Text

Description automatically generated

Enschede 2022

Authors:

L.M.B. van der Neut

Dr. ir. V.C. Schulze Greiving

Dr. ir. K. Visscher

Science, Technology and Policy Studies Department (STePS), Faculty of Behavioural, Management, and Social Sciences (BMS) of the University of Twente

For additional information and more cases please visit: https://cta-toolbox.nl/

Contact person: Klaasjan Visscher, k.visscher@utwente.nl

Involved institutes: University of Twente, RIVM, MESA+, TU Delft, Saxion University of Applied Sciences

We wish to thank all those involved in the project and the development of the cases. Special thanks go to: ECSens, QDNL, and the 4TU Plantenna project

These are the results of a project related to the NWA Route Quantum Nanorevolution funded by NWO.

Grant number: NWA.1418.20.002

A picture containing text, clipart, sign

Description automatically generated© Content is made available under a Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License (International)

# Table of Contents

[Table of Contents 3](#_Toc107481781)

[Role Descriptions 4](#_Toc107481782)

[Chief Executive Officer of LQBio 4](#_Toc107481783)

[Manager of the Public Health division of the Ministry of Health, Welfare and Sport 5](#_Toc107481784)

[Chairperson of the Royal Dutch Medical Association (KNMG) 6](#_Toc107481785)

[Chairperson of the Prostate Cancer Foundation 7](#_Toc107481786)

[Manager of the Center for Population Screening 8](#_Toc107481787)

[LQBio Shareholder 9](#_Toc107481788)

# Role Descriptions

## Chief Executive Officer of LQBio

As the Chief Executive Officer of LQBio you lead an ambitious private start-up that developed a nanofabricated electrochemical sensor to detect prostate cancer. The start-up is a spin-off from your PhD research, which you concluded three years ago. Alongside your academic expertise, early investors have been providing you with expert business advice. The company consists of you and three colleagues and is financed in full by private investments since half a year. This has been an exciting step for your company but comes with the responsibility of delivering growth.

The reproducibility and reliability of your test have been perfected in a home test for COVID-19. Now, you reached a stage where the liquid biopsy test only requires certification and procedural standardization to allow for its uniform implementation throughout the medical practices. Your product can be delivered in bench-top form, to be operated by medical professionals, and in the form of self-tests.

By promoting the liquid biopsy test to be part of a large, nation-wide screening program you are hoping to secure your first large scale implementation in the medical sector. This would enable further growth of your company in the long term, with the aim of increasing expected revenue and thereby the value of the company at the request of private investors. You are looking for partners to realize this ambition.

*Interests:* Entering the medical market, improve lifespan of men/reducing deaths by prostate cancer through early detection, increasing revenue.

*Irritated by:* Lack of ambition, bureaucratic processes, competitors such as large companies who have an interest in building a similar screening test.

*Habits:* No-nonsense attitude, tough negotiator, very convinced of own developments, visibly annoyed when irritated by others.

|  |
| --- |
| **Factsheet** |
| Pre-clinical testing has shown that the liquid biopsy test is 99% accurate, which is comparable to other technologies such as glucose sensors for diabetes patients or tests used in the screening program for cervical cancer. (Reliability) |
| The price of the home-test is expected to reduce by 30% after initial production optimization. For the price to reduce by 40% large scale operations over multiple provinces are required. (Finance) |
| The bench-top systems are rather expensive (around 25.000 € per system, including a contract for regular maintenance and cassettes of 20,- a piece for testing) which would provide you with much revenue in the short term. Home tests are cheaper (currently around 50 € per test) and generate higher revenue more steadily for the duration of the screening program. |
| The home test kit includes the liquid biopsy test, a disposable blood lancet and a manual on how to carry out the test. First, a drop of blood is obtained with the blood lancet from a fingertip. The sample is introduced in the device by pressing the fingertip on a dedicated area of the test. The result can be read from the test window after a few minutes. There are no concerns for the reliability of the test when conducted by a lay person. (Context) |

## Manager of the Public Health division of the Ministry of Health, Welfare and Sport

As a manager of the Public Health division at the Ministry of Health, Welfare and Sport (VWS) you represent the political decision maker. You are responsible to take executive decisions of the division and present policy proposals to the Minister that promote the goals of your division. The overall goal is to promote the wellbeing of the population, prevent illness, and establish an adequate infrastructure to provide health care while minimizing socio-economic health differences.

You closely cooperate with the RIVM, general practitioners, local governments, insurance companies, and the Minister of VWS to ensure political and operational implementation of policies. On urgent matters regarding public health, healthcare research and public screening programs you are advised by the health council, an independent scientific advisory body.

The expected rise of 32% of prostate cancer related deaths has caught the full attention of your department. Public screening is seen as one of the few ways to combat this rise. Self-testing has the risk of misinterpreting results, inducing anxiety, or not reporting results at all. This makes you skeptical about home-testing procedures. While on the other hand, home testing has shown to increase willingness of citizens to take a test, as showcased during the COVID-19 pandemic.

*Interests:* Being seen as a catalyst, establishing reliable health infrastructure, wide support of involved stakeholders.

*Irritated by:* Plans that cause unrest among politicians, cost-ineffective projects, shifting and unclarity regarding interests of involved stakeholders, negative stance towards government involvement.

*Habits*: Aims for consensus but can play a political power game; tries to be nice to others but gets formal and stand-offish when irritated.

|  |
| --- |
| **Factsheet** |
| In the case of the well-established screening program for cervical cancer, the program has been based on a mixture of testing at the GPs office and home-testing.[[1]](#footnote-2) (Responsibility) |
| To aid the public commitment to the minimization of socio-economic health differences, there is a small budget available to increase accessibility of medical treatment that has proven to be effective. (Finance - accessibility) |
| Insurance companies have indicated willingness to contribute financially, yet indicate that the price of the test needs to drop by 40% for them to include full coverage of test costs. (Finance) |
| The health council assesses the risk and benefit of a screening program, based on the Criteria of Wilson and Jungner: 'All screening programs do harm; some do good as well, and, of these, some do more good than harm at reasonable cost.' |

## Chairperson of the Royal Dutch Medical Association (KNMG)

As chair of the KNMG you are the spokesperson of the Royal Dutch Medical Association and responsible for promoting the field of medicine. The KNMG is the national lobbying organization for all doctors and medical students and has over a hundred employees. You regularly organize local meetups with the eight sectoral associations, the General Assembly, to discuss relevant topics.

You are dedicated to realize high quality health care which enables citizens to be as healthy as possible. You have taken up this role to ensure that the voice of medical staff is heard. The association is critical of large-scale check-ups on diseases when the test is not extremely accurate and effective.

Aside from being critical on the effectiveness, you hold several operational concerns: Who will conduct the test? What are procedures for home-testing? What if people are unable to carry out the home-test themselves? Ultimately, you expect the introduction of a large-scale screening program to affect the capacity of health care services. If such a screening program is introduced, this additional pressure on the health care sector has to be taken into account.

*Interests:* Safe, accessible, effective forms of prevention, satisfaction of members, maintaining a reliable reputation.

*Irritated by:* Negative attention for doctors, increasing procedural scrutiny, reducing significance of doctors in society.

*Habits:* Authoritative attitude, can make derogatory comments to others when irritated.

|  |
| --- |
| **Factsheet** |
| General practitioners have reported difficulties comprehending the descriptions of self-test procedures for COVID-19 among elderly. (Accessibility) |
| Member organizations have showed large interest in the liquid biopsy test if the accuracy of the test remains as high as indicated in the early trials after scaling up production. (Reliability) |
| Member organizations are worried about whether individuals will report the outcomes of the self-tests to their general practitioner and the subsequent ability of the General Practitioner to ensure the health of his/her patients. (Responsibility) |
| Member organizations have expressed worries about the ability of individuals to conduct a self-test on their own in which blood is required. Many people have a fear of blood, which is a frequent problem doctors must deal with. (Accessibility) |
| Men who are diagnosed with a benign form of prostate cancer are directed to a monitoring program coordinated by hospitals autonomously. (Responsibility) |

## Chairperson of the Prostate Cancer Foundation

As the chairperson of the Prostate Cancer Foundation, you are the main voice for men who have, had, or passed away due to prostate cancer. Your foundation actively supports men who have prostate cancer, runs information campaigns, and promotes interests of men with prostate cancer in local and national media.

Early detection of cancer is high on the priority list of the foundation, and you make a continuous effort to inform men about the possibility of taking a PSA-test at the general practitioner office – currently the state-of-the-art test for prostate cancer although with a relatively low reliability. You find the individual choice for an early test extremely important since there exists a trade-off between the early detection of cancer and the loss of ‘quality of life’. The loss of quality of life is considered to be the adverse health effects of the related treatment and the anxiety that can be caused by the diagnosis with prostate cancer without being actively treated against it.[[2]](#footnote-3)

It is important to your association that early detection is improved. However, you are weary of false positive diagnosis and possible over-treatment since that unnecessarily decreases the quality of life of those involved. You would welcome an effort to support those who want to take a test and make liquid biopsy home tests widely available.

*Interests:* Promoting early diagnosis;being a voice for every patient; reliable, accessible and affordable screening.

*Irritated by:* Disregard of impact on the patient, unclarity about effectiveness of available tests, limited or incorrect information about technology.

*Habits:* Constructivist attitude, not afraid to speak up, can be slightly activistic. Gets agitated when being marginalized*.*

|  |
| --- |
| **Factsheet** |
| A European study found a lower risk of death from prostate cancer for men who underwent early screening (done about once every 4 years). The researchers estimated that about 781 men would need to be screened (and 27 cancers detected) to prevent one death from prostate cancer.[[3]](#footnote-4) (Large scale impact) |
| A recent workgroup of the foundation has indicated that a low threshold test on prostate cancer is important for men to have themselves tested. They have indicated the fact that these tests are not pro-actively offered to men over 55 as a reason for the limited testing that currently takes place. (Accessibility) |
| Men who are diagnosed with a benign form of prostate cancer are directed to a monitoring program coordinated by hospitals separately. Several men have indicated the stress that this induces. “A subject (N1) on regular testing: “It’s not that I don’t want to go there, I know I have to go, and I’m going. But it does create some anxiety because of the uncertainty, yeah there is some of that definitely. I’m sure it can’t be avoided actually.”10 (Responsibility - impact) |

## Manager of the Center for Population Screening

As manager of the Center for Population Screening you are part of the RIVM and an important advisor to the Ministry of Health, Welfare, and Sports regarding the operability of a potential public screening program.[[4]](#footnote-5) It is the task of the RIVM to research how a program can be implemented and, at a later stage, to implement the program. Your unit coordinates the collective effort of all involved stakeholders to successfully provide a public screening program.

The goal of your unit is to improve public health through high quality, accessible and affordable public screening programs. High quality in your eyes means an effective, public request-driven, safely standardized, and innovative public screening program. Accessibility implies a local presence, timely execution, and free choice for those involved whereas affordability requires oversight of involved costs and a (cost-)effective implementation.

You are mostly concerned about the safety and the environmental impact of the wide dissemination of a large number of tests among the population, the safety of the test itself, and the establishment of a safe and reliable test environment by the test subject. Another important requirement is that the screening program must be implemented in accordance with EU and national law and regulations related to e.g. procurement, privacy, data protection, medical devices.

*Interests:* Maintaining the reputation as being highly reliable, independent, and legitimate in the eye of the public; feasibility of screening programs.

*Irritated by:* Cutting corners, high uncertainty, ignoring environmental impact and safety of technology.

*Habits:* Procedure focused, sticks to role, insistent on concerns, hard to convince, plays with glasses or pen when irritated.

|  |
| --- |
| **Factsheet** |
| Questions have been raised in your center about the effects of large-scale production on work safety and environmental sustainability. It is also still unclear whether the elements of the test-kit can be recycled and used for another application or whether elements can be harmful when handled incorrectly. (Safety) |
| The center usually starts with small scale implementations (~10.000 participants spread across different locations) to develop the standard and test the influence of relevant variables, before a standard is implemented widely. (Standardization) |
| Currently, the well-established screening program for cervical cancer involves self-testing upon request (as an alternative to the test at the GP's office). (Reliability) |
| You are concerned about the accessibility of a self-testing program for those who might not understand the test procedures and those who are physically unable to conduct the test themselves. (Accessibility) |

## LQBio Shareholder

As an early investor in LQBio, you have followed the development of the company closely. Now, LQBio is invited to a public stakeholder meeting by the Ministry of Health, Welfare and Sport and has requested you to join them to provide your economic expertise and be able to make financial decisions on the spot.

This position is well-known to you, you have backed several start-ups before and guided them in their developmental process. Your motivation for this issue lies close to yourself, five years ago you have been diagnosed with benign prostate cancer. At the moment, you are in a program to monitor the cancer and have a biyearly check-up with at the doctor’s office. This monitoring provides you with confidence and lowers your anxiety about the cancer. You have indicated to the Ministry that you would be willing to financially contribute to a public program regarding prostate cancer if your conditions are met.

Your most important conditions are:

* LQBio has to be the sole supplier of test equipment;
* The national program has to include all men over 50 in the Netherlands;
* The program has to be accessible for the physically and mentally impaired;
* The program has to include an information campaign to raise awareness of the severity of prostate cancer;
* The program has to be specific, dependable, and supported by the actors at the table.

*Interests:* Contributing to a healthy and inclusive society, enabling LQBio to become an established actor in the market, enabling initiatives for the public good, ensuring return on investment.

*Irritated by:* Lack of ambition, lack of specific planning, indecisiveness.

*Habits:* Can be denigrating when people think in problems, tends to whisper during meetings to give strategic pointers.

|  |
| --- |
| **Factsheet** |
| You are willing to support the pilot financially by paying 30% of the test costs. This can evolve into a continuous sale of the product when a public screening is implemented. Additionally, if a public screening program were to be implemented you would be interested in funding a widespread information campaign to increase awareness of the threat of prostate cancer and the test of LQBio (additional 10.000€). |
| Pre-clinical testing has shown that the liquid biopsy test is 99% accurate, which is comparable to other technologies such as glucose sensors for diabetes patients or tests used in the screening program for cervical cancer. (Reliability) |
| LQBio has received solely positive attention from other investors and their development of the product has lived up to your expectations. Recently, LQBio has been winning several prestigious grants, confirming the potential you see in the company. |

1. [Zelfafnameset | RIVM](https://www.rivm.nl/bevolkingsonderzoek-baarmoederhalskanker/zelfafnameset) [↑](#footnote-ref-2)
2. [Prostaatkankerstichting](https://prostaatkankerstichting.nl/individueel-vroegonderzoek-en-expertdiagnostiek/), Individueel vroegonderzoek en expertdiagnostiek [↑](#footnote-ref-3)
3. [Schröder et al.](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60525-0/fulltext#articleInformation), *Screening and prostate cancer mortality: results of the European Randomised Study of Screening for Prostate Cancer (ERSPC) at 13 years of follow-up*, The Lancet, 2014 [↑](#footnote-ref-4)
4. [RIVM](https://www.rivm.nl/bevolkingsonderzoeken-en-screeningen/bevolkingsonderzoek-organisatie/wie-voeren-bevolkingsonderzoek-uit), Wie voeren het bevolkingsonderzoek uit? [↑](#footnote-ref-5)