

Chapter 3

Frugal Medical Technologies and Adaptive Solutions: Field-Based Applications



In our previous chapter, we explore the various innovation processes that comprise frugal innovation as well as novel innovation paradigms including open and reverse innovation. Importantly, we not only define the theoretical dimensions of these innovation processes but also the functional outputs in the form of tangible technologies/devices. But while the intellectual components of these processes are critical, what does this mean for the future of humanitarian medicine and innovation? The fact of the matter is that the deployment of innovation processes in conflict and crisis situations will likely consist of an amalgam of these processes that is utilized as a catalyst for high-functioning problem-solving in the field. The reality is that crisis and conflict situations are not black and white; thus the solutions developed in the field are likely to reflect this. This is where we examine the field-based applications of these technologies and their specific capacities to preserve human life. But before we delve into these medical devices, who are these devices meant for? There are three critical stakeholders in any humanitarian healthcare operation: humanitarian practitioners (i.e., doctors, nurses, aides, relief workers), community health workers (i.e., frontline public health workers from indigenous communities), and crisis-stricken communities themselves. While the scope and capacity to utilize devices varies among these groups, nonetheless, it is vital that each one of these stakeholders be properly retrofitted with the most basic of equipment, technology, and devices. In this book we take this a step further and examine how we can not only enhance the retrofitting of humanitarian operators but also their respective problem-solving and innovation processes to create “adaptive solutions.” We define these as high-utility, unconventional solutions that are derived in resource-poor settings. The reality is that while we can provide frugal devices to individuals, how do we stimulate continued innovation and the implementation of adaptive solutions on the ground? The innovation process is just as important as the device itself—a paradigm that is often overlooked.

3.1 Enhancing the Interventional Capacity of Community Health Workers and Crisis-Stricken Communities

The allocation of health services during humanitarian emergencies is generally non-existent or extremely frail due to the environment of violence and conflict. This weakened state is often overloaded at during times when the need for healthcare is exponentially increased. The impact of humanitarian emergencies on a population's health is severe and exacerbated by increases in food insecurity, population displacement, crowding and poor access to water and sanitation, lack of resistance to infection, the physical and psychological effects of weapons and exposure to violence, and the collapse of basic healthcare services (Van Berlaer et al. 2017). The impact of humanitarian emergencies on health workers and service provision is also extensive and includes the destruction of health facilities, infrastructure, shortages in drugs and equipment, loss of health staff, and restricted access to healthcare (Van Berlaer et al. 2017). Very often during periods of humanitarian crisis, particularly in that of resource-poor settings, we see a catastrophic failure in healthcare provisional services. So how do we overcome these deficiencies? How do we promote innovation in the face of adversity? How do we foster collective motivation and collaboration in crisis environments?

Ultimately, it comes down to a number of factors, but first we begin with community health workers (CHWs). Community health workers (CHWs) are unpaid or paid lay health workers, with a varied range of training, experience, and scope of practice (Namakula and Witter 2014). These trained individuals are often employed to mitigate against the ongoing human resource for health crises, in which 2–4 CHWs provide essential primary care at the household and community level (Gilmore et al. 2016). While the specific training and roles performed by CHWs differ across various contexts, their purpose within local healthcare systems is universal: to improve the delivery and extend the reach of primary healthcare services in a cost-effective and equitable manner (Gilmore et al. 2016). CHWs are primarily deployed in low-income and middle-income countries (LMICs), in which local governments and humanitarian organizations deploy CHW programs to increase access to care for marginalized populations (Gilmore et al. 2016). Challenges in CHW development have been well documented in countries such as Afghanistan, in which CHWs have reported difficulties with resource supply allocation, community recognition, as well as overall health systems functioning (Gilmore et al. 2016). But despite these challenges, CHWs demonstrated innovative strategies in order to functionally adapt to these challenges. CHWs are often innately tied to their communities and serve as vital representatives of the healthcare provided in the area. In order to enhance the interventional capacities of these important agents, enhanced medical device procurement must be garnered. While certainly improving the delegation of medical devices is important, the reality is that these individuals must learn how to develop these devices in resource-poor settings. This is where frugal medical devices and interventions come into play. In our next section, we explore the precise types of devices that can be developed cheaply and effectively in humanitarian crises to enhance the care delivered by CHWs in the field. The medical devices

created and deployed will not only be utilized in an acute manner but also set the stage for long-term innovation processes and device development to be distributed within their local communities. The key to keeping further enhancing the treatment paradigms rendered by CHWs can also be improved by improving incentives, supervision, motivation, and continuing training (Namakula and Witter 2014). CHWs bridge the gap between humanitarian practitioners such as doctors and aid workers and crisis-stricken communities themselves.

Given how important CHWs are, how has innovation been utilized to enhance their capacities for treatment? One of the most interesting innovation initiatives has been spurred by UNICEF and is known as the “Backpack PLUS Collaboration” (UNICEF Innovation 2013). This is the product of a joint initiative between UNICEF, Save the Children, the MDG Health Alliance, and the One Million Community Health Worker Campaign and is very much the product of harboring an open innovation process paradigm. These organizations worked together to create a kit of critical tools and instruments for empowering and supporting CHWs in the field. Specifically, this toolkit was developed in order to increase their relative impact on such pressing problems such as child mortality and improve overall effectiveness and efficiency. The Backpack PLUS (BP+) contains medicines such as zinc, ORS, antibiotics, and antimalarial drugs as well as medical treatment plans and data collection devices in order to enhance the interventional and service-delivery capacities of CHWs (Figs. 3.1 and 3.2).

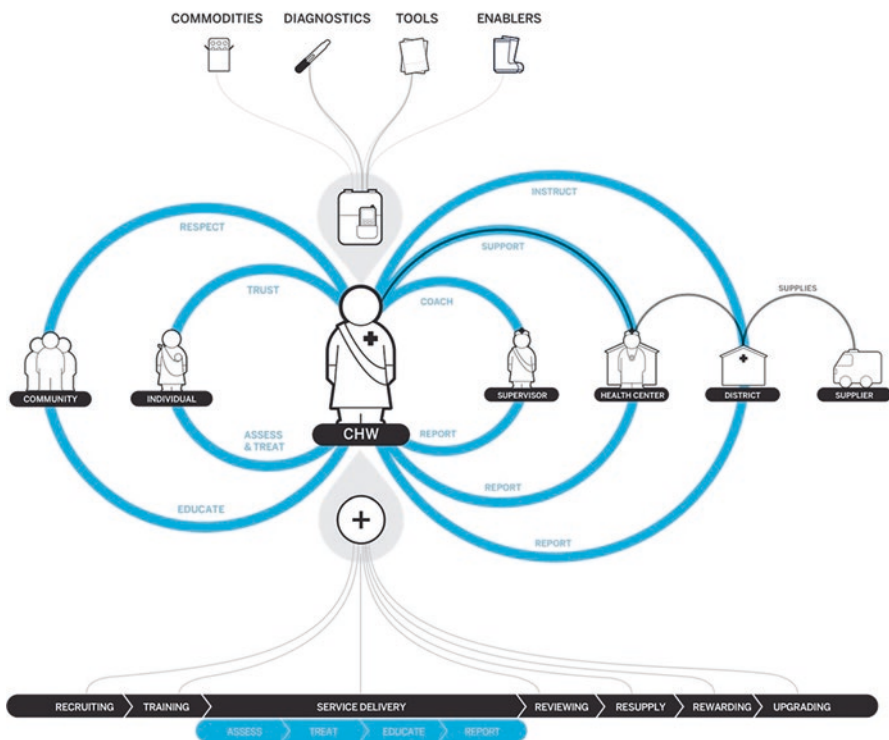


Fig. 3.1 CHW network capacity. (UNICEF Innovation 2013)



Fig. 3.2 Backpack PLUS. (UNICEF Innovation 2013)

Perhaps one of the most vital elements of CHWs is their capacity to transfer and outfit crisis-stricken communities with the tools and knowledge garnered from humanitarian practitioners. Crisis-stricken communities are oftentimes not in control of their own health but can harness simple technologies that could change their relative health outcomes. There are two critical elements to this: the ability to transfer knowledge and the ability to transfer technology. Knowledge transfer is often the most misunderstood element, as oftentimes we see a unilateral transfer of information from aid agencies to disaster-stricken communities. This means that these communities often do not have the capacity to relay information back to humanitarian operators/agencies, leaving them in the dark. This dissonance in knowledge transfer also hinders the innovation process, as many times it is the very victims of conflict that create some of the most innovative ideas to problems. The ability to dictate one's health is a fundamental human right, and the provision of frugal medical technologies can allow for the preservation of human health. The devices and applications explored in the following sections are not only reserved to enhance the interventional capacities of humanitarian practitioners/operators in the medical field for the short term but also to facilitate the long-term health outcomes and enhance the healthcare infrastructure of these communities as well.

In addition to enhancing the overall intervention treatment capacities of CHWs, what about the individuals in these crisis-afflicted communities themselves? The power of *refugee and conflict victim innovation* is perhaps one of the most overlooked elements of innovation. Oftentimes we focus on the interventional capacities of aid workers and the agencies they work for at large, but we forget that the capacity

to innovate is harbored within all of us. Who better to know the needs of a community than the members of the community themselves? With regard to refugee and conflict innovation, there have been several exciting developments that seek to empower conflict victims to tackle real challenges they face. Perhaps the most promising is that of 3D printing and creating access to important supplies. One of the organizations that are at the frontier of this is that of the Jordanian organization “Refugee Open Ware” (Levin 2015). This organization was developed in order to bring important medical equipment, including prosthetic limbs, to injured survivors of the Syrian civil war (Levin 2015). The aim of the organization is to create an open-source movement for 3D printing prosthetics for refugees and disseminating innovation into the humanitarian sector. We explore the development of these innovative prosthetics in the next section, but before we delve into this, there are indeed challenges that must be observed.

Perhaps one of the biggest challenges facing refugee innovation is that of scaling. It is important to note how vast and massive many refugee and displaced-individual camps are. As depicted in Fig. 3.3, the Za’atari refugee camp located in Jordan occupies an area of more than 2 square miles and hosts more than 75,000 refugees (Jabbar and Zaza 2014). Given how large and dense these settlements are, the sufficient diffusion of innovations to meet the needs of their targeted stakeholders is vital. This is where the power of crowdsourcing and open innovation can come into play. Refugee camps often harbor an immense array of intellectual talent and human capital. Harnessing the power of engineers, academics, and other displaced



Fig. 3.3 Aerial view of the Za’atari Refugee Camp. (Behind the Fences of Jordan’s Za’atari Refugee Camp 2016)

members of society is indeed vital to not only enhancing interventions but ensuring the sustainability of these interventions to help people in need.

When it comes to deploying the innovation processes we have explored in humanitarian medicine, there are an array of various medical disciplines that have and can utilize it. In the coming sections, we explore how basic innovation processes were utilized to harbor powerful, cost-efficient, yet highly efficacious medical innovations that have the distinct potential of enhancing humanitarian medicine.

3.2 Scaling Adaptive Solutions in the Humanitarian Field

The initial impetus for the development of low-cost, quality innovations in developing countries is the ability to satisfy acute need in the local setting and not the potential for export back to rich countries—and thus the deployment of the reverse innovation paradigm. But yet the need for low-cost, high-quality innovations for medicine, in essence, truly knows no borders. When it comes to general surgery and surgical care, surgical tools and instruments are perhaps one of the biggest areas that have benefited from the collective creative intelligence of physicians practicing in resource-poor settings. There are an array of surgical innovations—that are now deployed as standard therapies worldwide—whose origins are from developing countries. But what is the capacity for these technologies/innovations to be deployed in surgical interventions in the humanitarian field? This, of course, we explore in this section and further delve into the applications and derivations of humanitarian field innovations ranging from 3D printing prosthetics for refugees to the use of microfluidic paper-based analytical devices for the quick and efficient diagnosis of chronic and pathogen-derived illness. The key to the practical implementation of these innovations is not only the ease of their relative innovation processes but also their practicality and low-cost nature that make them easy to utilize in resource-poor settings. This not only enhances the interventional capacity of the humanitarian practitioner but also that of displaced/conflict victims and refugees of whom can utilize these devices. The further development of these devices via “refugee innovation” processes could indeed serve as a focal paradigm shift in the way medical care is deployed in relief settings.

3.2.1 Surgical Care and Prosthetics

When it comes to refugee and conflict victim displacement in humanitarian crises, oftentimes these individuals are resettled in remote areas. Many refugee camps in countries such as Uganda, Bangladesh, Syria, Jordan, and Kenya are often far from urban areas and settlements. Given the remoteness of these areas, technology and innovation can indeed be vital in addressing some of the enormous issues facing the

ever-growing refugee populations. But deploying technologies in these remote areas requires highly adaptable solutions that can function in often austere environments. What is fascinating is that these resource-poor settings often spur the most interesting innovative processes related to medicine—particularly orthopedics and prosthetics. We examine not only the medical devices/applications themselves but also the innovation processes behind them. In particular we examine the intersection of frugal, open, and crowdsourcing innovation in developing 3D-printed prosthetics as well as the process of reverse innovation in the development of the Arbutus Drill Cover System.

Innovation is no stranger to the creation of prosthetics, as the creation of the highly effective and cost-efficient Jaipur leg in India is perhaps one of the most cited examples of frugal innovation today. But what about the future? The future of prosthetics lies in the provision of custom-made prosthetics via 3D printing to people living in refugee camps. But the innovation is not simply harbored via this creative notion of fabricated custom, low-cost prosthetics, but the cultivation of an innovation ecosystem to accompany it. This is perhaps no better emulated than by the organization known as Refugee Open Ware (ROW). ROW works to create and develop 3D-printed prosthetic limbs for Syrians and refugees that could not afford to receive conventional prosthetics. Specifically, they are working on deploying the “E-Nable hand prostheses” (Fig. 3.4) to refugee camps in Jordan, where thousands of Syrians escaped from the ongoing civil war in one of the most dramatic humanitarian disasters in history (Sher 2015). Given that a high number of injuries caused by the conflict require amputation, ROW is looking to help those affected by producing 3D printed prosthetics faster and cheaper than via conventional methods. Estimates of the number of amputations caused by the Syrian conflict are as high as 200,000 individuals, and in countries such as Jordan, there is a dire need for functional, low-cost, and rapidly produced prosthetics (Sher 2015). This is even more critical for pediatric applications as there is often a dire need for frequent prosthetic replacements for the many child amputees as they grow. ROW has thus far created 3D-printed prosthetic hands for a Yemeni child and a Jordanian boy and have further

Fig. 3.4 The E-Nable hand prosthetic. (Sher 2015)



Fig. 3.5 Custom 3D-printed hand prosthetic for refugees. (Levin 2015)



developed a finger replacement model for a 13-year-old Syrian refugee who lost several fingers (Figs. 3.4 and 3.5).

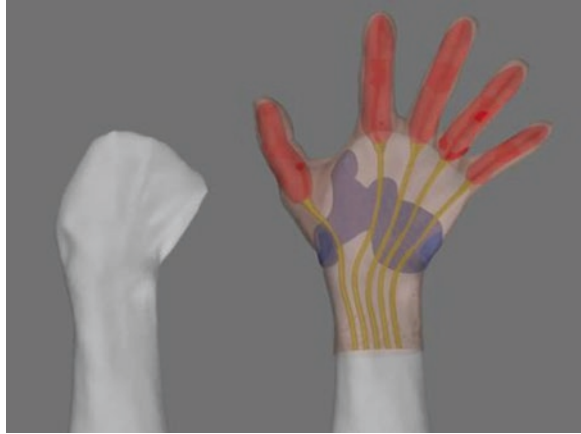
What is perhaps the fascinating element in regard to ROW's operation is not only the frugal innovation it proposes in the low-cost prosthetic, but the frugal and open ecosystem they wish to establish within the refugee camps themselves as stated by ROW founder, Dave Levin:

We aim to build a digital fabrication lab (fablab) in Za'atari Camp, on the Jordanian border with Syria. Za'atari hosts 85,000 Syrian refugees who have built a DIY informal settlement with little more than basic tools...this lab will offer educational programs, vocational training, business development and psychological treatment through interactive art. We expect the lab to grow organically into an Open Innovation Center: a place to crowd-source, co-create and test solutions to moonshot humanitarian innovation challenges.

This approach to custom prosthetics is rooted in the tenets of frugal (specifically the opportunistic innovation process) and open innovation, whereby an opportunity is identified and the associated barriers to entry for a custom prosthetic are overcome by lowering the per-unit cost while delivering the same value, with open and direct user feedback. Furthermore, ROW is in the process of developing a human-centered design approach to create a new open-source 3D-printed prosthetic that will be culturally appropriate in the Middle East. What we see here is that the innovations are not only developed for humanitarian applications, but further utilized in more conventional applications (Fig. 3.6).

While indeed there is much novelty in this approach, perhaps the most exciting element of this venture is the idea of training those affected by a humanitarian crisis to use certain technologies to create tangible solutions they require. An individual who has grown up in a conflict region could be equipped with the skills and knowledge that can help rebuild their community and create new industries and jobs, for a whole generation. This knowledge transfer and the use of technology and human capital to foster it is what is vital in creating sustainable innovation. The key to any innovation is the human element, and the facilitation of education and skill development for refugees and conflict victims serves to not only serve them in the short

Fig. 3.6 Digital rendering of custom hand prosthetic. (Levin 2015)



term, but the long term. Given the immense benefits of this, a network of humanitarian actors has set up a base in Jordan to train refugees in what is known as “open source tech” (Levin 2015). The goal of this initiative is for the refugees themselves to harbor the intellectual capital and resources to utilize these skills to address issues rising from conflict areas such as Syria. The key is the open-source nature of the technology associated with 3D printing including mobile computer-aided designs (CAD) which are crowdsourced blueprints for an array of products including medical devices and tools (Bhatia and Ramadurai 2017). The simultaneous deployment of human capital in conjunction with open-source technology such as 3D printing creates a paradigm shift whereby no longer are humanitarian operators conventional agents such as aid workers, but, rather, the conflict victims and refugees themselves. This creates an instantaneous feedback loop in which designs and applications of prosthetics can be modified based on infield feedback but also input from online communities that can further adapt and configure prosthetic designs. This ultimately creates a lower barrier to entry to the deployment of prosthetics to conflict victims in the field. The use of open and frugal innovation processes can lower the price and functionality of the devices for practical deployment.

The intersection of open and frugal innovations in humanitarian medicine is profound, but what about reverse innovation? This fascinating innovation concept, while in its infancy, is actually a highly practical process that seeks to radically change the fiscal barriers to entry not only in developing countries but also developed countries as well. In the field of orthopedics, there are quite a few examples of devices and applications that were fostered in developing countries and can be vital not only for humanitarian medicine, but medicine in general. One of the cleverest cost-saving innovations has been utilized in Malawi and Uganda to reduce the medical device equipment costs associated with orthopedic surgery. It is certainly unconventional, but if it reduces costs while maintaining practical functionality, it is an innovation worth deploying! This innovation is the application of a sterile bag to house a standard power hardware store drill, more formally known as the “Arbutus Drill Cover System” (Darzi 2017). This simple innovation costs less than \$50 and

can turn any standard drill that costs less than \$100 into a functional surgical drill. This compares to high-cost surgical drills that can cost more than \$15,000, creating a significant cost barrier for humanitarian applications (Darzi 2017). The drill is constructed with heat-resistant materials, allowing it to be sterilized, in which only the wrapping needs sterilizing—thus saving money on the expensive heat-resistant materials needed for conventional surgical drill fabrication. As shown in Fig. 3.7, the drill cover is a waterproof, autoclavable surgical bag that connects to the drill's mechanics via a sealed bearing mechanism. Furthermore, this drill was found to be just as safe and effective as expensive versions.

Surgical drills cost tens of thousands of dollars, yet from a mechanical standpoint, they are no different from ordinary household drills. But why the massive price disparity? This is because a surgical drill must be sterilized after each use, in which the drill must be capable of withstanding 30 min submerged in an autoclave—a pressurized steam sterilizer heated to 250° Fahrenheit (Darzi 2017). The drill cover seals a regular household drill so that only the drill bit and attachment need to be sterilized with the removable cover after each use. But where does reverse innovation come into play? Given the significant cost savings of this frugal innovation, the opportunity to scale it from Malawi and Uganda to more established healthcare systems such as England's National Health Service (NHS) was intriguing. Given that the average surgical drill is in operation for approximately 5–7 years, the turnover cost of replacing all those needed in the NHS is estimated at more than \$160 million (Darzi 2017). With the frugal drill cover innovation, the cost of replacing these drills would only amount to a few hundreds of thousands of dollars—a massive cost savings for the system. Given this, the adapted drill has been successfully used to treat 30,000 patients so far in 50 hospitals across more than 10 different countries.

What we see with the example of the drill cover system is not only the frugal and reverse innovation processes in play, but the important theme of creating bilateral knowledge transfer. By this we mean that no longer are innovations derived in

Fig. 3.7 Low-cost sterile orthopedic drill cover. (Drilling to the Problem: Low-Cost Sterile Drill Covers for Surgery 2014)



developed countries for applications for developing countries, but vice versa. Another fascinating medical device innovation that is similar in scope and application is the use of mosquito net mesh for inguinal hernia repair: at a cost of more than \$125 per patient, commercially produced mesh is generally deemed as unaffordable for the majority of hernia patients living in LMICs as well as refugee and internal displacement camps (Cotton et al. 2014). Faced with this cost barrier coupled with the high demand for hernia repair, a contextualized adaptation innovation process was deployed to create a novel solution, i.e., mosquito net mesh for hernia repair. This involved repurposing a device—in this case, a mosquito net—for a novel application, i.e., hernia repair (Fig. 3.8). The cost of the mosquito net mesh is only \$1, yielding a savings of more than 99% when compared to conventional mesh (Löfgren et al. 2016). Furthermore, after the use of the contextualized adaptation process, reverse innovation was applied to scale this medical device application from developing to developed countries. The use of mosquito net for hernia repair traces its roots to South Africa, where surgeons utilized cheap, readily available sterilized mosquito net mesh to repair hernias instead of expensive commercial mesh (Cotton et al. 2014). This frugal version and application is just as effective and safe as commercial mesh, but the cost difference is more than \$120 per piece of hernia mesh (Löfgren et al. 2016).

With regard to the reverse innovation processes behind this innovation, hernia repair is one of the most common surgical procedures in the United States and the United Kingdom. The procedure generally involves the use of a piece of surgical mesh stitched into the abdominal wall to strengthen it, with hundreds of thousands of these operations being performed annually. Given the per-unit cost of the commercial mesh, the use of sterilized mosquito mesh could indeed be scaled to level whereby healthcare systems could be saving tens of millions of dollars related to the operational cost of just this one procedure. With regard to the implications of innovations such as this as well as other contextualized adaptations in humanitarian medicine, there are truly no limits to scope, application, and importance. When it comes to refugee and internal displacement camps, utilizing basic resources such as mosquito nets—which are low cost and readily available—is absolutely vital for

Fig. 3.8 Mosquito net for hernia repair. (Operation Hernia 2018)



breaking down the barriers to care in these resource-stricken settings. This can allow for the adequate delegation of vital surgical procedures in humanitarian settings, thus enhancing the care and surgical service provision paradigm for both patients and physicians in the field. The ability to develop contextualized adaptations in the surgical field is vital to not only tearing down the barriers for accessible care for conflict victims, but further enhancing the delegation of surgical care and delivery on a global scale. We further see this trend in our next segment that explores the development of low-cost medical interventions for humanitarian applications related to neonatal and maternal conditions.

3.2.2 *Maternal Conditions*

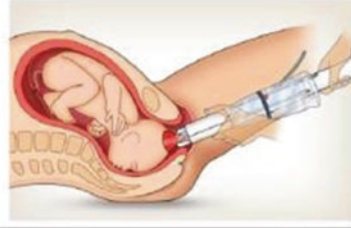
In the next segment, we examine the applications of medical device innovations and humanitarian medicine in relation to an essential medical area—neonatal and maternal conditions. One of the most common areas for medical treatment related to refugee and conflict victim displacement is that of neonatal and maternal conditions.

Worldwide, more than 13 million births each year face serious complications, in which more than 800 women die each day from preventable causes related to pregnancy and childbirth (Schvartzman et al. 2018). In crisis and conflict settings, the susceptibility to fatal maternal and neonatal conditions exponentially increases due to a lack of access to basic medical care and services. The importance of adequate treatment of patients with the conditions we discuss in this segment is paramount in not only promoting mother-baby health, but women's health equity in general. Crisis and conflict situations place immense stress and burden on expectant mothers, and the inability to have access to sufficient maternal care could have dire consequences. Maternal health conditions including postpartum hemorrhage and preeclampsia can lead to severe pregnancy complications resulting in perinatal morbidity and mortality. The ability for practitioners to deliver care to circumvent these conditions is vital, but in order to do so, low-cost, highly efficacious medical innovations must be developed.

The first innovation we explore is that of the “Odón device.” This device is a low-cost technological innovation that facilitates operative vaginal delivery and is designed to minimize trauma to both the mother and baby (Schvartzman et al. 2018). These features combined make it a potentially revolutionary development in obstetrics, particularly for improving intrapartum care and reducing maternal and perinatal morbidity and mortality in humanitarian settings. The low-cost device consists of a plastic sleeve that is inflated around the baby's head and is used to gently pull and ease the head of the infant through the birth canal as shown in Fig. 3.9. (Schvartzman et al. 2018; McNeil 2017). The use of forceps and other mechanical devices in the extraction of a baby in a difficult delivery can cause internal bleeding in the mother or may result in injuries to the baby's head, neck, or spine (Schvartzman et al. 2018; McNeil 2017). The Odón device has the potential to allow for vaginal delivery in complicated pregnancies where cesarean section, the use of

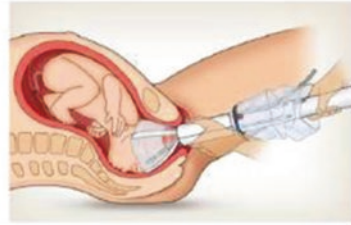
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The inserter is applied on the head of the baby. A soft plastic bell assures perfect adaptation to the fetal head and prevents damage.



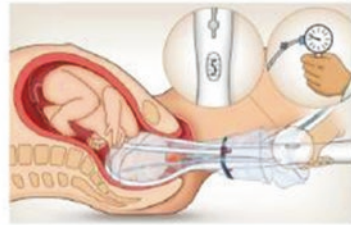
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The inserter progressively positions the Odón device around the head of the baby. Positioning occurs as the inserter gently produces the sliding of the two surfaces of the folded sleeve along the birth canal and around the baby's head.



3

When the Odón device is properly positioned, a marker on the insertion handle become clearly visible in the reading window. A minimal and self-limited amount of air is pumped into an air chamber in the inner surface.



4

This produces a secure grasp around the head of the baby that fixes the inner surface and allows for traction. The inserter is removed.



5

The head is delivered taking advantages of the sliding effect of the two surfaces of the folded sleeve. Lubrication of the surfaces further facilitates the extraction process. If needed, traction can be applied up to 19 kg (which is equivalent to the force applied with the metal vacuum extractor).



Fig. 3.9 Use of the Odón device for vaginal delivery. (Schvartzman et al. 2018)

forceps, or the use of a ventouse vacuum would be utilized. By reducing contact between the baby's skull and the birth canal, the risk of infection is also reduced.

What is fascinating about the Odón device—and the reason we explore it in this section—is the innovation process deployed behind it. The device was not developed by a physician or engineer, but rather a car mechanic from Argentina named

Jorge Odón, who had seen a YouTube video showing how to retrieve a loose cork from inside an empty wine bottle (McNeil 2017). This was done by inserting a plastic bag into the bottle, inflating the bag once the cork was inside, and then pulling out the inflated bag together with the cork (McNeil 2017). Odón conceived of the use of this same technique that evening in bed and spoke with a local obstetrician who believed the idea held merit for further development. The prototype of the device was created by sewing a sleeve onto a cloth bag and was tested using a doll inserted into a glass jar to simulate the use of the device in the delivery process. This is an excellent example of both a lean technique and opportunistic solution innovation process being deployed that ultimately took to fruition as a reverse innovation as well. The device's \$50 cost will likely be further reduced for use in LMICs as organizations including the World Health Organization have fully endorsed the product for use in the field. The device is a fantastic example of how innovation can be fostered by anyone regardless of specialized expertise and background.

The next device we explore is a low-cost uterine balloon tamponade to control postpartum hemorrhage. Specifically, we explore an evidence-based package called Every Second Matters for Mothers and Babies-Uterine Balloon Tamponade (ESM-UBT) to treat postpartum hemorrhage (PPH) as shown in Fig. 3.10. The ESM-UBT is a simple innovation that consists of a condom fastened to a French Foley catheter by string (Makin et al. 2018). A condom is utilized as it provides a low-pressure system which can accommodate a high volume and conforms to the space it is inflated within (Makin et al. 2018). PPH accounts for approximately 127,000 deaths worldwide annually, 99% of which occur in low-resource settings (Makin et al. 2018). PPH is utilized when first-line treatments for postpartum hemorrhage fail to sufficiently control bleeding. In order to stop the bleeding, one potential option is to

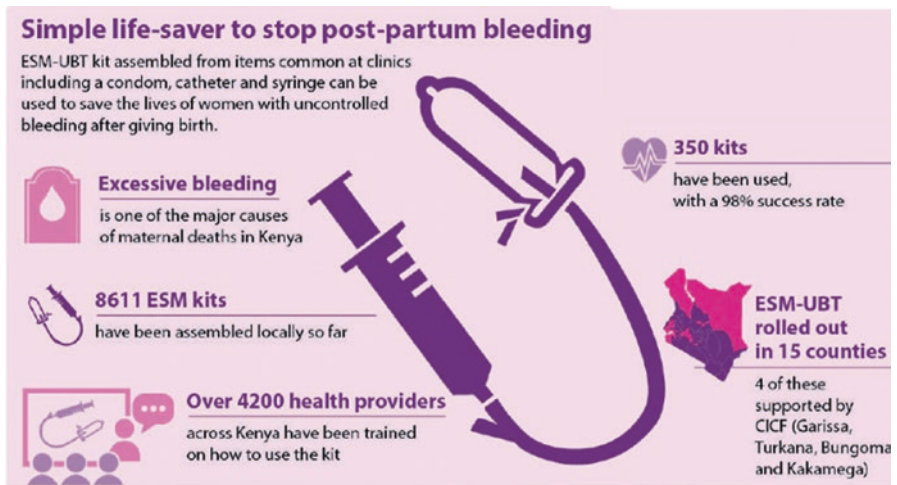


Fig. 3.10 ESM-UBT Kit. (Scaling Up Life Saving Innovations for Mothers and Newborns 2018)

insert a balloon tamponade in the uterus. While indeed uterine balloon tamponades have been utilized in developed countries for many years, the associated costs and lack of access to equipment and training have limited their use in low-resource and humanitarian settings (Makin et al. 2018). The ESM-UBT consists of a condom that is tied to a Foley catheter and then inflated with clean water through a syringe and one-way valve. Using readily available materials, it is especially suitable for use in remote low-resource settings and offers the same efficacy of traditional commercial UBTs. The uterine balloon tamponade can be made available to all women who give birth in a variety of settings and costs only a few dollars per kit. The ESM-UBT is indeed a vital medical device in the humanitarian practitioner's toolkit and further serves as a gender-equity promoting agent, via its capacity to preserve women's health and fully prevent preventable death from childbirth.

The final innovation we explore in the treatment of neonatal and maternal conditions in the humanitarian field is that of the Congo Red Dot (CRD) test to diagnose preeclampsia in unconventional, resource-poor settings. This diagnostic device requires minimal equipment, is extremely cost-effective, and can be deployed by almost anyone. This innovation is not only novel in the scope of its application, but the disruptive innovation paradigm it represents related to mobile health—otherwise known as mHealth (Jonas et al. 2015). In recent years, the concept and applications of mHealth have dramatically expanded in scope and scale beyond simply electronic health (eHealth). Specifically, it now refers to the “use of mobile computing and communication technologies in health care and public health” (Jonas et al. 2015). What is fascinating about the advent of the smartphone is its relatively untapped potential. Specifically, these devices are often equipped or retrofitted with powerful embedded sensors, processors, and applications that have largely been underutilized. Given this untapped potential, developing smartphone-based diagnostics represents the new front of disruptive innovation in mHealth. The disruption, however, is not emulated in the simple duplication of existing tests but the creation of new tests that sufficiently utilize the defining molecular characteristics of a disease pathology to lead to its acute detection and diagnosis. In this case we explore the deployment of the CRD test as an mHealth application to detect and diagnose preeclampsia in female refugees and internally displaced conflict victims.

Preeclampsia affects 1 out of every 20 women and is a completely treatable, yet highly prevalent pregnancy-related disease that is responsible for maternal and fetal morbidity and mortality around the world. In settings with limited medical resources, this condition is responsible for the preventable deaths of thousands of women each year due to the lack of sufficient screening in healthcare facilities. Preeclampsia is typically diagnosed based on the symptoms of hypertension and proteinuria occurring in pregnancy after 20 weeks of gestation (Jonas et al. 2015). Given the preventable nature of morbidity with the detection of preeclampsia, there is indeed a clear need for a new diagnostic testing paradigm specifically developed for humanitarian settings that is easy to use. The Congo Red Dot (CRD) test is a molecular diagnostic test for preeclampsia—developed by researchers at the Ohio State University and

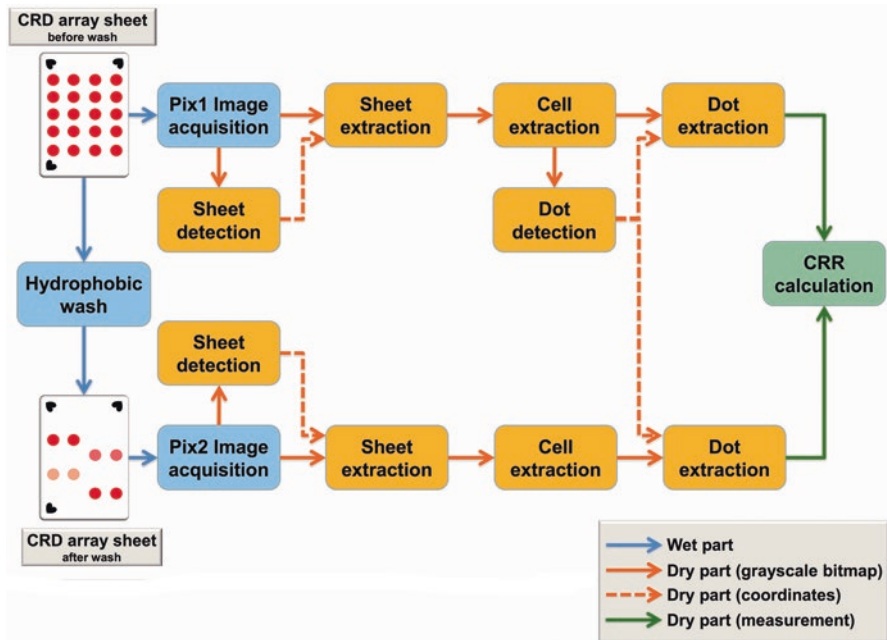


Fig. 3.11 CRD test and processing schematic (Jonas et al. 2015)

Nationwide Children’s Hospital—that works via the bonding of amyloidophilic dye Congo red to misfolded proteins in the urine and is more than 85% effective at diagnosing the condition (Fig. 3.11) (Jonas et al. 2015). These misfolded proteins represent a molecular feature that is directly proportional with disease severity. This test can be coupled with smartphone-based imaging in order to significantly shorten the processing and diagnostic timeframe. The interventional capacity for device utilization is also a key feature, as it enables minimally trained personnel to effectively diagnose preeclampsia in the field.

According to the United Nations Children’s Fund (UNICEF), approximately 80% of women in developing countries receive antenatal care (ANC) from a skilled health provider at least once during the course of their pregnancy (Jonas et al. 2015). Given the extremely low frequency of ANC visits, this makes the detection of preeclampsia extremely difficult, as the failure to measure blood pressure and proteinuria at each ANC visit is indeed a missed opportunity to diagnose preeclampsia. However, when it comes to humanitarian, crisis, and conflict situations, ANC is essentially eliminated, increasing the likelihood of undiagnosed preeclampsia exponentially. Due to its simplicity and the low cost of required materials, the CRD test has the potential to fill this gap for diagnosing preeclampsia in humanitarian settings and developing countries in general.

3.2.3 *Infectious Diseases*

When it comes to monitoring human health in humanitarian crises, there is perhaps no greater threat than that of infectious diseases. Infectious diseases remain a significant contributor to the global burden of disease in LMICs. This includes an array of diseases ranging from tuberculosis and malaria to diarrheal diseases and lower respiratory infections. These conditions kill more than 11 million people in LMICs each year and are, in many times, entirely preventable (Black et al. 2016). In looking closer, the burden of disease often falls disproportionately on vulnerable parts of the population. Specifically, more than 95% of deaths from respiratory infections and 98% of deaths from diarrheal diseases occur in LMICs and plague-specific demographics such as the elderly and children under the age of 5 (Black et al. 2016). Furthermore, war, conflict, and natural disasters open the door for disease epidemics and contribute to significant loss of life. The outbreaks of cholera during the Haitian earthquake and the recent diphtheria crisis in the Kutupalong refugee camp that is home to thousands of displaced Rohingya refugees in Bangladesh are prime examples of infectious disease that knows no bounds. Infectious diseases often plague conflict and internally displaced victims as they do not have sufficient access to infrastructure such as internal plumbing, clean water, hygiene stations, and medical clinics. Thus, the efficient diagnosis and treatment of diseases such as cholera, dysentery, diphtheria, typhoid, pneumonia, tuberculosis, and other diseases is vital in preventing death and suffering (Black et al. 2016). Innovations in diagnostic technologies are vital in the diagnosis, monitoring, and expanded coverage of lifesaving treatments. This is particularly important in pediatric applications, as children under the age of 5 are extremely vulnerable and susceptible to an array of infectious diseases leading to death. The best treatment of infectious disease is prevention—if we are able to prevent the onset of illness, this radically simplifies the amount of resources and capital deployed in the accompanying treatment and care paradigm. But once again, how does the innovation process play a role in this, and what are some examples of highly efficacious and simplistic disease treatment/prevention innovations?

The first innovation we explore is that of chlorhexidine—a perfect example of a contextualized adaptation innovation. Chlorhexidine, a low-cost antiseptic, has recently been discovered as a highly effective, easy-to-use application in umbilical cord care to prevent life-threatening neonatal infections in newborns born in unconventional, unsanitary conditions. On a global level, neonatal infections account for over 1 million newborn deaths annually, many of which could be prevented with simple interventions such as chlorhexidine (Gathwala et al. 2013). The reason why umbilical cord treatment is so vital is that after it is cut, it is prone to bacterial infections that can travel into the bloodstream and cause acute newborn sepsis and death (Gathwala et al. 2013). Chlorhexidine digluconate comprises of various forms and has been used for nearly 50 years with applications across a broad range of veterinary, dental, and medical indications (Gathwala et al. 2013). With regard to umbilical cord treatment, chlorhexidine costs less than \$1 per application and is a clinically proven intervention that has been reformulated as 7.1% chlorhexidine digluconate

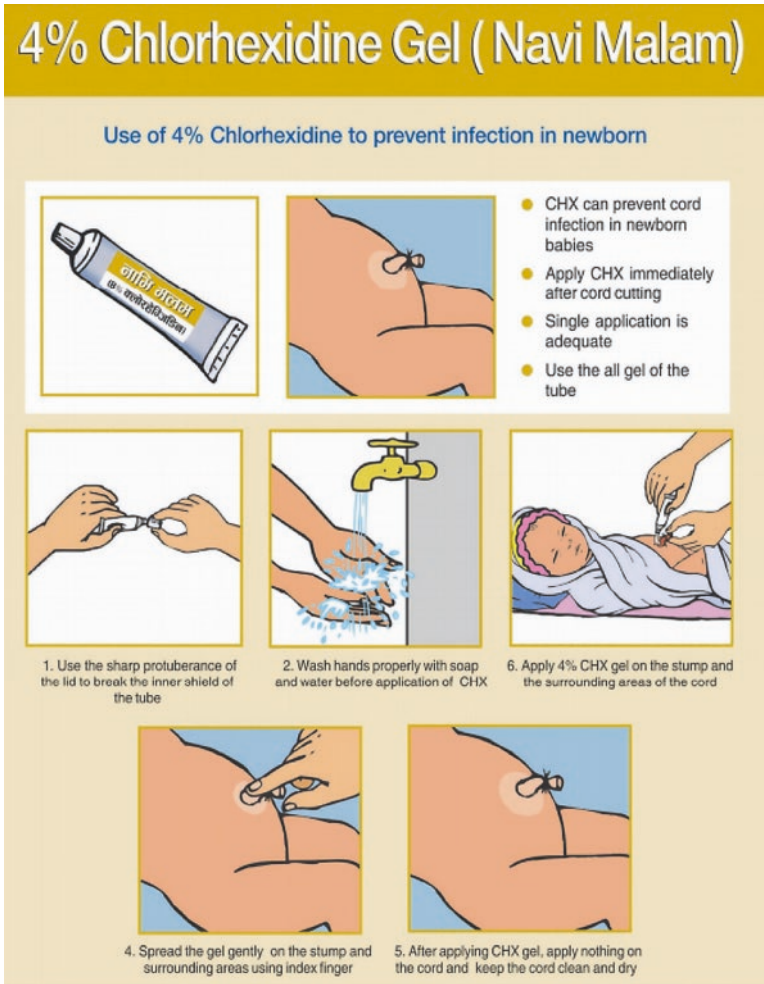


Fig. 3.12 Chlorohexidine application schematic. (Demand Generation I-Kit for Underutilized, Life Saving Commodities 2018)

solely for umbilical cord use (Gathwala et al. 2013). Chlorhexidine has no known toxicity risks and can rapidly reduce newborn deaths. Furthermore, it has a long shelf life and can be utilized with minimal training and no equipment. Thus, it is extremely efficacious for the use not only in conventional environments such as hospitals and healthcare centers but also in the field in humanitarian settings (Figs. 3.12 and 3.13).

Contextualized adaptations and innovations such as chlorohexidine show that the innovation process does not have to reinvent the wheel, but rather utilize it for novel purposes. In further developing this analogy when it comes to innovation in

Fig. 3.13 Chlorhexidine application to a newborn in India. (Segre 2013)



humanitarian medicine, we can further examine how we can create different types of “wheels” that further propel innovation paradigms. The next innovation we explore is that of microfluidic paper-based analytical devices otherwise known as μ PADs (Lam et al. 2017; Martinez et al. 2009). These diagnostic devices are a new class of point-of-care diagnostic devices that are inexpensive, easy to use, and designed specifically for use in developing countries and unconventional, resource-poor settings and applications (Martinez et al. 2009). According to the World Health Organization, diagnostic devices for developing countries should be “ASSURED” (Sher et al. 2017). This acronym stands for affordable, sensitive, specific, user-friendly, rapid and robust, equipment free, and deliverable to end users (Sher et al. 2017). This simple acronym is a powerful set of guidelines that encompasses the true ability for devices to properly work in various environments. ASSURED devices should be the benchmark for innovation in humanitarian medicine and for devices utilized in any environment regardless of economic classification. μ PADs are a novel, innovative platform designed for ASSURED diagnostic assays, in which they combine the capabilities of conventional microfluidic devices with the simplicity of diagnostic strip tests (Sher et al. 2017; Martinez et al. 2009). What is fascinating is that this represents a combinatorial innovation—involving the fusion of previous device components into a novel, comprehensive innovation. For μ PADs this is represented in the mix of the simplicity of a diagnostic test strip with that of the functional capacity of a microfluidic device. The resulting innovation is that μ PADs hold promise in providing rapid, inexpensive bioanalyses that require minimal volumes of bodily fluid such as blood or saliva. Furthermore, these devices can operate with limited equipment or power since fluid movement in μ PADs is controlled via capillary action (Lam et al. 2017; Martinez et al. 2009).

μ PADs represent an inexpensive point-of-care (POC) device that can provide rapid and accurate results in the field (Syedmoradi and Gomez 2017). A μ PAD consists of paper, which is hydrophilic in nature and allows hydrophobic demarcations to be made with various polymers. Paper is one of the promising materials for

making bioanalytical devices such as μ PADs since it is inexpensive, widely available, and hydrophilic, which allows solutions to flow through it via capillary action. The innovation in these diagnostic devices is not only present in their efficacy and efficiency but also their adaptability complex. These devices can be utilized in conjunction with camera-enabled phones in order to collect data and images that can be transmitted to centralized laboratories in order to garner results in real time (Fig. 3.14) (Syedmoradi and Gomez 2017).

We can see that the efficacy of this device is promising, but what is the interventional capacity for this device in humanitarian medicine? μ PAD biosensing platforms have been developed to detect various infectious diseases including human immunodeficiency virus, *E. coli*, tuberculosis, pneumonia, and *Staphylococcus aureus* (Lam et al. 2017; Martinez et al. 2009). These devices often utilize a modified gold nanoparticle solution—with specific pathogen or biomarker recognition elements—that is transferred to cellulose paper. When placed on the cellulose paper, the bacterial samples induce nanoparticle aggregates that can be detected. The

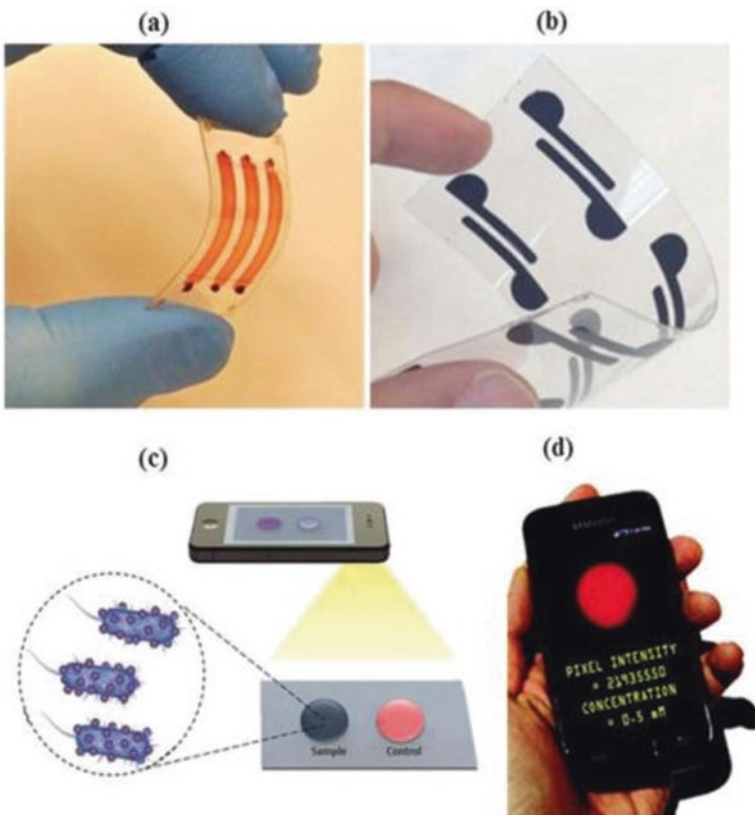
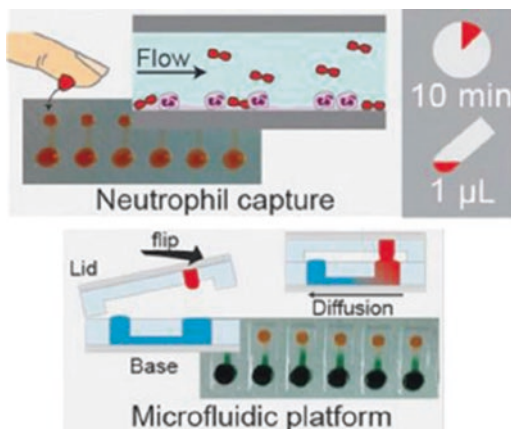


Fig. 3.14 μ PAD device (a, b) used for pathogen detection with cell phone (c, d). (Sher et al. 2017)

Fig. 3.15 A μ PAD for the detection of ARDS via neutrophil capture from patient blood. (Wu et al. 2018)



resulting color change in the nanoparticles can be easily detected by the naked eye, and a cell phone camera can be utilized to take a picture of the nanoparticle aggregation. But this is just the tip of the iceberg; the fact of the matter is that these modular devices hold immense promise for detecting an array of communicable and non-communicable diseases ranging from dengue fever to colon cancer (Lam et al. 2017). When it comes to humanitarian settings, one of the most critical conditions to treat are those known as acute respiratory distress syndromes (ARDS). This umbrella term consists of diseases such as pneumonia and is characterized by pulmonary inflammation as well as a mortality rate of 45% (Hansen and Lam 2017). The reason this condition is so deadly is due to its complex nature, which makes it difficult to identify and treat, ultimately resulting in diffuse alveolar damage and pulmonary microvascular endothelial injury leading to death (Hansen and Lam 2017). The pathogenesis of ARDS is primarily mediated by neutrophils; thus they make for ideal biomarkers in the diagnosis and detection of ARDS in patients before it is too late. Once again, μ PADs make for an excellent diagnostic tool for this application as shown in Fig. 3.15. The μ PAD depicted in this figure can efficiently and effectively detect neutrophil levels in a patient's blood for the diagnosis of ARDS in the field such as pneumonia.

μ PADs are excellent platform for innovation as advances in paper and flexible material-based biosensing platforms make for powerful POC assays in resource-limited settings. The key to this continued innovation lies in the integration and incorporation with different detection strategies and technologies to enhance the detection and biosensing of an array of biological targets (Zarei 2017). For example, the integration of cellulose paper and flexible polyester films with optical biosensing platforms using antibodies and peptides has led to the enhanced detection of multiple biological targets including HIV, *Escherichia coli*, and *Staphylococcus aureus* and CD41 T lymphocytes as shown in Fig. 3.16 (Zarei 2017). This can all be done with just a single fingerprick's worth of blood and deliver clinical-level detection and sensitivity.

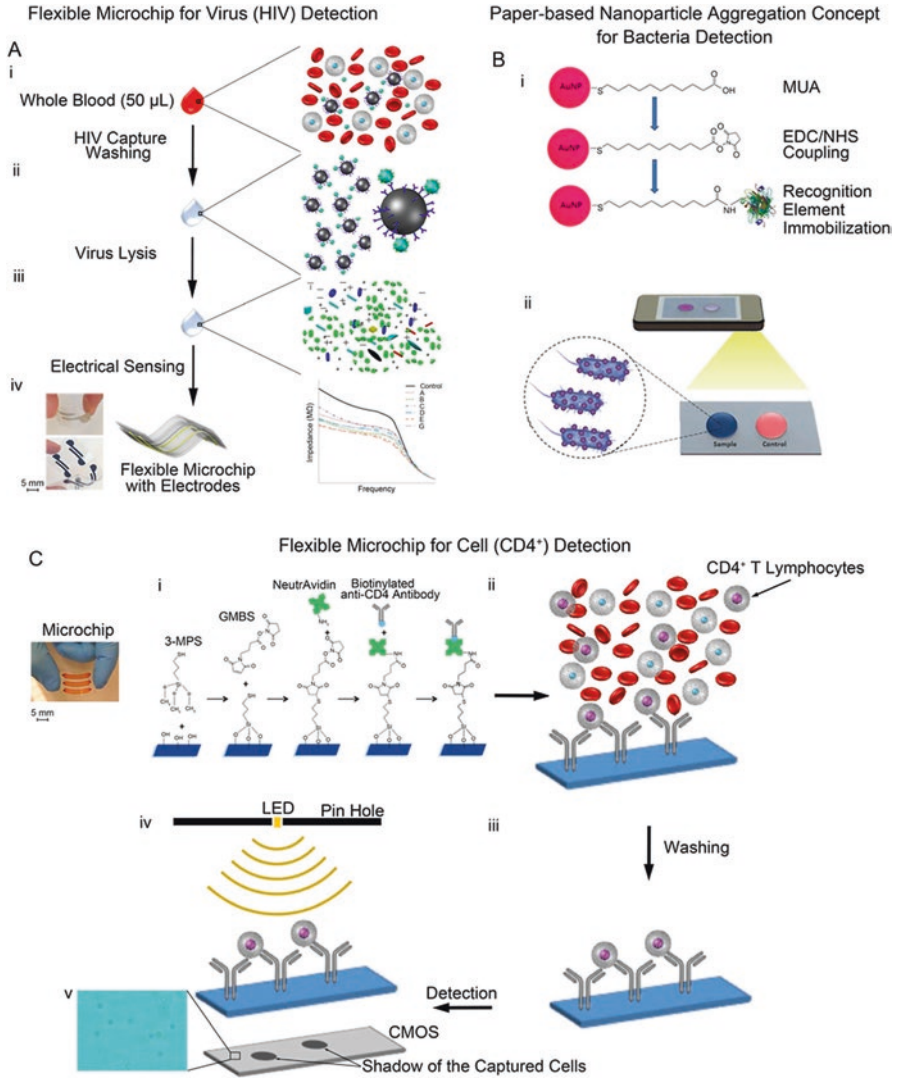


Fig. 3.16 Integrated paper and flexible substrate-based μ PAD platforms. (a) HIV-detection via microchips on polyester film. (b) Paper-based nanoparticle aggregation for bacterial detection on a cellulose paper with smartphone camera. (c) CD4⁺ T lymphocyte detection on polyester film. (Zarei 2017)

While indeed these devices are simple and user-friendly, μ PADs still require a trained healthcare provider to interpret the data they provide and to prescribe any necessary treatments (So and Ruiz-Esparza 2012). In crisis and conflict situations, this is where the community health worker would serve as a provider, but since this book is on the humanitarian innovation, we couple these devices with telemedicine. Telemedicine has the revolutionary capacity to connect highly trained healthcare

workers in countries around the world to patients in remote settings (So and Ruiz-Esparza 2012). This of course is made possible by substantial improvements to mobile communication technologies such as cell phones. Diagnostic results from a patient could be securely sent via smartphone to a physician both locally and internationally for quick diagnostic feedback and suggested treatment regimen. For example, a community healthcare worker would test a patient using a μ PAD, photograph the results with a camera phone, and transmit the image to a central laboratory (So and Ruiz-Esparza 2012). An expert would then analyze the image and respond to prescribe an appropriate treatment regimen to pursue.

Over the course of this unique chapter, we have explored the feasible and functional deployment of several medical interventions and medical device innovations that would be appropriate for use in humanitarian settings. Once again, the functional deployment of these interventions lies in the bilateral transfer of knowledge and the cultivation of a suitable innovation environment that allows for the sufficient access to the building blocks of knowledge, the strategic use of intellectual property and innovative financing to meet public health goals, as well as the collaborative elements of multiple innovation paradigms including open, reverse, frugal, and disruptive innovation (So and Ruiz-Esparza 2012). In our next chapter, we further expand the realm of our inquiry into redefining innovation in humanitarian medicine and take an integrative approach beyond medical devices. In this next chapter, we hope to show how indeed innovation is cultivated in both a micro and macro-scale that truly knows no bounds.

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