

Advanced Biomedical Research and Innovation

Harnessing Nurse's Experience and Characteristics to Advance Medical Technology & Innovation Edith Bianchi

Nursing Lead Technology group leader and Wearable Medical Device expert, Israel

Introduction: Nurses are one of the human resources that are always in high demand as a much needed and important part of any healthcare establishment. It is a global phenomenon that has even taken its expression in special immigration schemes for nurses to countries striving for skilled work labor in this sector.

The recent Covid19 pandemic, has been yet another reminder that this critical human resource, is mandatory. Covid19 has turned our world upside down and dramatically changed our lifestyle, behavior and consumption.

The pandemic struck every continent on our globe and put medical teams in an unprecedented situation – one they have never witnessed during their career paths and work experience. These medical teams led by nurses and doctors, have faced complex situations, extreme medical conditions and treatment challenges with limited means. Many have been exposed to the risk of contamination or have been victims of the virus themselves.

In parallel to these heartbreaking and demanding days, we have witnessed a global wave of public appreciation and gratitude to the remarkable and dedicated medical teams. We've seen doctors facing impossible decisions and nurses watching their patients fear and agony, often dying with no human face present nor having the comforting touch of a family member by their beds as they took their last breaths.

Beyond the significant role nurses have played and still do, there is another aspect of nursing that was overlooked for many years and recently is more and more noticeable. That is the fact that nurses unique characteristics and experience may have a valuable contribution for technological and structural breakthroughs.

Technology is no longer a nice-to-have luxury. In today's reality the use of technology, wearable devices and digital health, is in fact a crucial mean in fighting pandemics. More than this, the tech solutions are providing adequate and efficient care for chronic disease patients, while at the same time it is optimizing medical staff work.

With nurses being constantly in touch with patients, medical technologies and treatments routines, they seem to know best where challenges lay and often may even have a concrete direction for potential solution of a specific challenge.

There are some excellent examples in which nurses took part in products development, resulting in not only a better design and functionality of the product but also with a more rapid adoption and implementation by the medical staff. Eventually this allows patients in need to enjoy the benefit of the innovation earlier, and the health organization and system is often becoming more efficient.

Moreover, the nurses' continuous need to provide care under extremely challenging conditions and shortness of staff, seem to be another factor that contributes to nurses' resourcefulness and initiative to creatively approach daily challenges. It is however a fact that needs to be seen also as a risk and continuous stress which may eventually impact staff motivation.

The above described features are turning this workforce population into a voice that should be getting the appropriate attention. Indeed, some commercial entities as well as hospitals have already recognized nurses' valuable perspective and have structured programs aiming to facilitate and encourage nurses' innovation. However, as logical as it may be, such initiatives are often not taking off due to several factors. Hence, opportunities for improvements that may create value for the nurses as well as the whole healthcare ecosystems and eventually the patients, are missed.

The current Covid19 pandemic is still ongoing in any parts of our world. It seems as if life may not be the same as we knew it. With the present and future health and economy challenges that we are all facing, innovation and time-to-market are key factors. Today's reality is giving an extra push to recent years' trends, such as affordable remote monitoring and out-of-hospital care.

In this 'social distance' era we all live in, the use of wearable medical devices is even more crucial. These are enabling early detection of medical conditions by monitoring vital signs and can even provide protection and self-care. High-risk populations, such as elderly, or patients with suppressed immune system, need to cope safely and effectively with their underlying chronic diseases and medical conditions. Instead of going to clinics and hospitals, where they might be exposed to health risks, and where they will need the assistance of professional medical staff, these patients must be able to receive the treatments in the safety of their homes or in isolated sites. They can check their heart, blood pressure, or even heart arrhythmias, and inject their medication on their own, using drug-delivery-devices such as infusion-pumps. Doing so is not only keeping them safe but also reducing the burden on medical staff and cutting costs.

One very relevant example is the case of cancer patients receiving chemotherapy and other immunosuppressive drugs. These patients are extremely vulnerable and prone to suffer from invaders and infections, as their immune system is weakened by the oncological treatments. They are exposed to their own bodies turning against them when the natural gut flora can become

violent, and also can easily catch hospital's infections. Since the outbreak of Covid19 pandemic, many of these patients had to miss treatments as they were anxious to visit the wards. Some hospitals had to transform their oncology wards, in light of the need for isolated Covid19 treatment areas.

An excellent solution for such patients is found in the home monitoring systems which are using wearable patches and sensors to evaluate their condition. At the same time, these patients are receiving their treatments via infusion pumps which are attached to their body and automatically inject their medications. All is done in the comfort and safety of the patient's home. The psychological added value of this home care system can be found in some cases when patients can remain with their loved ones in their natural environment. They don't have to experience anxiety while visiting the hospital, and can still feel safe knowing they are monitored and treated by reliable devices.

To make all this happen, many of the wearable medical devices which are developed and used, require a reliable interface to the skin – what we at Med-S2T coined as the term: 'Skin-to-Thing' solution.

The challenge of attaching the device to the skin in a conformable manner, while using medical grade materials, is critical to the success the product. Such tailored solutions require a multidisciplinary approach and firm understanding of clinical aspects. They also require comprehensive knowledge and experience with biocompatible materials, usability challenges, and the right spectrum of manufacturing technologies.

This notion and understanding is indeed more present than previous years, yet still very often, developers are not entirely aware of the challenges and obstacles which they might encounter in the attachment of their device to the human body.

It is mandatory to remember that the skin- our largest organ - is a living thing. Having a material connected to our skin can present challenges such as skin irritation, redness, and even extreme harmful situation such as skin tearing, infection and maceration. If you ever had a Band-Aid on your finger, even for just a couple of hours, you may have probably noticed the skin state once the Band-Aid has been removed. Now, imagine the challenge of placing a device on an impaired skin of a baby, or an elderly patient, a diabetic or a cancer patient. This challenge is amplified with certain extreme requirements such as heavy devices, long wearing time, humid conditions, hairy surface and many more factors.

I often explain to R&D and engineering teams that there is no 'one-fits-all' material or solution. Developers need to thoroughly consider the use scenarios and factors related for their device in order to make the right choices and decisions. They must make sure they efficiently deal with relevant questions such as:

- What will be the length of wearing time?
- Will the device be used in a hospital setting or in a community setting?
- Placed by the patient or by a care provider?
- Where will it be placed on the body?

- What is the device weight?
- And what about showers or swimming with it?
- And we still didn't start talking about the manufacturing aspects and cost-efficiency optimizations.

Developers should also consider the interaction between different materials and the variety of manufacturing methods and technologies. It is not impossible to find skin friendly material which once combined with another material, laminated or welded to a device, might change its properties and fail biocompatibility tests. It is essential to avoid such hurdles as these tests are an essential part of the regulatory process during development and need to be taken into consideration with awareness of false positive scenarios which sometime occur even when using medical grade materials.

Evidently, a huge lesson learnt from Covid19 and passing weeks: when the pandemic is accelerating the need for quick development and prompt 'go-to-market', it is highly important to effectively address the critical pillar of Skin-to-Thing solution for wearable devices.

Covid19 and the challenges it has reinforced and created in daily leaving and medical care, requires all developers to minimize error in order to bring to the market desired devices which can influence coping with the virus outbreak.

Governments as well as commercial entities need to embrace the understanding of how important it is to include a clinical view of nurses in development of medical devices. A supportive and tailored structure needs to be formed in order to overcome obstacles that prevent nurses from cooperating while addressing nurses' concerns and tremendous stress. It is also important to educate nurses on innovation ecosystem and acknowledge their value with such designated programs. By doing so, we will all benefit from a rapid development of an ideal solution for many existing health concerns.

Biography: Edith Bianchi is a senior global business development expert, specializing in the medical device industry. She has an impressive and quite extraordinary multi-disciplinary background and qualifications. Those are combining both clinical records as a registered nurse (RN) with CICU experience and CRA credentials, as well as strong business management orientation with an MBA degree from University of Derby. She has a long track international record in medical device firms and was a key person in some meaningful strategic cooperation

between major global players in the industry. She has proactively raised initiatives such as the International group-Nurses Lead Technology, and continuously advocates for patients, medical staff and biomedical companies.