

Topic idea submitted to IHI - Reference Number: TI_001172

Are you submitting the idea:

- in your personal capacity?
 on behalf of an organisation?

1 Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea:

Multi Cancer Early Detection - finding cancer in asymptomatic citizens

2 Scope

Explain the specific challenges/problems to be addressed by your idea and how these affect relevant stakeholders, taking into account what is already known and/or available in the field:

Diagnosis is done on patients with first symptoms and hopefully in early stage. Early detection (also known as secondary prevention) happens in asymptomatic citizens and can be done every 2 to 5 years (depending on the cancer and country policy). This idea is about the latter: early detection for multiple cancers. In the future it can be the replacement of the existing detection tests. In early detection, sensitivity and specificity of the test are of great importance. You try to raise the sensitivity when set the specificity as high as 99%. This idea wants to focus on 'Finding cancers in asymptomatic citizens.'

There are now screening tests (in general and depending on the country) for breast cancer, colorectal cancer, cervical cancer, skin cancer, oral cancer, lung cancer and prostate cancer. We need to prove that the new approach in comparison with the existing techniques is valid, good (i.e., sensitivity and specificity), cost effective and acceptable to the population and the health system. We have to take into consideration the harms of screening: i.e., the issue of over-diagnosis and consequently over-treatment. Screening programs also detect cancers that are "latent" (e.g., 10% of all breast cancers), that means that they will remain without progressing.

Please indicate which IHI specific objective(s) (SO), as described in the IHI Strategic Research and Innovation Agenda (SRIA), your idea addresses:

["SO1: contribute towards a better understanding of the determinants of health and priority disease areas"

"SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-

users

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"SO3: demonstrate the feasibility of people-centered, integrate health care solutions"

"SO4: exploit the full potential of digitalisation and data exchange in health care"]

Please select the keywords that are most relevant to your idea:

["Oncology"
"Paediatric"
"Prevention"
"Detection"
"Diagnosis"
"Health technology"]

In alignment with the IHI specific objective(s) selected above, specify the objectives of your idea:

In some countries early detection is the unique option because a screening program is not feasible due to limited diagnosis and treatment capacities. Mainstream for new technologies for screening is now NGS/cfDNA and MCD with the use of liquid biopsies. There are now several mature technologies on the market, but they have never been compared with the existing techniques.

The objectives of this idea are to promote/threefold:

1. Can we detect more cancers than in the conventional tests?
2. Can we compare the new techniques with these tests?
3. We might keep high risk population in mind as a good possibility to start with (for example: hereditary pancreatic cancer). It's a small and probably more easy to include group.
4. If detected early, it will be beneficial to the patient (better prognosis and quality of life) and to the healthcare system (lower treatment cost, less human resources and equipment needed). It also means that if a cancer is detected, there is a treatment to propose and we know that the treatment is likely to cure or stop the cancer progression (because it is not metastasized yet).
5. The test needs to be easy to use (also, for illiterate people), efficacious, acceptable for the population, cost-effective and affordable.
6. The proposals need to work on the implementation of mature technologies and NOT on comparing technologies.
7. We think this project can only be done through good cooperation between science and industry. It needs a lot of technique(s) and devices to be involved (for example: blood draw at home).

3 **Expected impacts to be achieved by your idea**

Briefly describe the expected impacts to be achieved by your idea, ensuring that they contribute to IHI general and relevant specific objectives, as described in the IHI SRIA:

Impacts are wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments. Impacts generally occur sometime after the end of the project, e.g. successful implementation of digital solutions supporting people-centred care.

***IHI general objectives:** 1. contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations; 2. foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to 'Europe's Beating Cancer Plan'; 3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.*

SO1: contribute towards a better understanding of the determinants of health and priority disease areas

Most certainly it does or it has to be. The outcome is a yes or no on the question 'Do I have cancer or not?'

SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users

Although for some cancers there are techniques to find tumors early (breast, prostate, colon among others), these techniques are often not precise enough (sensitivity and specificity) there are also tumors that can not be found in an early phase (pancreatic cancer and glioblastoma among others). Therefore the combination of science and technique (academia and industry) is necessary.

SO3: demonstrate the feasibility of people-centered, integrate health care solutions

Yes, the liquid biopsy is/needs to be user-friendly, needs to be done at home and must be acceptable for the citizens and physicians (in other words: needs to be good).

SO4: exploit the full potential of digitalisation and data exchange in health care

Yes. The outcome can only be delivered with modern techniques of IT and AI.

4 Why should your idea become an IHI call topic?

Explain why collaboration through a cross-sectoral and multidisciplinary public private partnership is needed in particular:

Why does it require collaboration among several industry sectors (e.g. pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?

Why does it require collaboration between private (industry) and public partners (e.g. academia, healthcare practitioners, patients, regulators)?

Diagnosis is done on patients with first symptoms and hopefully in early stage. Early detection (also known as secondary prevention) happens in asymptomatic citizens and can be done every 2 to 5 years (depending on the cancer and country policy). This idea is about the latter: early detection for multiple cancers. In the future it can be the replacement of the existing detection tests. In early detection, sensitivity and specificity of the test are of great importance. You try to raise the sensitivity when set the specificity as high as 99%. This idea wants to focus on 'Finding cancers in asymptomatic citizens.'

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Why is the contribution of industry needed to achieve the expected impacts?

Contribution of industry: Large companies that are members of the IHI industry partners (i.e. COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe) contribute to the programme, primarily through 'in-kind' contributions (e.g. their researchers' time, laboratories, data, compounds). At least 45% of each project's total costs have to be in-kind contribution.

New techniques of blood draw are necessary to make it possible that citizens do this at home. It needs to be able to be transported over long distances in many weather circumstances (cold and heat, among others).