with LDCT has inherent risks and benefits.\textsuperscript{21,22,28,127,244} These risks must be understood to determine whether screening is beneficial. The possible or projected risks of screening for lung cancer using LDCT scans include: 1) false-positive results, leading to unnecessary testing, unnecessary invasive procedures (including surgery), increased cost, and decreased quality of life because of mental anguish; 2) false-negative results, which may delay or prevent diagnosis and treatment because of a false sense of good health; 3) futile detection of small aggressive tumors (which have already metastasized, preventing meaningful survival benefit from screening); 4) futile detection of indolent disease (ie, overdiagnosis), which would never have harmed the patient who subsequently undergoes unnecessary therapy; 5) indeterminate results, leading to additional testing; 6) radiation exposure; and 7) physical complications from diagnostic workup. Patients with several comorbid conditions may be at greater risk than those with few or none.
Lung Cancer “Screening”

An IHA intervention which may become true screening

1. IHA CT for lung cancer detection should not be offered to people under the age of 55 as they are unlikely to benefit.
2. IHA CT for lung cancer detection should not be offered to people who have never smoked, or those with a pack history of less than 20 years with no other risk factors as they are unlikely to benefit.
3. Individual risk prediction models should be used to select those patients at risk of developing lung cancer. IHA CT may be offered if the risk is equivalent to 5% in 5 years. If the risk is lower IHA CT may still be offered but the balance of risk and benefit is not known. Annual or biennial screening may be offered from age 55 to 74 but few people aged 55 to 60 will be at sufficiently high risk.
4. IHA CT should only be offered by expert clinicians (radiologists and respiratory physicians), able to explain the risks and benefits of CT for IHA.
5. Information packs on the risks and benefits of CT for IHA, detailing in lay persons’ language the limitations, and the risks and benefits of IHA should be made available to individuals prior to undergoing CT scanning.

Justification of Computed Tomography (CT) for Individual Health Assessment – UK Dept of Health – Expert Working Group July 2014
Lung Cancer “Screening”

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