Cancerworld

Digital Solutions in Cancer Care: from Prevention to Diagnosis

Adriana Albini / 11 November 2022

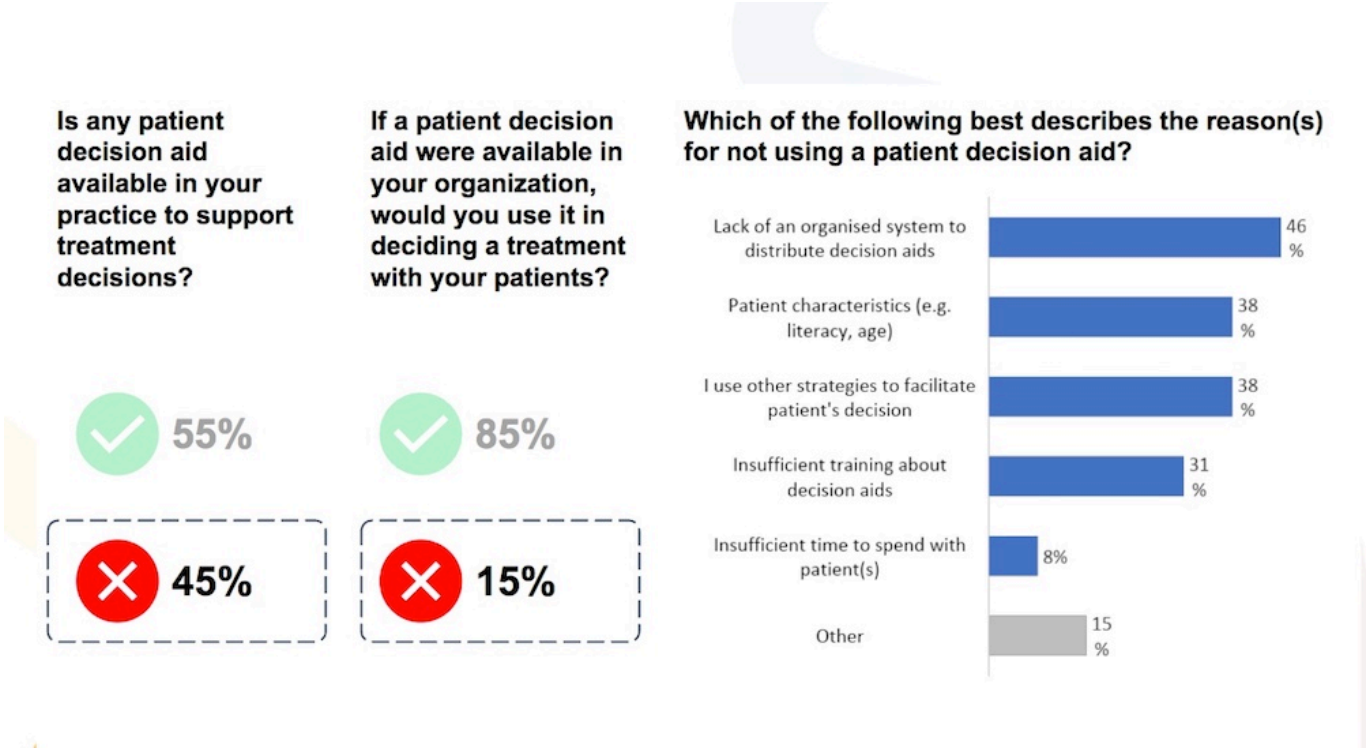
Held on 12 October 2022, this was the first of the four live webinars in Phase 2 of the Telemedicine Educational Project developed by SPCC in collaboration with the American Society of Clinical Oncology (ASCO). Subtitled, “The Implementation and Integration of Telemedicine in the Cancer Care Continuum”, the second phase of the project focusses on how to overcome barriers and address challenges in order to best implement and integrate telemedicine throughout the entire cancer care pathway.

Discussant of the session was **Rosanna Tarricone**, Associate Dean at SDA Bocconi School of Management, Milan, Italy. Prof. Tarricone spent a few minutes to introduce the topic which has become one of the most prominent in the scientific community. Digital solutions came to the fore during the Covid-19 pandemic, and we soon saw the benefits that could also be derived for preventing, diagnosing, and treating a wider spectrum of diseases. We also learned that digital solutions can help counteract the rising increase in healthcare costs. They can bring gains in terms of efficiency but also of health outcomes. However, we are still at the beginning of the journey into these new technologies, and they need to be thoroughly evaluated in terms of benefits from both provider and end user perspectives. This webinar offers us the opportunity to gain a deeper insight in what it means to adopt digital solutions for the whole cancer continuum, starting from prevention and diagnosis.

Digital solutions to enable shared decision-making in the cancer care continuum

Oriana Ciani is Associate Professor of Practice at SDA Bocconi School of Management. She is a leading scholar in health technology assessment, and one of her main areas of research is in

surrogate endpoints in cancer trials.

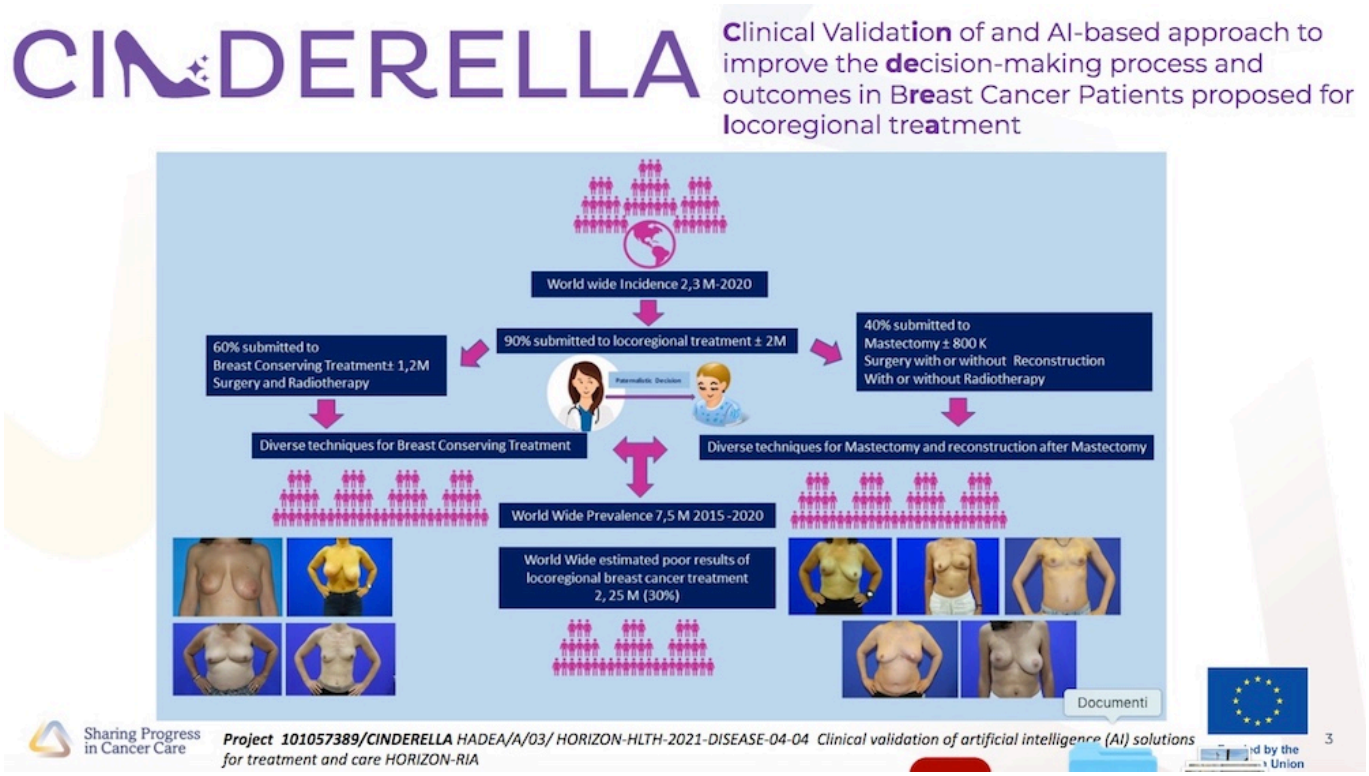


Nowadays we have digital health technologies addressing issues that may occur at different stages in the cancer continuum, from smart watches that encourage and monitor physical activity or sleep hygiene, to apps that can, for instance, remotely detect skin cancer, to AI powered software assisting the radiologist in the reading of scans, to solutions that allow for remote monitoring of symptoms and treatment emergent adverse events. This presentation focussed on those digital solutions that enable shared decision making, whereby the clinician and the patient reach a decision through a process of collaboration – a fundamental step to ensure quality of care. Prof. Ciani is involved in two international projects at the moment. One is the ShareView Project: supporting shared decision making and communication in metastatic breast cancer. This is funded by Pfizer Global Medical Grants and SPCC, under the “Improving care of metastatic breast cancer (MBC) patients in Europe” research initiative. It involves Bocconi University and another four institutions across Europe, including a patient association, Europa Donna. The other research initiative is the CINDERELLA Project, funded by the European Union’s Horizon Europe research and innovation programme, an artificial intelligence-based solution to improve shared decision-making processes for patients with breast cancer who are proposed for locoregional treatment.

In recent years there has been growing emphasis on increasing quality of cancer care. This includes providing appropriate information on the different options available to patients, family members and caregivers, and taking into account their values and preferences. In contexts where there are multiple clinically effective alternatives, such as in breast cancer, a discussion with the patient about the healthcare team’s treatment plan recommendation is crucial to arrive at a shared decision. Shared decision making (SDM) is associated with less regret about the decision taken, better coping, and higher treatment compliance. SDM requires good communication skills, understanding the patient’s preferences and wishes, and their concept of a good outcome from treatment. Recent updates to international clinical guidelines for breast cancer encourage the adoption of SDM in clinical practice. Shared decision making can be achieved through the use of decision aids (DAs) or patient decision aids (PDAs), which are tools that facilitate the transfer of information to the patient. Patient decision aids started in paper form, booklets, option grids, etc., but over time, they are increasingly becoming digitally based. The background work leading to the ShareView Project

consisted in studying the current use of PDAs, especially in the context of breast cancer. A large number of papers were identified that reported about the development and implementation of patient decision aids. Across the 15 years of observation, the vast majority of those articles came out in the last four years, after 2018, probably in consequence of the publication of those clinical guidelines and international standard frameworks mentioned before, that advocate the use of shared decision-making processes to improve quality of care. This seems to be mostly a North American phenomenon. Many of the examples came from Canada and the U.S., probably because in the U.S. it is mandatory to involve the patient in all the decisions that concern his/her health. Nearly half of the approaches and tools mapped in the study were paper-based: brochures, booklets, workbooks, but the other half included web-based decision aids, interactive or static apps, and other digital approaches. One of such digital aids is Breconda, a breast reconstruction decision aid. Another one is the Age-Gap Decision Tool, which allows to compare breast cancer treatment for older women.

After the mapping of the relevant literature, the second stage of the ShareView Project was to investigate the real-life use of decision aid tools. A questionnaire was sent out to breast cancer specialists in Europe through various oncology networks. It was structured in three sections. The first was about demographics; the second was about the communication style adopted in breast units, to understand whether the experts had a more paternalistic or inclusive communication style. The final part asked questions about the actual use of PDAs, including barriers and facilitators for their uptake in clinical practice. About 200 replies were received, mostly from medical oncologists and breast surgeons. 55% of the respondents declared that there was a DA available at their institution. When such tools were available, the vast majority used them but still mainly in paper form, with only a minority, about one in four, adopting interactive web-based tools. The patterns of use before, after, or during consultation varied, and also, there was a variety of professionals involved in the delivery of the tool. For those who did not use DA even when available, a number of factors were mentioned as barriers to the adoption: other alternatives already in place, patient characteristics, such as age and literacy, lack of an organised system to distribute the decision aids or insufficient training in the use of the tools. The majority of participants who did not have DAs available stated that they would be willing to use them. So, there is an openness to this innovation, and the factors that would encourage its use are the evidence-based information it contains, time spent on using it, accessibility in different formats and languages, integration into the workflow and electronic health record systems. About 15% of participants declared that they would not use DAs even if available. From the survey it appears that the main barriers for the use are logistics, patient characteristics, and educational needs, in other words, the same ones we encounter when discussing digital solutions in general. The third phase of the ShareView Project will be to pilot test one of these digital solutions for shared decision making applied to the individual patient data from the PEARL study. PEARL is a randomised control trial that tested the comparison between Palbociclib and chemotherapy in metastatic breast cancer.



The vast majority of breast cancer patients now survive their diagnosis for many years and have to live with the consequence of drugs, surgery, and radiation. Overall survival should now be matched by other types of outcomes such as satisfaction with treatment and also cosmesis. It is difficult to measure cosmetic outcome in a reproducible and objective manner, but a system is being designed for such purpose. **CINDERELLA** stands for **C**linical validatio**n** of an AI-based approach to improve the **de**cision-making process and outcomes in b**re**ast cancer patients proposed for **l**ocoregiona**l** tre**a**tment. It allows to show the results of randomised clinical trials to patients in a way that takes into account the patients' preferences for the different endpoints measured in the trial. The system matches the patient's picture with previous similar cases in order to show the outcome of the procedures, from excellent to poor. The machine learning approach is coupled with CANKADO, a cloud-based healthcare platform, to deliver an educational interactive module that illustrates procedure and expected results, thus ensuring a shared decision-making process. A trial will also be carried out with clinicians, medical oncologists, breast surgeons, and patient representatives to test the use of this tool.

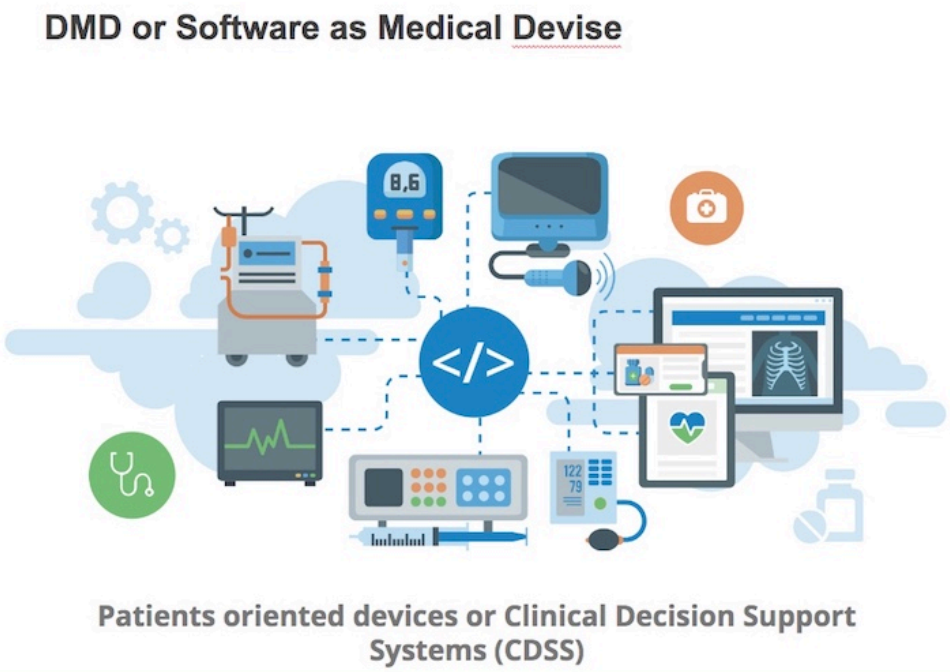
Whilst interactive digital solutions for decision making are frequently reported in literature and tested in experimental settings, in real life those solutions are still lagging behind and paper-based tools are still preferred. This calls for a better understanding of facilitators and barriers in order to develop appropriate implementation strategies that lead to a sustained adoption in the clinical setting.

Clinical Evaluation of Digital Medical Devices

Sarah Zohar is Director of Research at the French National Institute of Health and Medical Research (Inserm) in Paris, France. She is an expert in innovative methods for interventional and observational health data modelling.

In the past, a medical device was a physical object, like a pacemaker, but now it can also be a piece of software. So, how do we evaluate software in real life? Mostly in Europe, we talk about Digital Medical Device (DMD), while in the US and more internationally the term used is Software as a Medical Device (SaMD). For the current European Regulation, DMDs fall under the more general

heading of medical devices, that is, health technologies for the prevention, diagnosis, monitoring, treatment, or alleviation of disease. DMDs may include smartphone apps, standalone software, online tools for preventing, diagnosing, or treating conditions, or for improving system efficiency, as well as programs to analyse data from medical devices such as scanners, sensors, or monitors. DMDs can benefit patients but also the wider health and social care systems. We are dealing here with a very broad definition. On the other hand, the International Medical Device Regulators Forum (IMDRF) defines Software as a Medical Device as, “Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.” So, the European definition is much wider, and the software can also be part of the hardware, while SaMD is standalone, not associated with medical hardware. In the European definition we may be talking about standalone software, software associated with hardware, and the users can be healthcare professionals, patients, caregivers. Each type of user will have a different perspective which will influence their clinical evaluation. Nevertheless, the main outcome remains the patient’s outcome, thus the evaluation needs to be carried out in clinical trials. Ultimately, it is all about the risks to the patient. What if a piece of software causes risk to a patient in terms of prognosis? For instance, a patient could be taking the wrong decision based on a wrong recommendation arrived at through a clinical decision support system. If a patient ends up with the wrong treatment or home care management, the prognosis of survival is at risk. So, it is not enough to talk about what kind of dataset is needed to construct the algorithm and validate it, we also need to know how to use this clinical study in practice, what kind of decisions can be taken, and if the medical doctor, the patient, or caregiver follows the decision support system or not.



There is some confusion about the CE marking. The CE mark certifies that the medical device or digital medical device functions properly. In the case of software, it means that the algorithm is solid, that it was trained or validated correctly, but it does not guarantee the patient’s outcome in terms of safety and efficacy, before it is HTA approved. Also, in European countries reimbursement is not guaranteed if clinical evidence is not supported by a prospective interventional clinical trial. And this is something that patients and healthcare professionals need to be aware of because patients sometimes do not understand why a device or software with the CE mark is still not available to them. The reason is that it is not the same regulatory process. The IMDRF identified three clinical evaluation components for AI based DMD or SaMD. The first is valid clinical

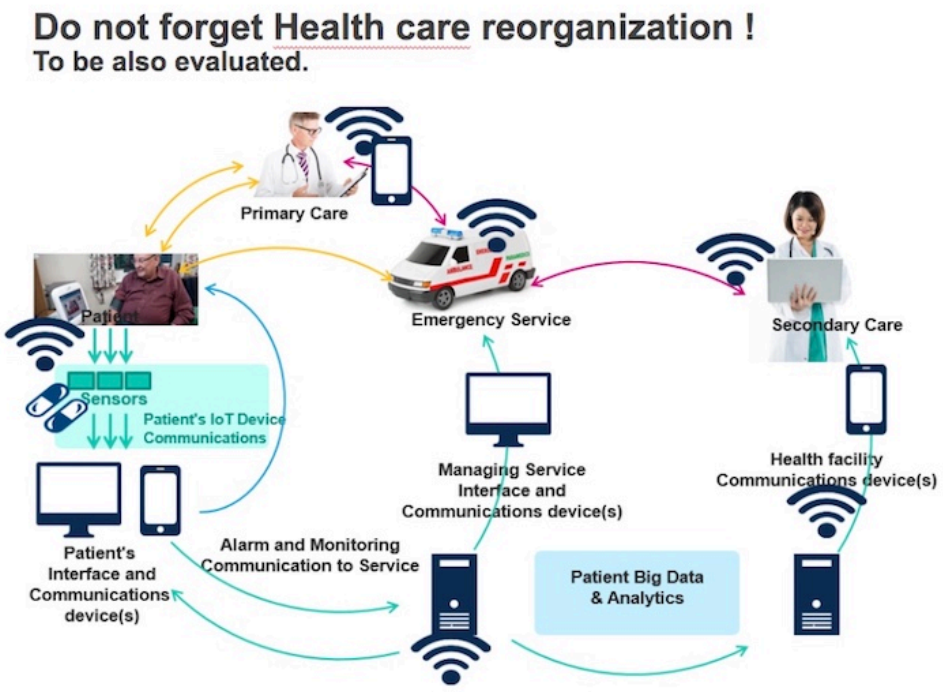
association. Is there a valid clinical association between the SaMD's output and the targeted clinical condition? The second is analytical validation, which is about the software's capability of processing input data to generate accurate, reliable, and precise output data. And this is where people confuse analytical validation and clinical validation. The third component is clinical validation. Does the software achieve its purpose in terms of safety and efficacy in the target population in the context of clinical care? Patient outcomes are not the same as algorithm robustness and reliability. We need to make a clear distinction between the two. However, we cannot stop at these three main evaluation components. There are other considerations that we need to make. There may be many SaMDs validated for reimbursement that can be prescribed by medical doctors, yet physicians are reluctant to use them as they were not validated for other types of outcomes, such as literacy and usability. Are the outputs clearly presented and understandable to the user? What about ethical and cultural acceptability? We need to do clinical studies that take into account first major outcomes, patient-oriented outcomes, but also secondary outcomes such as usability and patient management. It is something we need to think about with these new kinds of device, how to evaluate both primary and secondary outcomes within one study in order to ensure that the device gets approved by the HTA, but also that patients get access to it and use it.

There are several international guidelines for clinical trials, and the most well-known are the ones devised by SPIRIT and CONSORT. Looking at CONSORT, for instance, they provide a checklist for doing clinical trials evaluating this kind of new devices. The checklist helps to ensure that the clinical trial conforms to HTA requirements for validation, reimbursement, or market authorization. But when we talk about algorithms, AI, what we would really like to have is continuous learning, which means continuous clinical evaluation, continuous corrections and adaptions. SaMDs clinical trial designs cannot be the same as those for drugs, where the formula does not change over time. Here, the algorithm will necessarily change. A clinical trial needs to be designed in a way to obtain some first results in order to get approved by HTA, but also to update those results over time in order to guarantee that the device is still efficient for the patient. Moreover, we should not forget, for example, that with clinical decision support systems, some require a healthcare reorganisation. The patient might use an app at home to measure their blood pressure. If they observe something they need to report, they send a signal by email, text or other means, and someone at the other end has to deal with the signal, deliver it to the physician and get back to the patient. And this means to reorganise all the healthcare around it. You cannot just sell your decision support system and expect the hospital to manage it, because there are costs involved, someone needs to pay for this organisation, someone needs to pay staff to read the signals, also at weekends, on holidays, etc. It is not easy to guarantee to the patient that their signal will be attended to 24/7. This reorganisation is something that must be evaluated in the clinical trial as well, including how much it will cost to the health system and who is going to pay for it.

We can reap huge benefits from digital medical devices, and they can provide real innovation for patients and caregivers. They can improve patient safety and drug management, facilitate better long-term disease management, decrease costs while improving patient care outcomes. But all of that must be evaluated properly and it needs to be a win-win situation for the patient, the caregivers and the health reorganisation around it.

What are the Patients Saying? What is out there for them?

The last speaker was **Emmanuel O. Abara**, Associate Professor of Surgery (Urology), Clinical Sciences Division Northern Ontario School of Medicine, Director of Richmond Hill Urology Practice & Prostate Institute, Ontario, Canada.



Source: https://theiotmagazine.com/digital-transformation-of-healthcare-iomt-connectivity-ai-and-value-streams-62edc0f2be1a

To illustrate what the patients are saying, Prof. Abara chose to share five anonymous cases, with previous consent of the subjects. The first case was a 63-year-old man living in a rural community in northern Ontario. The family doctor performed an ultrasound and found a renal mass. He arranged a telemedicine consultation with the Urology Practice, the patient was evaluated by video call, and a request was made to the radiologist for a CT scan, which he received within a couple of days. The scan suggested a mass, and this was followed up by another video conference, and within a few weeks, from the options offered to him, the patient chose surgery. Surgery was carried out, and he was sent back to recover in his daughter's home. Within a few weeks, he had a follow-up appointment. This case illustrates the use of digital health in terms of teleradiology, telepathology, follow-up evaluation, without much disruption to the patient's life. The second case was a 58-year-old man who had a lesion in his penis for six years. It was treated with topical agents, but it was not going away. Prof. Abara's practice received a referral from the rural community nurse, 600 kilometres away. With good telemedicine consultation and advice, the wife agreed to send digital photos of the lesion. In a video conference with the patient, it was discussed what could be done. Because Prof. Abara goes to that region frequently to perform minor surgeries, it was easy for him to get there. They did an excisional biopsy. Again, by telepathology, the results were back to the practice within a few days, and it turned out to be carcinoma in-situ. The patient has now been followed up for about seven years, and he never had to leave his village. It was all done digitally through telemedicine.

One of the advantages of digital health is that it gives an avenue for a multidisciplinary approach to care, for interprofessional collaboration. In the third case examined, a 75-year-old man had an abdominal mass, which was causing obstruction to the kidney, and yet it was not a urological case. This is where multidisciplinary approach through digital health became very important. It was easy to coordinate care using digital applications between various specialties, radiology, pathology, oncology, general surgery, nursing and urology, all worked together to ensure that this gentleman had good care.

So, what are these digital innovations? Who is in control? We know there are wearables, we know

there are smartphone apps. But do we have clinical validation? Patients know that these devices are out there on the web, but they are not sure which ones are safe. They want to know, what are these devices going to do for me? Are they going to be helpful? And who is validating them? There is a need for judicious regulation and compliance through collaborative dialogue.

The fourth case presented by Prof. Abara illustrates the value of second opinions. A 45-year-old male had a biopsy, which was benign. Then he was sent for a second opinion. By this time, his PSA had gone up, he was assessed via telemedicine in December 2006, had a repeat biopsy in January 2007, with a diagnosis of prostate cancer, chose surgery, and had a successful radical prostatectomy. With this plan of a digital health platform, he had a good second opinion, and prompt tele-diagnostic and pathology innovations in telemedicine were helpful in ensuring that he received good care. The fifth case was an 88-year-old man, who had gross haematuria, and investigation way back in 1997 showed a right renal mass, multiple tumours along the ureter and also in the bladder. He had surgery, a kidney was removed, and because of the tendency of this disease to recur, he had regular follow-ups. Although he lived about a thousand kilometres away, it was possible to maintain that patient-doctor relationship for 24 years. He was cancer free until three months ago, when he developed gross haematuria. And again, his treatment was carried out, and follow-up has always been done digitally. The key thing about this gentleman is that he does not want to leave his community to go to a big town. And over the years his goals have been successfully met.

Digital health is here, and patients want to be engaged. They also want to know what is out there for them. What are the dangers? Is it safe? Which device should they trust? There are many digital health innovations in cancer prevention and diagnosis. There are health education materials for patients and care givers. There are cancer support groups and organizations, platforms where patients can share experiences and have a voice; training and mentoring healthcare workers in digital health applications and transformation are very important. There are also new technologies in pathology, including tumour serum markers that can be done at home. All one needs to do is take the kit, download the smart-ware, and do the tests in one’s own home, then send the results to the doctor. And the doctor can set up a video conference or a telephone call and have a discussion. Patients feel very comfortable when counselling is done in the comfort of their home, in the presence

of their family. There are also innovations in teleradiology, in cancer treatment and diagnosis. **What can digital health do for us?** It is going to bring the patient closer to the healthcare professionals, it is going to make the patients the centre of care, to empower the patient to take ownership of their health. Now we have wearables that we can use to monitor our physical activities. We have smartphones that can monitor urinalysis and test cancer cells without having to visit a laboratory. Some of these tools are still in progress, some have been approved. Patients are ready and want meaningful and productive experience with digital health technologies. Digital Health technologies are here and poised to improve access to quality care, through preventive and diagnostic innovations. Judicious regulation and Compliance through meaningful conversations are good ingredients for success.