Memoirs of an eHealth Device Development

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Abstract— **Despite the rapidly growing industry interest in wireless remote home health care solutions a number of technical, regulatory and business challenges bridle more rapid telehealth device growth. The current paper highlights several challenges encountered in a Qualcomm internal development of a telehealth-targeting wireless hub. These include: 1) supporting non-standard protocol implementations across a number of wireless medical devices 2) determining optimum carrier and the appropriate wireless modem provider 3) navigating through a myriad of certifications and 4) managing development amidst undefined volume expectations.**

Keywords-Remote health care, Telehealth, 3G router, mHealth, medical hub, Android health hub, ISO13485 hub

I. INTRODUCTION

By now, the compelling image of a patient walking through a daily routine armed with a cell phone which captures and enables over-the-air monitoring of health statistics has prompted more than a few device companies to begin to chart their course in the emerging telehealth market. For Qualcomm (one of the world's leading suppliers of wireless technology), wireless enablement and promotion of the wide variety of devices which are beginning to emerge is an obvious goal.

In late 2010, as part of a larger healthcare targeted initiative, Qualcomm kicked off planning for development of what it hopes will serve as a functional, cost-effective, and practical model to help pave the road for device manufacturers leveraging its core technologies to serve the home telehealth market. Whereas traditionally leaving the commercialization of products based around its technologies to its partners, Qualcomm has invested its resources in the current project hoping to a) understand and hopefully help to iron out some of the obstacles facing device-minded manufacturers and b) commercialize a design useful as reference for others to leverage, imitate, and improve upon.

While continuing to support a growing number of partners to integrate cellular capabilities directly into their medical devices, Qualcomm realized that for a large class of current devices this was not practical. In addition to size and cost, many medical device manufacturers are new to the complexities of wireless technologies and need to assess regulatory obligations by a variety of U.S. government agencies.

For these devices a simple means allow them to capture the data from medical devices and transmit this data securely back to a server where it can be distributed is essential. The handling of the sensitive user/patient data must be consistent from end-to-end -- from the device to the provider, so the data does not become "stale" and events are reported when they matter most. This requirement for timeliness and the need to report at the time data is collected is becoming prevalent even in low risk medical devices that present a minimal potential for harm.

While Qualcomm expects that "mobile" devices will have the capability to send their health data directly to the server there is the "fixed" home application which is initially better served through the use of a home located "gateway" device.

To provide what is perceived as an enabling component, Qualcomm is developing a wireless gateway, or "hub", capable of collecting the healthcare data from the various medical devices in the home and sending this data over the cellular network back to a centralized server. Including the wireless cellular network as a backhaul creates a standalone ubiquitous system –removing any need to rely on the presence of a Smartphone or WiFi network to collect and forward patient data (especially relevant in applications involving senior citizens and/or developing markets). While this architecture requires the medical device to support one of the short-range wireless technologies like Bluetooth, the need to support cellular capability on each medical device (and pay a monthly data plan to a carrier) is replaced by the hub device.

The target user for the hub is the home user and it is therefore being designed to make installation and use as simple as possible. Plugged into a standard wall electrical socket, the hub will search out and pair with pre-identified home use medical devices such as blood pressure monitors and glucose meters which include one of the several short range wireless technologies supported by the hub.

The hub will collect the data provided from the various

devices in the home, package, and send back to a central server using a 3G cellular network. Believing that ease of setup, lack of complexity and security afforded by the end-to-end system handling the data are the keys to successful adoption, the hub will require no user set up. A home user will simply plug the hub into an electrical outlet to activate the device and it will pair up with those medical devices that specifically allow for interoperability with this product that are within its range. The transfer of data and the security associated with its handling are maintained throughout the system. Multiple short range radios are supported in the hub design to accommodate a variety of yet to be determined devices. To allow for the "universal donor" capability while remaining cost-minded, the Qualcomm hub relies heavily on industry standards and based on open source software components.

Development of the hub and associated backend server platform are expected to complete in the 2nd half of 2011 with the hub design to be made available to one or more manufacturing partners who will ultimately bring the product to market. Because of its longer term, industry-enabling business focus, Qualcomm is in a position to share details of its hub development, where a device manufacturer would typically not. It is the hope that by providing some details on the challenges found during the Qualcomm internal hub development that at least in some small way the gap between the wireless and healthcare worlds is narrowed.

II. Stages of Hub Device Development

To serve as a common frame for reference, the stages involved in commercializing a product such as the telehealth hub are outlined in the chart below.

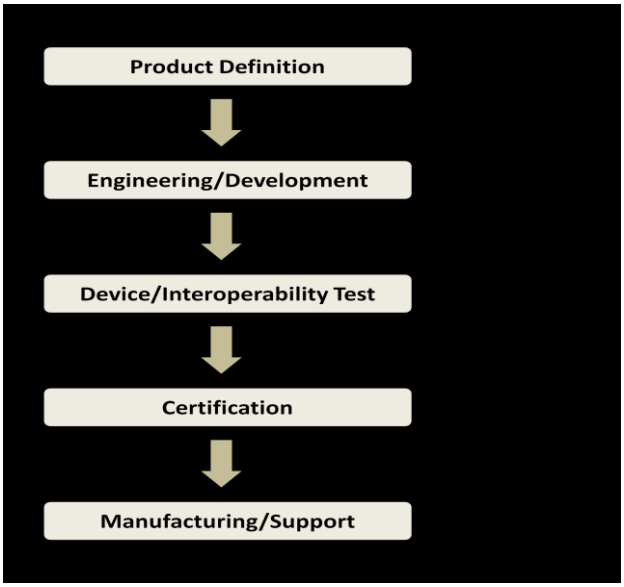

Fig. 1. Listing of the major steps in a standard commercial device development. Estimated time span assumes a wireless product similar to the hub described in this paper.

The wide range of development time is included less to remind that that "Rome wasn't built in a day" and more to emphasize that complexity of the design (particularly the software portion), will have a considerable impact on the length of schedule (and therefore costs) associated with development. At the risk of pointing fingers, typically the initial stage of product definition consumes considerably more time than anticipated, holding back the engineers from being able to kickoff development. One of the most helpful tools in this stage is reaching agreement on the project priorities. By setting forth on paper the ranking of main variables of a product including time-to-market, development cost (NRE), bill of materials cost optimization, product performance, product extensibility, and agreeing to this prioritization will serve as a guide which can be an effective way to resolve trade-off disputes throughout the development.

The outputs of the product definition stage serve as the keystone for development and should not be rushed. Nevertheless, the impact of a protracted product planning stage is often felt by engineering which is put in a position to make up overall schedule which was unexpectedly consumed in the this initial stage. Specifically, in the case of the Qualcomm internal hub development, this stage comprised approximately 3 months, providing some indication of the extended discussions and complicated set of decisions required to articulate a plan.

III. Specific Challenges Presented by "The Hub" Development

to other mainstream consumer devices such as cell phones, the telehealth hub requires decisions on several "unique" topics. As the hub project is not due to complete for several months, there are likely to be additional challenges and obstacles to manage but those most prominent to this stage of development are listed below.

A. Need for end-to-end standardization

To become a "universal" hub to handle health-sensitive data implies an exceptional amount of monitoring and policing on both the device and server-facing sides. Multiple radios each potentially serving multiple devices increases the complexity of design and consequently the decisions required to implement in the design. Additionally, the care in handling this sensitive data must be considered from the air interface out of the medical device until it reaches its "slot" in the server database on the backend server (and eventually into the hands of the patient, doctor, and/or healthcare provider). The goal is to allow manufacturers of various medical devices to be able to pair up with the hub without significant changes in their devices and avoiding any need to expose their protocol or data. The hub will truly serve as a data-in/data-out device

with its only function to collect, package and faithfully transfer this data to a dedicated server. Summed up, the success or failure of the hub depends almost entirely upon the level of coordination/co-development with the other "actors" in the larger wireless system. These actors include the medical devices which pair and send their data to it on the front end, the wireless carrier's network in the middle that allow the exchange and communication between the server platform on the back end.

Initial brainstorming meetings between the development team and several medical device companies evidenced a wide gap in competencies between cell phone-centric wireless Mustangs and the medical savvy device Thoroughbreds. The plan to copy-paste the standard cell phone wireless approach was quickly met with a host of issues, obstacles and challenges specific to the healthcare field. Sadly, "plug and play" would not play here. While not surprising, this gap appears to be prevalent as companies and their staff have either grown up wireless or grown up healthcare with few areas of overlap.

With pride returned to back pockets, the hub development team began an extended product definition/product planning phase with whatever learning's they could obtain in ongoing meetings with the medical device manufacturers. While their goal will be to hit a grand slam with the hub project, with limited roots or understanding of the idiosyncrasies of healthcare, leaving any kind of mark on the telehealth scorecard will be considered an accomplishment.

Whereas initially there was hope for near 100% leverage of the established hardware and software short range radios typically featured in cell phones, it quickly became obvious that there are host of special considerations and modifications required to satisfy the medical device-hub interaction.

The reasons for this are two-fold. First, since the medical device manufacturers are making their forays into wireless in many cases for the first time, their implementations of standardized protocols are often far from standard. Whereas in some cases this is due to insufficient understanding of the options available, in some cases the addition of the wireless functionality (e.g. Bluetooth) was made near the end of development of the medical device. In these cases, pre-existing battery size, key locations and number, and software architecture can quickly hamstring the engineering team to implementing the wireless capability in a way that will not easily lend itself to end-user usage. Home medical devices which require the user to interact with the device to force uploads and do not contemplate in their architecture a means to provide the user feedback when the data is successfully uploaded threaten to detract from the adoption and use of these devices. Unfortunately, in the case of several of the medical devices surveyed, the addition of the wireless function appears to have been done as an afterthought to the main development with the hope that by adding the radio the connectivity would "just work".

Ultimately, the variety and unknowns related to how device manufacturers were planning to integrate wireless caused the hub planning team to continue to add flexibility. In addition to supporting multiple radio protocols including Bluetooth, WiFi and ANT+, a software scheme was developed to accommodate a wide range of customization. As a fallout, the selection of the operating system migrated from initially a very low level model to one which included the latest full-featured version of Android. To allow for the expanded flexibility, the size of the memory was also increased to allow for "headroom".

Although the phenomenon known as "feature creep" is widely known in Product Definition circles, the infancy stage of the telehealth market created a need for flexibility (otherwise known as cost) to this initial product. Certainly, as a by-product of market maturation device manufacturers are likely to embrace one or two of the main radio protocols and therefore reduce the drain on the hub/backend. While too early to call a winner, there is considerable excitement in the air about the lower power consuming Bluetooth Low Energy (LE) protocol which is soon to debut. This appears to offer functionality appropriate for these kinds of devices without the battery drain associated with some of the others.

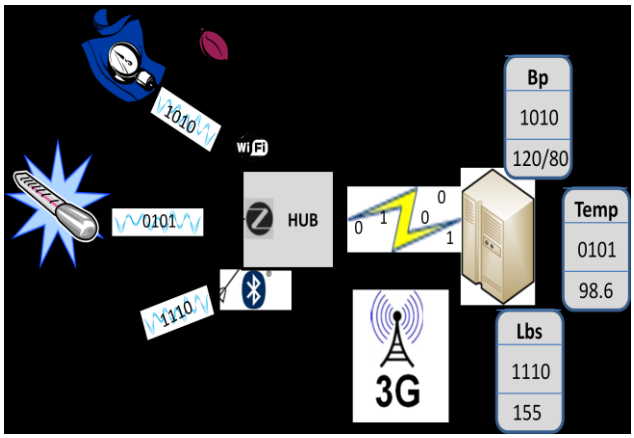

Fig. 2. Illustration of flow of data from the various medical devices to the hub over three established short range radio protocols. The data collected from each device must be securely managed from end-to-end so that the each data set is stored in its own format (often proprietary), by device, and by technology. The number of formats which must be segregated increases geometrically with the number of devices, wireless protocols and formats supported.

Regrettably, the challenges of interdependency do not end with the medical device-hub relationship. Based on previous experiences in the adjacent M2M sector where the missing component has proven to be the backend server, Qualcomm determined that, due to the high level of interdependencies, it

needed to develop a fully featured server platform to be able to ensure a commercially viable model. Although not the focus of this paper, the importance of close coordination with a backend server can not be overemphasized –especially when the handled data "product" is something as personal and sensitive as patient health readings.

B. Selection process for wireless cellular technology and carrier was both time consuming and complicated

As an active participant in the wireless markets having developed, certified and shipped countless devices worldwide, the task of selecting the technology and carrier would appear to be a task which would come as second-nature. On the contrary, the selection of carrier turned out to be one of the more complicated and time-consuming tasks within the product definition stage. Working hard to avoid exposing the ultimate choice of carrier for this project (attempting to remain neutral "Swiss") , the three main considerations included in helping to down select to a single technology/carrier were:

1. Target launch market/s.

2. Optimization of data plan

3. Availability and cost of the wireless module

While not in any particular order of importance, any one of these topics can whip even the most wireless savvy product definition team into a team into an uncomfortable and time-wasting lather. Far too easily, inability to focus the launch scope to at least an initial market leads to a decision to try to support a device which can work "worldwide". In most cases, however, this is not only prohibitive from a cost perspective but also impractical.

Unless device cost is not a consideration (read: "unicorn"), the option of a true "worldwide" product which supports virtually all the carriers in the world is not practical. While there are a few wireless modules available on the market with the functionality, the advantages of this kind of functionality is easily outstripped by the hidden costs related to additional testing, more challenging antennae, complexities in software, and the resources required to obtain multiple carrier certifications. Additionally, considering that these types of home-based telehealth products are unlikely to need to "roam" around the world, it is probably best to plan for variants on the initial product even if the plan is to support all markets in the world.

The selection of target markets is tightly linked with the selection of the wireless module. The reason for this is simple. Wireless cellular module manufacturers have defined their product offerings to obtain the lowest cost by grouping the supported bands into combinations to suit different markets. Akin to the tradeoffs of the world mode module, wireless module manufacturers recognize that the great majority of their users will remain in the market that they purchase their product and will not need the ability to roam significantly internationally. To achieve the lowest cost, the modules they offer support either CDMA or UMTS/GSM technologies with bands which will work in either in North America or in Europe/Asia. Despite the perception that the UMTS/GSM combination module should cover both North America and Europe/Asia, currently available modules are typically either North American or European/Asian bands in UMTS with a fallback support in GSM. The result is that while there are plenty of cases where these modules can work, the North American-targeted version will operate in UMTS in North America, GSM in many European/Asian areas and not work at all in Japan or Korea. Conversely, the European version will work throughout Europe and Asia but will operate only in one of the two main GSM bands in North America(leaving large coverage holes).

Similarly, on the CDMA side, although CDMA has excellent coverage in North America and is rapidly expanding coverage in areas of Asia, there are still quite a number of areas where there will not be support, including Japan which maintains CDMA support but on a different frequency band.

Although the least expensive module available continues to be those classified as having the lower data rate capabilities of "2G" it is prudent to take into consideration the requirements and preferences of the carrier where the products will be deployed. To improve the efficiency (read: reduce cost) of their networks many carriers are working to transition their users onto UMTS and phase out the older, less efficient GSM network. Although the carrier incentive to reduce its operating costs and improve its efficiency and quality might not match the top priority of the low data rate device developer, the carrier has the ultimate power to influence module selection in two ways. As the data plan for these special devices is usually intensively negotiated, the carrier may show "preference" for a 3G-based product by offering better data rates. Secondly, as each product will need to be certified by the carrier before commercial launch, a carrier might place a lower priority to certify (or refuse to certify at all) a product which is 2G-only.

In any event, because the decision is complex as well as critical, plan to invest a considerable amount of time during the product definition phase debating the various options while negotiating with the specifically targeted carriers for the optimum data plan for the product.

C. Decisions about how the product should be classified and certified were difficult to conclude

As is the case for all developments, the product planning team needs to set forth the testing and product certification requirements for a commercial product. There are a number of certifications which are required by regulatory agencies, industry forums and the carriers. Among this category are FCC, CE, GCF, PTCRB, WiFi Alliance, Bluetooth SIG, and carrier product certification. Additionally, in the case of healthcare-related devices, consideration and interpretation of the direction provided by ISO, FDA, CE Medical Device Directive and even privacy and security considerations are essential. Finally, there is an alliance that promotes medical device interoperability by the name of the Continua Health Alliance which develops interoperability specifications based on commercially available standards that warrants attention.

Carrier product certification testing is definitely one of the areas worth underlining in the plan to avoid being surprised by the effort late in the development. Certainly, because carriers prefer to certify products which incorporate a pre-certified module on their network, the strong recommendation is to base development around one of these modules. The effort to undertake a complete product certification which included a non-certified module (assuming the carrier would even agree to work with a product of this type) is enormous for both the manufacturer and the carrier. On the other hand, if the product submitted to the carrier for certification includes a pre-certified module, the time, effort, and costs are minimal. As the process and requirements vary widely from carrier to carrier, it is best to discuss the product plans with the carrier at or near the kickoff of the project. This will not only allow the engineering team to know the requirements they will be evaluated on (generally antenna performance and some other product-level parameters) but allow for advanced scheduling and preparation of paperwork, sample units and any test tools required.

Of the other certifications, we considered the importance of compliance with the medical ISO 13485. Whereas the hub might be sold as a standalone product, the more likely scenario is for it to be sold in combination with one or more medical devices as a system.

The need for ISO 13485 development of the hub is based on this "system" view of the telehealth product. Analogous to a "post office" the hub collects and forwards on the data which it receives. As of today there are no known ISO 13485 compliant cellular modules which perform a large portion of the "post office" function in handling data.

D. Volume does matter –in many ways

Although certainly not unique, it may be useful to highlight perhaps the biggest challenge facing device manufacturers preparing products for the budding industry --volume. Inability to predict accurately the ultimate volume of units which will result from a development will potentially influence decisions and actions throughout the development.

Whereas the product marketing leads can be expected to emphasize the need for low cost of the product, without commitment to volumes, this priority runs counter to the forces of the market. This "chicken-and-egg" predicament puts the product planning and components engineering people in an awkward (yet familiar) position. At a high level, the toggles to reducing product cost are

a) Lowering the bill of material cost (BOM)

b) Reducing the features/extensibility of the device

Reductions in the cost of components used starts with close coordination between the components sourcing and engineering leads. Almost inevitably, there will be opportunities to reduce cost at the expense of a feature or function called out in the product requirements document and that is where some "tug-o-war" may ensue. None of this is special to the telehealth product development. What increases the complexity is lack of precedent "icon" products and immature market. While no one questions the massive scope and scale of the healthcare markets and the obvious opportunities for telehealth devices within it, even the best marketing/product manager will have difficulty guaranteeing the market acceptance rate for one feature over another. The adjacent M2M markets provide some clues but the reality is that there are not enough examples of similar products to be able to accurately predict the potential for a product. The dilemma which results for the sourcing lead is what to forecast to the various suppliers to obtain initial pricing. While the hope is for millions of units to be sold, in a new market where the factors leading to market acceptance are far from clear, it is probably unwise to predict high volume (especially since sourcing people need to continue to maintain relationships with the supplier base).

Low volume forecasts leading to higher component costs, combined with uncertainty of features required to suit the market creates an environment ripe for debate. As the marketing/product leads continue to emphasize the importance of low pricing, sourcing will press for commitment to volumes. The unfortunate sacrifice made in this standoff is removal of previously agreed upon features to continue to meet cost targets. Unfortunately, not knowing the impact of the feature vs. volume trade-offs, the decisions made in these panicked discussions are knee-jerk, at best.

The challenge of launching a product for a non-established market with unknown volumes extends to the selection of manufacturer. Assuming manufacturing is outsourced, a campaign to "sell" the product to a suitable contract manufacturer is inevitable. This is done to secure the interest and the allocation of resources controlled by the contract manufacturer. Because of the heavy capital component of their business, the contract manufacturer typically prioritizes volume over margin/unit, needing to maintain maximum capacity of the facilities to be profitable. Because customers have forced contract manufacturers to breakdown costs into set up, component, support and profit margins, attention to the volume commitment has recently intensified, as it is one of the few remaining negotiable variables. Understandably, DVD player and cell phone designs which have a track record for reaching high volumes naturally take priority while innovative, market-enabling products like the telehealth hub require a considerable amount of self-promotion.

Finding a contract manufacturer willing to take a chance on a new product category with its limited resources is necessary. Finding a contract manufacturer willing to take that same chance while offering its services at competitive market rates for no/low commitment of volumes is essential to the commercial success of the product.

IV. CONCLUSION

During the development of a wireless hub specifically designed to support telehealth products a number of challenges were identified. As most of these challenges are expected to be common across telehealth device developments, the authors hope that outlining their experiences will benefit those planning similar developments, resulting in more devices coming to market in an efficient manner.