The value of urine-based home sampling for disease screening in a (post-) COVID-19 era

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May 2021

INTRODUCTION

The COVID-19 pandemic has changed the world in many ways. Besides the unseen economic impact, the pressure on (public) healthcare systems is by far the most impactful consequence, leaving many hospitals and intensive care units beyond capacity at multiple occasions.

However, the impact on healthcare goes far beyond COVID-19. The peaks have led to a severe decrease and sometimes even a complete standstill of non-SARS-CoV-2 related disease detection and treatment, resulting in unnecessary morbidity and mortality.

Due to these hurdles , hospitals and clinical centres around the world have been forced to rethink new or alternative ways to continue healthcare practices. As an example, the telemedicine market, which makes patient-doctor visits a virtual experience using online communication tools, is expected to grow towards a USD 155 billion industry by 2027[1].

HOME SAMPLING

Self-collection of samples in a remote location offers potential to continue care and essential medical services. Home-sampling (or patient-centric sampling) allows individuals to use the comfort and privacy of their home environment to deliver a sample, without needing to travel or visit a clinic. In addition, home sampling reduces the pressure on healthcare workers and protective materials required for clinic-based testing[2].

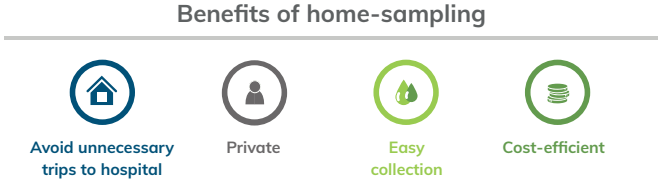

Figure 1: Benefits of home sampling

Unfortunately, uptake of home sampling has been slow, both in clinical trials and especially in routine clinical diagnostic settings. Questions around quality and stability of the collected samples have caused concerns. Further, comparability of results to standard sampling methods have also limited the scope and uptake of home-sampling[3].

In order to maximize the full potential of self-sampling and home-sampling, both during the COVID-19 pandemic and beyond, methods to optimize the process are necessary. Sampling devices should be designed in a way that allow for a maximal ease-of-use. Additionally, more efficient, reliable communication channels should be used that can also support a patient psychologically, especially for virtual patient-doctor meetings or when a positive test result needs to be communicated[2].

URINE AS A SAMPLE TYPE FOR HOME COLLECTION

Urine as a biological sample is exciting, especially when looking at home-based collection. Urine sampling can be done easily without the help of a clinician, and is completely non-invasive, giving it a strong advantage over other sample types like blood and cervico-vaginal (self-)samples. Urine can also be sampled in a serial manner, making it well-suited for patient follow-up. Moreover, sampling is not limited by the health status of the patient. Many studies have also shown patients expressing a decisive preference to urine sampling over other sampling methods[4,5,6].

Urine contains many biomarkers for disease detection, reaching far beyond the obvious urogenital tract associated diseases, making the sample attractive for multi-omic analysis.

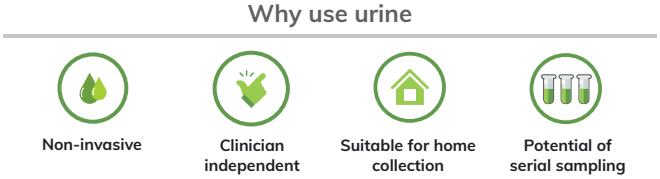

Figure 2: Benefits of urine

APPLICATIONS OF URINE FOR HOME SAMPLING

Urine as a sample has a lot of promise in several application fields, such as infectious disease testing (including sexually transmitted infections) and oncology.

Given the challenges women face with a Pap smear, and the global strategy set by the World Health Organization, ways to improve screening are required to accelerate the elimination of cervical cancer. Human Papillomavirus (HPV) based self-collection techniques have been recommended, which can offer better acceptance. Several publications have shown the value of first-void urine as an equivalent sample type for the detection of HPV, offering a way to reach more women, especially those who are often reluctant to participate in screening for cervical cancer[7,8,9,10].

Next to HPV infections, other sexually transmitted infections can strongly benefit from the use of urine-based home sampling. First-void urine has shown to be the sample of choice for the detection of *Chlamydia trachomatis* (CT), *Mycoplasma genitalium* (MG) and *Neisseria gonorrhea* (NG) in men using nucleic acid amplification tests (NAATs)[11].

Additionally, urine as a sample type is also showing promise in oncology research. For prostate cancer, the Prostate Specific Antigen (or PSA) serum-based test can lead to overdiagnosis, causing a high number of unnecessary biopsies[12]. Various biomarkers for prostate biomarkers can be released in urine including first-void urine[13,14,15] . To date, already several approved urinary tests for prostate cancer are commercially available[16,17].

COLLI-PEE® POSTAL KIT

Currently, there is a lack of user-friendly and high-quality urine sampling devices for use at home that can be delivered in a simple and cost-efficient way. For this reason, Novosanis has developed a Colli-Pee postal kit, that can include the device for collection and methods for safe storage and transport of the sample.

The Colli-Pee® Small Volumes variant was designed to be fully compatible with local postal services that allows for distribution of the sampling device directly to a patient's home, as well as for the return of the collected sample, using postal service delivery. The postal kit components were selected in such a way that the use of the kit is fully compliant with UN3373 regulations, which give guidance on the transportation of potentially infectious substances.

The device architecture enables immediate mixing of the first-void urine sample with a preservative, improving stability of the urine specimen. Recent in-house data has shown that Novosanis' Urine Conservation Medium (UCM) is capable of stabilizing human and HPV DNA in urine samples, for a period of up to 7 days at room temperature, and for a period of up to 14 days at 4°C, without any significant loss of stabilization performance[18].

A full standard Postal Kit is comprised of the following items:

- A rigid distribution envelope, used to distribute the Colli-Pee® and all the necessary accessories for sample return to the patient
- A rigid envelope, used to return the collected sample to a clinical laboratory
- A safety bag and absorbing tissue, used as a secondary container to prevent contamination of the return envelope, in case of any damage to the collection tube

Next to the packaging components, labels can be added to the postal kit, to capture address and patient ID details.

Furthermore, a comprehensive return instruction sheet can be added, to offer additional guidance on the kit components and sample return. These labeled items, as well as the composition of the postal kit, can be fully tailormade to fit the needs of any study or clinical setting, in which the Colli-Pee® can be used.

MAILING STUDY

In a recent mailing study, the ease of use of the postal kit was evaluated by 30 participants. Participants each received a Colli-Pee® postal kit via the mail. They were asked to simulate urine collection using the Colli-Pee® device, and then to use the return envelope to ship the dummy sample back to Novosanis.

A questionnaire was used to assess the practical ease of use of the postal kit and all its components, and to assess the clarity of the return instructions in guiding participants through the process of returning the sample. Likert scale responses were captured, with answer possibilities ranging from 1 (completely disagree /completely unclear / very difficult) to 8 (completely agree / completely clear / very easy); 29 out of the 30 participants responded to the questionnaire. The main results are summarized in Figure 3.

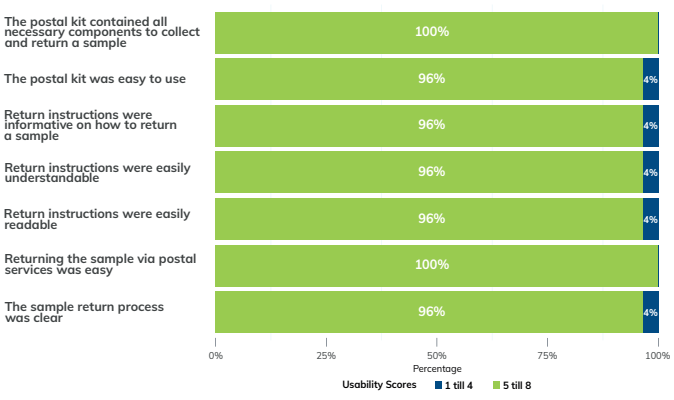

Figure 3: Usability results - Postal Kit mailing study

Overall usability results were positive, with 96% to 100% of all respondents scoring '5' or greater, depending on the question. Two lower scores were observed (a '3' on the overall clarity of the sample return process, and a '1' on the informative nature of the return instruction sheet). The lower scores, in combination with the feedback were used to improve instructions on the return sheet.

Furthermore, the time between the postal stamp date and the receipt date of the sample at Novosanis was monitored for 28 out of the 30 participants (for 2 participants, data information could not be retrieved). An average time period of 4.96 calendar days was observed in between the sample return date and the sample receipt date, with 3 samples being returned after only 8 days. The longer return periods could be a result of the study being conducted during a long holiday weekend. Overall, very good results were obtained, and no damage was observed to the postal packages, both in sending the kits and in returning the samples.

CONCLUSION

Colli-Pee® offers great potential to push back on unnecessary disease incidence, not only during COVID-19, but also beyond. Using the recently developed postal kits, patients can now stay in the comfort and privacy of their home location to deliver a sample, without having to compromise on the turn-around time and the reliability of the analysis result.

Reach out to Novosanis to find out more!

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