

1. Publishable summary

Summary description of project context and objectives

The aim of the selfPOCNAD project was to develop an industrial prototype for a rapid (*same day*) platform for cervical cancer screening using patient collected samples. The platform will be based on Lab-On-Chip (LOC) technology, and includes automated sample pre-treatment, preparation, nucleic acid based amplification and target detection.

The industrial prototype uses up to one ml of lysed cells that has been collected from a vaginal and cervical tampon based self-collected sample. The detection instrument will operate with the same detection method proven for the well documented cervical pre-cancer screening method PreTect HPV-Proofer; amplification of E6/E7 mRNA of carcinogenic human papillomaviruses by Nucleic Acid Based Amplification (NASBA). However, the software and hardware is operating as a standalone unit able to directly operate self-collected sample detecting oncogene expression from up to 14 HPV types reporting only the E6/E7 mRNA expression that reduce the false negatives and positives to a minimum.

Description of work performed and main results

The development for the industrial platform for rapid "same day" cervical cancer screening has been completed during the project. The consortium decided to divide the platform into three modules; a sample container, a cartridge and an instrument. The sample container allows the patient to collect the sample in the privacy of her home. Upon arrival at the doctor's office, the sample container will be assembled with the cartridge and placed into the instrument. The complete automatic sample processing from sample pre-treatment to target detection will take place within the cartridge and the instrument. Extensive literature searches and reviews of the trends in self sampling point-of-care (POC) nucleic acids screening were carried out to ascertain state of the art related to advances in cervical pre-cancer screening, microfluidics, technical developments and commercial trends in POC, as well as the scientific work in this area. We found no products, papers or projects which presents a direct competitor to the SelfPOCNAD concept.

The development of the sample container, cartridge and instrument has been completed, taking into account a risk assessment. The prototypes of the sample container and of the cartridge have been produced. The initial testing shows promising results for sample pre-treatment, nucleic acid extraction, target amplification and detection. The extensive verification of the concept and developed technologies is in on going post project.

Expected final results and potential impacts

The introduction of this platform in doctors' offices (Point of Care) is expected to significantly improve compliance of women within national Cervical Cancer screening programs. This increased compliance may drastically reduce the national incidence of Invasive Cervical Cancer (ICC) and save lives.

ICC is the second most common cause of cancer in women. Each year there are more than 470 000 new cases globally; 33 000 of these in the EU. Once the disease is established, it is difficult to cure, leading to the death of 233 000 women annually - 30 000 of these in the EU-25 according to ECCA. However, if discovered in the early stages, it is preventable (and treatable). Some EU member states have a well-organized screening and prevention program, but the weak link is the use of cytology in the primary screening settings and the compliance with the program. Therefore, means of improving the compliance, especially in new member states, may save the lives of 3 - 5 000 European women each year. However, if self sampling may increase the national coverage to more than 90% within all members states including the use of technologies similar to the Self POCNAD the incidence rate of cervical cancer may be significantly reduced and save more than 25 000 European female lives every year.

Project public website address: www.selfpocnad.com