NEW TECHNOLOGIES FOR LOW-COST CONNECTED DRUG DELIVERY DEVICES

Here, Charley Henderson, PhD, Applied Scientist and Electronic Engineer at PA Consulting Group, provides an overview of the various wireless connectivity options that are now available for devices and looks at how the corresponding electronic system costs can be reduced to drive widespread adoption.

The current high activity in reporting the development of connected drug delivery devices suggests it is a fast growing trend. Yet, whilst inhalers and auto-injectors are emerging that have electronics, sensors and communications built in to monitor how patients use them, we are far from these items being prolific in the market. This is true across multiple sectors. As designers of new products, we see a growing aspiration to connect ever more categories of device.

One of the key challenges for widespread adoption in drug delivery applications remains the cost effective integration of simple to use electronic communications systems. This is because delivery devices are currently simple, mechanical and made at low cost in extremely high volumes.

In terms of cost, electronic hardware does not come for free. The price of even simple wireless modules can exceed that of the mechanical parts of an inhaler or auto-injector by an order of magnitude. This is a significant challenge for the business case, and may require different business models to realise the value.

Secondly, a standard printed circuit board assembly does not naturally integrate into an existing device design as a retrofit; and add-on housings add bulk and cost.

Lastly, connecting to any existing wireless network generally involves pairing processes, passwords, apps and/or subscriptions. These may detract from the reliability and usability of the system for the patient.

New Technologies Address the Challenges

The good news is that there are new technologies emerging. We are frequently challenged to develop novel connectivity solutions for medical, consumer and industrial products alike. Whilst every product has unique requirements and the solution needs to be customised, in this article we describe some of the key enabling technologies we envisage for future drug delivery applications.

MAKING CONNECTING EASIER

Whilst it may seem obvious, wireless communications require two ends to the link. One side needs to be on the device which sends and/or receives the information. The second matching side of the link needs to bridge the data into the cloud where the data can be stored and presented back to engage patients, caregivers and other stakeholders.

There are clear cost benefits to using infrastructure that already exists as the second side of the link; rather than making and servicing a separate hub. And this second side of the link is now available almost universally to consumers through smartphones and telecommunications networks.

However, this reduces the solution space to the standards supported by these existing devices. Namely near field communication (NFC), Bluetooth and cellular, of which Bluetooth is currently the leading choice in drug delivery.

The issue is that none of these technologies were necessarily developed for the connected device applications we are considering, and this poses some practical issues. The trade-off is illustrated in Figure 1.

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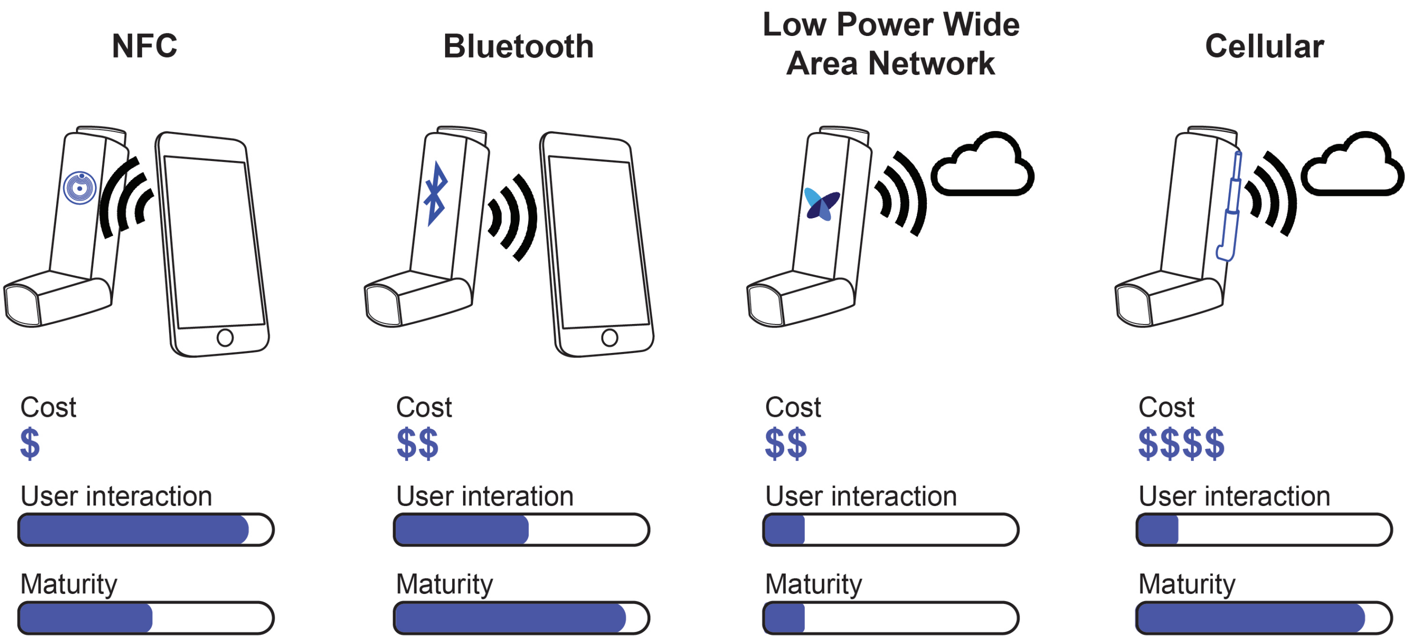

Figure 1: Wireless connectivity options.

Near Field Communications

NFC connects two devices over a very short distance, of the order of about 1 cm, using coil antennas. The key advantage is that one side of the link can be extremely simple and low cost because the other side of the link, or reader, provides the power supply and reference oscillator. The simplest example is a passive HF RFID tag that returns a pre-programmed number, and this is one of the only electronic systems that is truly cost optimised for disposable applications. However, sending back data from a sensor or other electronic system on a drug delivery device can equally be done, and single NFC chip solutions are emerging to do this.

Practical usability issues remain. Firstly users will always need to read data from the device by holding their smartphone close to it, having installed an app. The interaction is similar to contactless payment and in the best applications may form an integral part of the patient engagement. However, as such, it requires patient compliance to work, so is unlikely to cover all incidences of non adherence. Furthermore, NFC is not yet available for this type of application on all smartphones, although this is likely to change.

Bluetooth

Bluetooth is one of many short-range digital RF communications standards that operate over ranges of 10-100 m, and has the benefit of being readily available on smartphones. This makes it a leading candidate for connected health solutions that use smartphones to engage patients. Whilst component costs are greater than for NFC, this is in part because component solutions have not been optimised for low-cost, simple, disposable devices.

Ongoing patient action is still required to make it work. At the present time, using Bluetooth to communicate with a drug delivery device is likely to require the user to install an app on the corresponding phone, and to keep it in range with this app and the Bluetooth function running when the device needs to communicate.

At this point, it is worth ruling out WiFi for low-cost applications. As a widely available short-range network, it doesn't have the restriction of needing to keep apps running on a phone. However, it is a complex protocol optimised for high bandwidth – this means it is fundamentally inconsistent with a small, low-power, disposable device in terms of hardware cost, power and size.

The middle ground, however, may be the integration of Bluetooth into WiFi routers. This technically may not be a big step as the two standards use the same frequency. This would address the challenge for many Internet of Things (IoT) applications, and dedicated Bluetooth routers are already emerging.

Cellular

Using a cellular network has the advantage that, in principle, a product can be supplied that communicates reliably, without any action or infrastructure required of the user. Cellular networks are commonplace, and commoditised modules are available for around US$5, though a substantive power source and network subscription is also required – making it impractical for most disposable drug delivery devices.

"Innovative approaches here include using the microphone and processing capability of the smartphone to listen for specific sounds that a drug delivery device is engineered to make."

Low Power Wide Area Networks

There are a number of new players looking to develop public networks specifically designed for large numbers of low-power, low-cost devices that send small amounts of data. This, in principle, could be ideal for connected drug delivery device applications.

There are several network services emerging at various stages of development, including SigFox, LoRa and narrowband IoT solutions from cellular providers. None yet have universal coverage, but it is definitely one to watch for future product iterations. This is particularly true if, as seems possible, the device end hardware could be comparable in cost and size to a current Bluetooth solution.

Figure 2: NEXThaler®: example of device connected to smartphone via non-electronic, audio communication. The app was developed by PA Consulting Group.

Acoustic or Visual Communications Using Smartphones

There are non-electronic means to connect devices with smartphones. Innovative approaches here include using the microphone and processing capability of the smartphone to listen for specific sounds that a drug delivery device is engineered to make. This is particularly applicable to inhalers. Figure 2 shows an example app we have developed, where the inspiratory flow profile from a specific inhaler is monitored acoustically.

Furthermore, the smartphone camera can be used to image and verify use of devices with mechanical visual indicators.

None of these solutions are more reliable, robust, or easier to use than the wireless approaches. But they are potentially useful for low-cost applications in the short term.

ALTERNATIVE INTEGRATION OPTIONS TO RIGID BOARDS

Conventional electronics assembles the main communications components onto a rigid, fibreglass, printed circuit board (PCB)-based module. This needs to connect with the mechanism so that it can, at a very minimum, detect actuation of the device. Integration into a device is the most effective way to achieve this. However, this adds bulk and assembly time/complexity at best. In the case of existing products, this typically requires either re-design or the addition of a costly add-on assembly from which sensing is non-trivial. Furthermore, all this has to be achieved without impacting performance of the device/system.

There are, however, alternatives that may both make integration more straightforward from a design perspective, and reduce overall costs (Figure 3).

Smart Label on a Flexible Substrate

Electronic systems can be assembled onto flexible substrates, which could, in principle, be applied to the inside or outside of the device casework in the form of an adhesive sticker, removing the need for significant internal feature design and assembly steps. The simplest existing example of a mature product that does this is an RFID tag sticker.

Flexible circuit assemblies are an established technology, using polyamide substrates that can withstand the high temperatures of the soldering process. Lower cost approaches using printed electronics are also on the horizon.

The simplest sensor in this case is an electrical track in the label that gets broken by a binary event (e.g. removing the cap), causing the event to be detected by the system. However, integration of switches or other sensors is also possible.

Moulded Interconnect Device (MID)

The integration of conducting tracks onto the surface of injection-moulded plastic parts is a relatively established technology, for applications such as mobile phone antennas or automotive switches. Advantages include removing the need to run wires or integrate metal parts to make switches, and ultimately the opportunity to make the existing substrate the circuit carrier, and place components directly, thus removing the PCB.

Given that many simple drug delivery devices are made from injection-moulded plastic parts, MID technology may be one route to integrate the sensing system with the rest of the device, without the need for PCBs and wiring.

COST OF CONVENTIONAL PCB-BASED ELECTRONICS

Conventional architectures and PCB-based electronics assembly approaches are unlikely to enable drug delivery device connectivity solutions for significantly less than the order of several dollars. Indeed, $5 for an assembled product is low cost for the electronics industry, and we don't think this is going to change easily.

Conventional printed circuit board and component-based electronics have evolved to become a standardised,

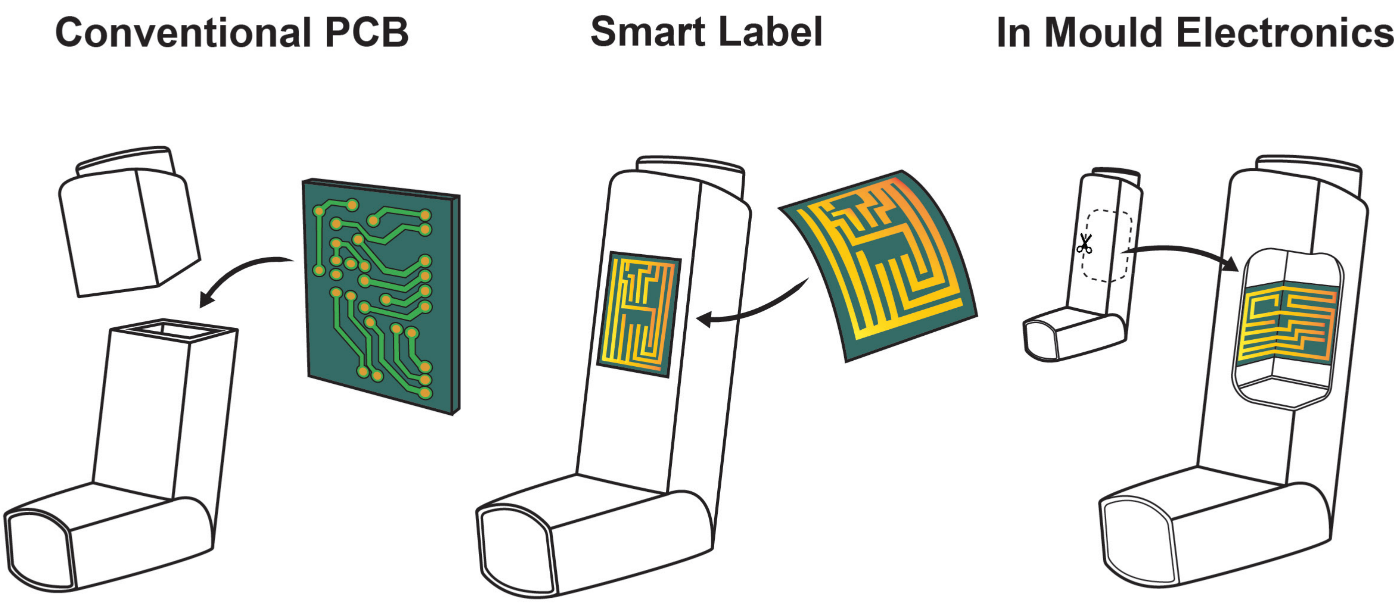

Figure 3: Approaches to the integration of electronics within devices.

sophisticated, automated and reliable means to mass-manufacture a diverse range of electronic systems. However, to achieve this, any product manufactured through it has an extensive supply chain and a number of manufacturing steps.

A simplified list, for purposes of illustrating the number of different steps and processes which contribute towards the cost, is as follows:

- **Component manufacture:** Standard components are manufactured using a wide variety of sophisticated processes and materials. They are placed into reels, and sourced through a supply chain. A typical board design may include tens to hundreds of parts.
- **Board assembly:** The PCBs are screen printed with solder paste. A bespoke set of component reels are loaded into a pick and place machine, the design is programmed in, and the components placed on each PCB. It is then placed through an oven to solder the components down. The process may be repeated on two sides.
- **Test:** Manufacturing errors do occur, and a test process may include both optical inspection, and functional test through loading the board onto a "bed of nails" test fixture.
- **Box build:** Boards are assembled into caseworks, and manually connected with any external wires required, e.g. to sensors in locations that are not on the board and planar.

Historically, the cost of electronic products has reduced whilst function has increased. This, however, has been largely driven by reductions in the cost of integrated circuit components (chips), driven by Moore's Law (the observation that the number of transistors in a dense integrated circuit doubles approximately every two years). However, the chip cost in a simple connectivity solution is only a small component of the total cost. The rest are commodity parts and assembly steps which are unlikely to change.

Taking the example of assembling a Bluetooth transceiver into a device, an approximate build-up of the cost is shown in Figure 4. The vast majority of these costs are commodity components or assembly steps that are well optimised and unlikely to achieve significant further reductions. The vast majority of these parts are commodity components or assembly steps that are not seeing significant reductions.

We therefore believe that a step change in the means of manufacture and assembly is needed. Furthermore, we see opportunities to do this through printed and flexible electronics.

PRINTED & THIN FILM ELECTRONICS

We see technologies to assemble electronic systems on low cost flexible substrates, and the printing of some of the components, as key enabling technologies to significantly reduce the costs of simple disposable systems.

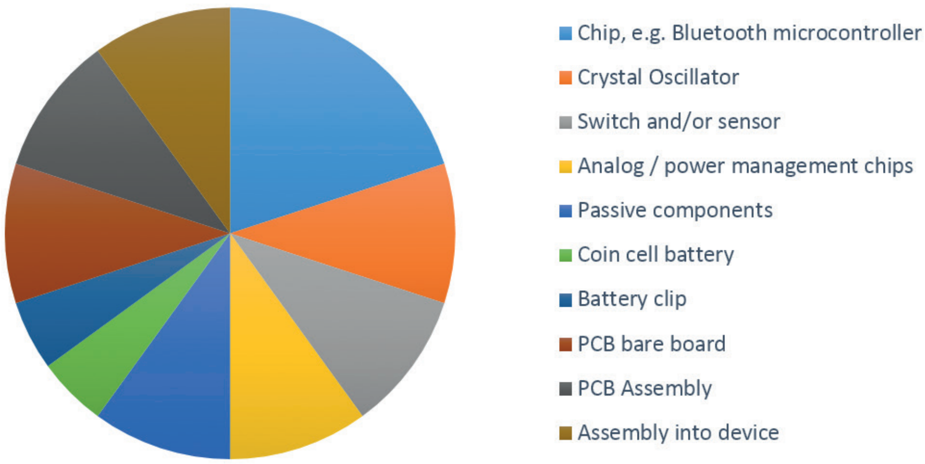

Figure 4: Approximate distribution of costs in a simple Bluetooth Low Energy (BTLE).

In this type of system, tracks are deposited or etched directly onto a low-cost substrate, and components mounted using low-temperature bonding techniques. In principle, this can be applied in a high-speed, roll-to-roll process. And, as the technology evolves, an ever greater proportion of components will be able to be printed.

For example, processes to print conductive tracks, passive components and batteries are increasingly well established; whilst technologies to print simple sensors, displays and transistors are demonstrated. Furthermore, where parts cannot be printed, they could in principle be integrated into a single custom chip (ASIC), minimising the component count.

This takes electronics much closer to printing and laminating technologies in terms of process.

Applying this to the cost breakdown for a wireless module in Figure 4, by removing or reducing costs for PCBs, clips, passive components and assembly, the total could be significantly reduced when extrapolated to high volumes – closer to $1 than $5 in principle.

The leading example of devices currently made in this type of process are HF and UHF RFID tags. These comprise a single, ultra-low-cost, silicon die mounted on a low-cost flexible substrate (e.g. PET), with printed or etched metallic tracks to form the antenna. They are made in high-speed processes, optimised for this specific type of product. The simplicity of the design, optimised process and low-cost materials enables them to retail for costs sometimes below $0.10 from commodity suppliers.

The principle of applying the same type of assembly process for more sophisticated systems has already been demonstrated. Examples include time temperature labels with printed tracks, batteries and displays. However, these have yet to make it into high volume, mass market, low-cost applications.

Scale-up of the volume manufacturing process to realise the cost benefits is still underway and needs market demand to drive investment. However, as a part of a product roadmap, this potentially offers device makers a route to significantly lower cost connected products in the longer term (Figure 5).

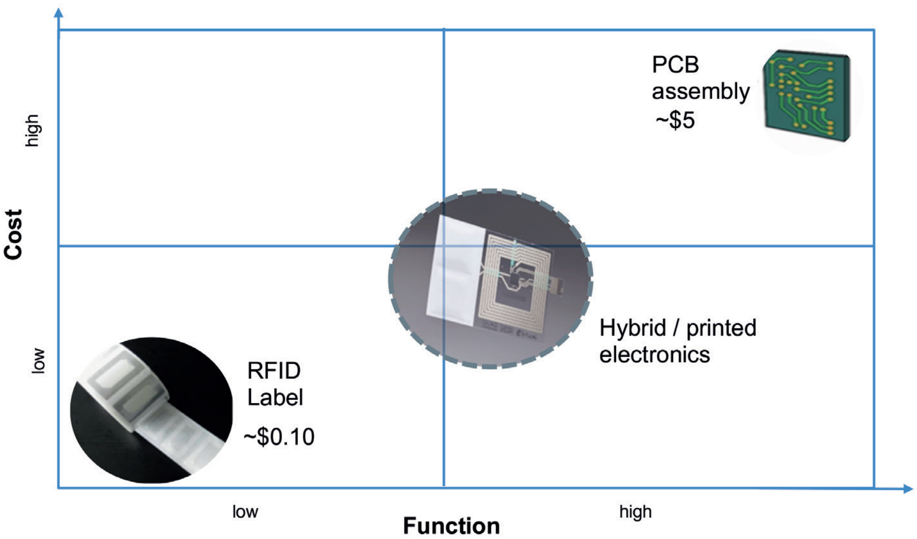

Figure 5: Cost versus function for different electronics assembly approaches. (Hybrid / printed electronics image (centre) Copyright © 2017 Quad Industries. Reproduced with kind permission.)

CONCLUSION

Smart connected drug delivery devices are starting to make it to the market, and for the immediate future these are likely to comprise the integration of Bluetooth and NFC modules at a cost of several dollars.

For the right application in which these connectivity and cost points are acceptable, this creates a useful platform technology upon which to build the complete solution, which includes the app and IT components; and together to demonstrate benefits such as improved patient adherence.

The proposition, however, becomes even stronger as there is a clear line of sight to much larger scale market applications, enabled by reduced costs, ease of integration into devices, and seamless communications. This is not unrealistic. Many of the new technologies to enable this are relatively advanced in development, but are awaiting scale-up.

PA therefore believes that the opportunity now exists for device makers to build this line of sight into their development roadmap. Through this, device architectures can take account of these technologies. Crucially, the strategic investment in specifying, designing and scaling up the new electronic subsystems, as well as building the necessary supplier relationships, can start now.

ABOUT THE AUTHOR

Charley Henderson is an applied scientist and electronic engineer at PA Consulting Group, with a strong track record in creating and delivering technically demanding products for medical and consumer applications. He has a particular interest in low-cost and low-power connectivity solutions for IoT applications, drawing on significant experience developing sensors, wireless and embedded electronic systems. Henderson holds a PhD in Photonics, MEng in Electrical and Information Engineering, is a Chartered Engineer, and member of the Institution of Engineering and Technology (IET) and the Institute of Electrical and Electronics Engineers (IEEE).

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