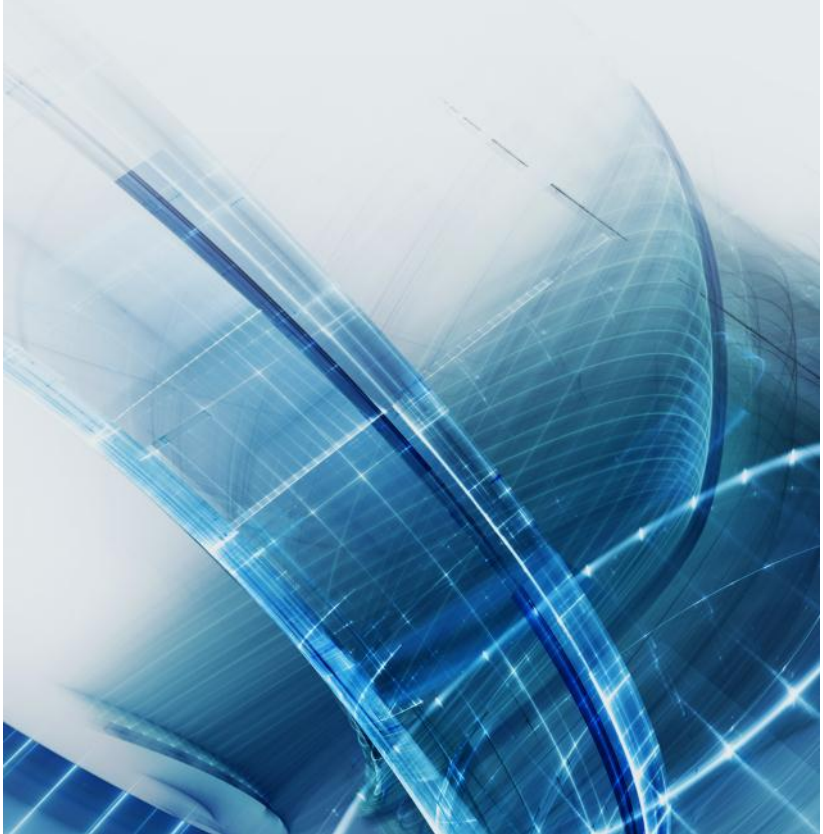
IHS **Technology**

The Role of Cellular M2M in the Healthcare Market - Topical Report

February 2014 **ihs.com**



Contents

The Role of Cellular M2M in the Healthcare Market - Topical Report

List of Figures

List of Tables

The Role of Cellular M2M in the Healthcare Market - Topical Report

Josh Builta, Sr. Analyst, M2M & Internet of Things

This Topical Report examines the market for cellular machine-to-machine (M2M) communications in the global healthcare industry. This report provides a current snapshot of this market while also offering visibility into the factors that are projected to drive or hinder growth of cellular M2M technology in this industry in upcoming years. Research for this report was conducted primarily from December 2013 to February 2014.

It should be noted that the forecasts in this report exclusively focus on healthcare devices and applications that use embedded cellular technology. Though they are discussed, this report does not provide forecasts on solutions that use a separate cellular-enabled device, such as a smartphone, to connect and transmit data.

This report is part of a series of Vertical Market Topical reports by the M2M Research Group at IHS. These dedicated studies are designed to complement the group's already extensive research portfolio by providing in-depth analysis on individual M2M vertical markets and applications. These focused reports allow IHS to provide a thorough understanding on the future growth and potential of cellular M2M technology within each of these diverse markets.

Key findings and implications

- At the end of 2013, IHS assessed that healthcare devices represented less than 1% of global cellular M2M connections. Among the obstacles that have inhibited greater uptake of cellular M2M in the healthcare space is the difficulty in overcoming the diverse regulatory approval processes required to bring a cellular-connected healthcare device to market.

- The potential for cellular M2M in the healthcare market is immense, as reflected by the segment's considerable total addressable market (TAM), which IHS forecasts will reach approximately 217 million by 2018. This exceeds the TAM of nearly every other vertical market in which cellular M2M technology is being utilized.

- While the cellular attach rate in healthcare will rise throughout the forecast period, a majority of devices will remain unconnected or use a short-range wireless technology, most notably *Bluetooth* and ANT+, to tether to a user's smartphone. IHS believes such solutions will provide a sufficient level of connectivity in most devices.

- Facing rising demand for services at a time when healthcare spending is under intense pressure, governments and healthcare providers worldwide are increasing reliance on remote patient monitoring and "telehealth" solutions to provide cost-effective, yet high-quality medical care. The shift presents the best opportunity for greater incorporation of cellular M2M technology in the global healthcare industry.

- The growth of wearable technology will create additional opportunities for cellular M2M in the healthcare space in upcoming years. However, concerns regarding power consumption and cost will largely limit uptake to devices that monitor critical healthcare conditions and in which transfer of patient data in all locations is essential.

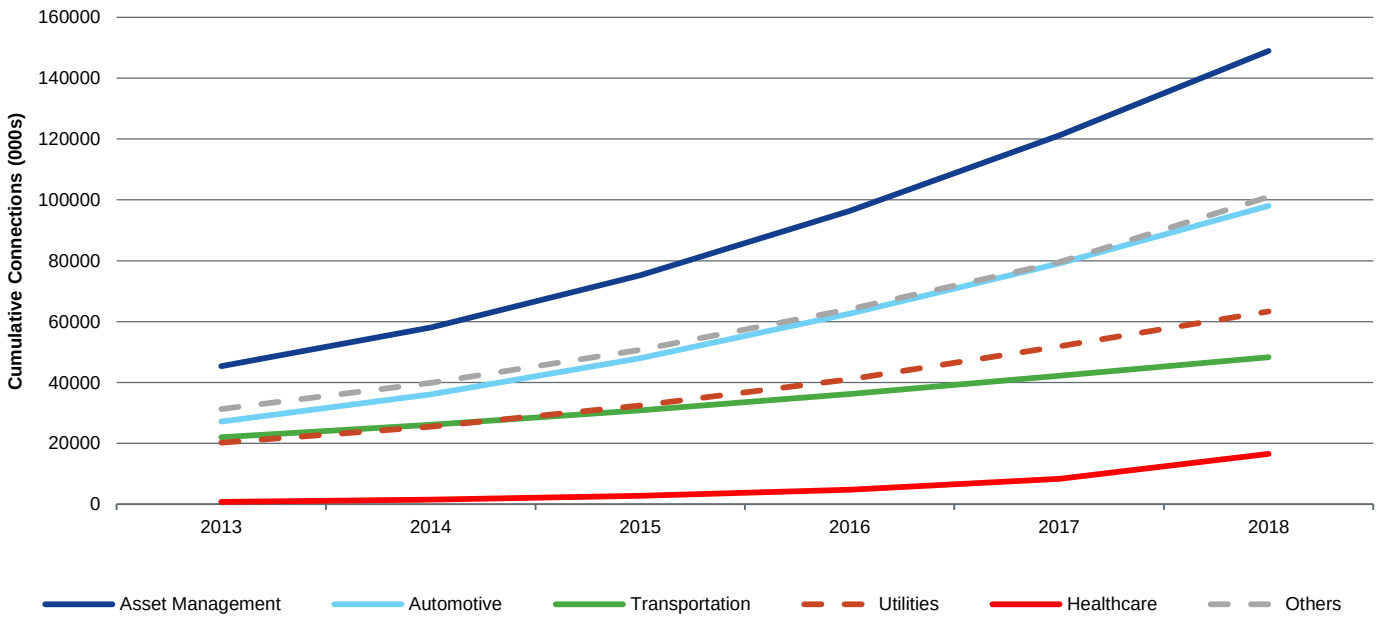
A small but potentially huge piece of the M2M market

IHS defines the cellular M2M market as the interconnection of remote devices, machines and sensors using cellular infrastructure for the purpose of largely autonomous monitoring and control or transparent content delivery. In recent years, cellular M2M technology has experienced increased use in a diverse group of vertical markets, ranging from automotive to security to digital signage. This utilization in such a wide variety of applications is one of greatest underlying strengths of the cellular M2M market. However, given the diversity of these industries, it is not surprising there are stark differences in the degree to which cellular M2M is being incorporated within each.

At the forefront of cellular M2M adoption are the automotive, utilities, transportation and asset management markets. The use of cellular M2M in these areas is relatively well-established and the services and applications provided by the technology in these markets are plentiful. In the automotive market, for instance, cellular M2M technology provides vehicle manufacturers with remote diagnostic information while at the same time delivering consumers a variety of advanced safety and entertainment options. In asset management, cellular M2M technology is used to track high-value goods in transit as well as monitor the status of remote industrial equipment and machines. Most importantly, the M2M applications in these markets have typically demonstrated a solid return on investment (ROI) and are viewed as integral in generating new revenue opportunities.

At the other end of the M2M adoption spectrum is the healthcare market. Despite the significant amount of attention this market has garnered from key M2M players—ranging from network operators to semiconductor suppliers—in recent years, IHS assesses, as mentioned above, that healthcare devices represented less than 1% of global cellular M2M connections at the end of 2013. As seen in Figure 1, it is expected that healthcare will continue to represent a relatively limited, albeit growing, portion of the overall cellular M2M market over the next five years. IHS forecasts that by the end of 2018, healthcare devices will account for approximately 3% of global cellular M2M connections.

Figure 1: Cellular M2M Connections by Vertical Market



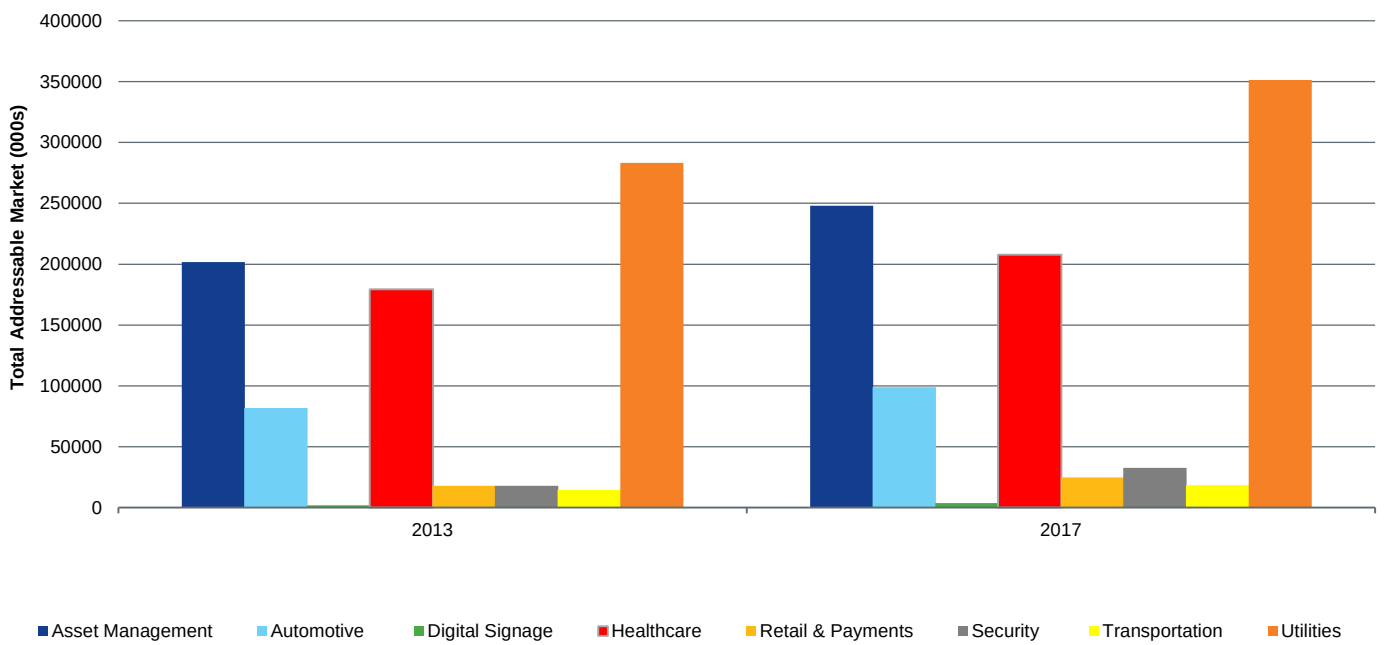
Source: IHS

As discussed further in the following section, the obstacles that have inhibited greater uptake of cellular M2M in the healthcare space are significant. They include the prevalent use of alternate connectivity solutions and the complexity of the regulatory processes required to bring cellular-connected healthcare devices to market. IHS believes overcoming these and other challenges will require time, and that most are unlikely to be completely addressed during the forecast period of this report.

However, despite these impediments and its limited employment within the current market, IHS believes the long-term potential for cellular M2M in healthcare is enormous. As this report will discuss, public and private healthcare systems in many countries are facing rising demand for services at a time when healthcare spending is under increased pressure and there are limited personnel to provide care. Consequently, there is a growing need for the industry to develop more affordable and efficient models of healthcare delivery. Particularly for the elderly or patients with chronic diseases, there is general consensus that technology, including cellular M2M, must be a key component of future medical care.

Optimism surrounding cellular M2M's potential in healthcare is also a reflection of the segment's considerable total addressable market (TAM), which IHS forecasts will exceed 184 million in 2014 and reach approximately 217 million by 2018. As seen in Figure 2, this exceeds the TAM of all but two vertical markets in which cellular M2M technology is being utilized.

Figure 2: Total Addressable Market for Cellular M2M by Vertical Market



Source: IHS

In order to provide an accurate portrayal of the TAM for cellular M2M in healthcare, IHS has only included those devices it believes have or will soon demonstrate a strong rationale to be connected. The devices that IHS has included within the healthcare TAM are captured in Table 1.

Table 1: Total Addressable Market for Cellular M2M in Healthcare – Device Categories and Examples

Device Category	Products Included	Current Use of M2M	M2M Product Examples
Personal Health Measure Devices	Blood measure monitors, blood glucose monitors, body composition analyzers, cholesterol monitors, weight scales, and pulse oximeters among others.	**Low**	Telcare BGM, YOFi Glucose Meter, BodyTrace weight scale
Sport and Fitness Devices	Fitness & heart rate monitors, activity monitors, and pedometers among others.	**Low**	BodyMedia FIT Armband
Telehealth Residential Gateways	Devices that acquire measurements from a range of peripheral healthcare devices such as a blood glucose monitor and communicate this data to an external location (e.g., the patient's healthcare provider) for analysis.	**Moderate**	Qualcomm 2Net Hub, Numura Home Hub, IDEAL LIFE Pod, Alere Connect' MobileLink/HealthPal, Verizon Converged Health Management Device, Hydra Healthcare Gateway
Treatment and Health Aids	Automatic pill dispensers, hearing aids, and nebulizers among others**.**	**Low**	Vitality GlowCap/GlowPack, Vaica SimpleMed/SimpleMed+
Wearable Technology	Devices worn on the body for an extended period. Wearables included within the healthcare TAM must provide a medical or wellness application. Other devices (e.g., watches that provide only infotainment functions) are not included.	**Low**	AT&T EverThere, Numura Libris Philips Lifeline GoSafe, GreatCall 5Star Verizon SureResponse, VESAG Advanced Health Watch, Everon PERSmobile

Source: IHS

As seen above, though the TAM for cellular M2M in healthcare is significant, to date only a handful of products within each device category are using embedded cellular M2M technology. A few key points about these devices:

- Though cellular M2M has begun to be incorporated into a few personal health measure devices and treatment and health aids, the overall availability of such products remains relatively limited. Sports and fitness devices with embedded cellular M2M are practically nonexistent.

- The use of cellular M2M in the wearable technology market is concentrated on mobile personal emergency response system (PERS) devices, such as Numera Libris and AT&T EverThere.

- As of early 2014, the healthcare device that most commonly features embedded cellular M2M technology is Telehealth Residential Gateways. However, it should be noted that the dedicated telehealth gateway market is increasingly under pressure from other devices, most notably smartphones, which can provide the same functions.

It is the unique mixture of immense potential yet persistent lackluster results (in terms of actual device deployments) that has made healthcare one of the most intriguing and highly-debated vertical markets in the M2M industry. It was, therefore, not surprising that the interviewees for this report expressed a range of opinions on its future, with some suggesting that this market will grow tremendously in the next five years, while many others expressed belief that it will take much longer to develop (or perhaps will never occur at all). What was agreed upon by most is that currently the use of cellular M2M in healthcare is being suppressed by complex obstacles that will not be easily overcome.

Regulatory requirements act as key obstacle

At the forefront of challenges facing cellular M2M in the healthcare market is the difficulty in overcoming the complex and diverse regulatory approval processes needed to bring a cellular-connected healthcare device to market. It is important to note that any cellular-connected device (whether a smartphone or M2M device such as smart meter) must receive approval from a government telecommunications regulatory body (e.g., CRTC, ANATEL, OFCOM, or FCC) and operator certification before being released. While seemingly complex, these processes are generally well understood by device manufacturers and are not generally viewed as a significant inhibitor to M2M market growth. On average, IHS assesses this process takes between 3-6 months, though circumstances, such as using a pre-certified cellular module, can reduce this time.

A wireless device with a healthcare function, however, adds another step to the process in that it typically also requires approval from a designated government healthcare regulatory agency (e.g., the FDA in the United States or MHRA in the United Kingdom). Obviously requiring this additional approval makes sense as it can protect the public from devices that are unfit or potentially dangerous to one's health; however, it is also clear that this stipulation has created a challenging environment for device manufacturers attempting to bring such devices to market. This is especially true for companies with backgrounds primarily in the wireless technology market (and are ideally suited to develop cellular M2M devices) as they are typically unfamiliar with healthcare device regulations.

Quantifying the burden of this process is difficult as there are various classifications of healthcare devices in each country (this classification is typically based on factors such as design complexity, potential for harm, etc.). For instance, in the United States, the FDA categorizes every healthcare device into one of three classes, each which has their own unique set of requirements. The specific time and cost associated with bringing a healthcare device to market, therefore, depends on the particular class level it falls into. However, feedback from companies that IHS spoke to for this report indicated that when FDA (or equivalent) approval is needed, it typically adds between 18 months to 3 years to the time to market. Furthermore, the device standards that must be met are different in each country, meaning the process is even more complex (and time consuming) if manufacturers want to sell their devices internationally.

This process has clearly impacted the growth of cellular M2M in the healthcare market. Some device manufacturers have opted to scrap their cellular-connected healthcare devices after numerous delays associated with gaining healthcare regulatory approval. IHS believes that other manufacturers have abandoned plans for cellular-connected healthcare devices at the development phase (before even beginning the regulatory approval process) after being advised on the probable delays and costs. Finally, due the lack of international device standards, any cellular-connected healthcare devices that are released are typically limited to a single region or country, thus limiting overall volumes.

While healthcare regulatory bodies have begun to explore ways to ease the approval process for connected devices, to date, these efforts do not appear to have led to significant improvements. In order to sidestep this process altogether, manufacturers have a few alternative paths to market. One "work around" is to design a device that does not require any healthcare regulatory agency approval. An example of such a product on the market is the Vitality GlowCap. Such "wellness" products (which include most fitness and exercise devices) are characterized as having less significant risks if they do not operate correctly and thus typically require minimal, if any, healthcare agency approval. However, this option obviously also necessitates that the functionality of that particular device is limited.

As discussed in the following section, another alternative for manufacturers is to use alternative connectivity solutions. While this solution does not eliminate the need for approval from a healthcare regulatory body, it does remove the need for telecommunications regulatory approval, thus reducing the overall time to market.

Use of alternate technologies also a deterrent

Another fundamental obstacle to uptake of cellular M2M in the healthcare market is that other technologies present a more practical connectivity solution in many devices. While some devices could offer multi-connectivity options (e.g., cellular and *Bluetooth*), for the most part the use of these alternative technologies will eliminate the use of cellular in that particular device.

In some stationary healthcare devices, such as Telehealth Residential Gateways, wired technology solutions including plain old telephone systems (POTS) and Internet Protocol (IP) are still often used to transmit patient data to a hospital or care provider. Because these wired solutions are perceived to be more secure and reliable by many stakeholders, this technology is likely to continue to serve as inhibitor to the uptake of cellular M2M in some healthcare devices (though obviously not in devices designed to be mobile).

The more significant alternative to cellular M2M in healthcare devices, however, is short-range wireless technologies, most notably *Bluetooth* or ANT+. By incorporating these technologies, healthcare devices can tether to a user's smartphone, which can then transmit the information to the healthcare provider through its own cellular connection. This eliminates the need for a separate M2M cellular-connection in the healthcare device itself. In almost all instances, healthcare devices that incorporate these short-range technology solutions are cheaper and easier to design than cellular-connected equivalents.

Short-range technologies also have far superior power consumption efficiency than cellular technology, especially with the development of *Bluetooth* low energy. This is a particularly important consideration in view of the emerging wearable technology market. IHS believes to provide a satisfactory user experience wearable technology must be able to run for at least an entire day between charges. However, an IHS study found that incorporating cellular into a typical wearable device would render the lifetime to a couple hours. While battery power can obviously be increased, this requires increasing the amount of electrode material, which increases physical size of the battery and results in a form factor and aesthetics that most consumers would find unfavorable in a wearable device. While is it plausible that the incorporation of efficient displays, low-power processing, energy harvesting, and creative battery placement could eventually address these power requirements, IHS assesses this is unlikely to occur until the tail end of the forecast period.

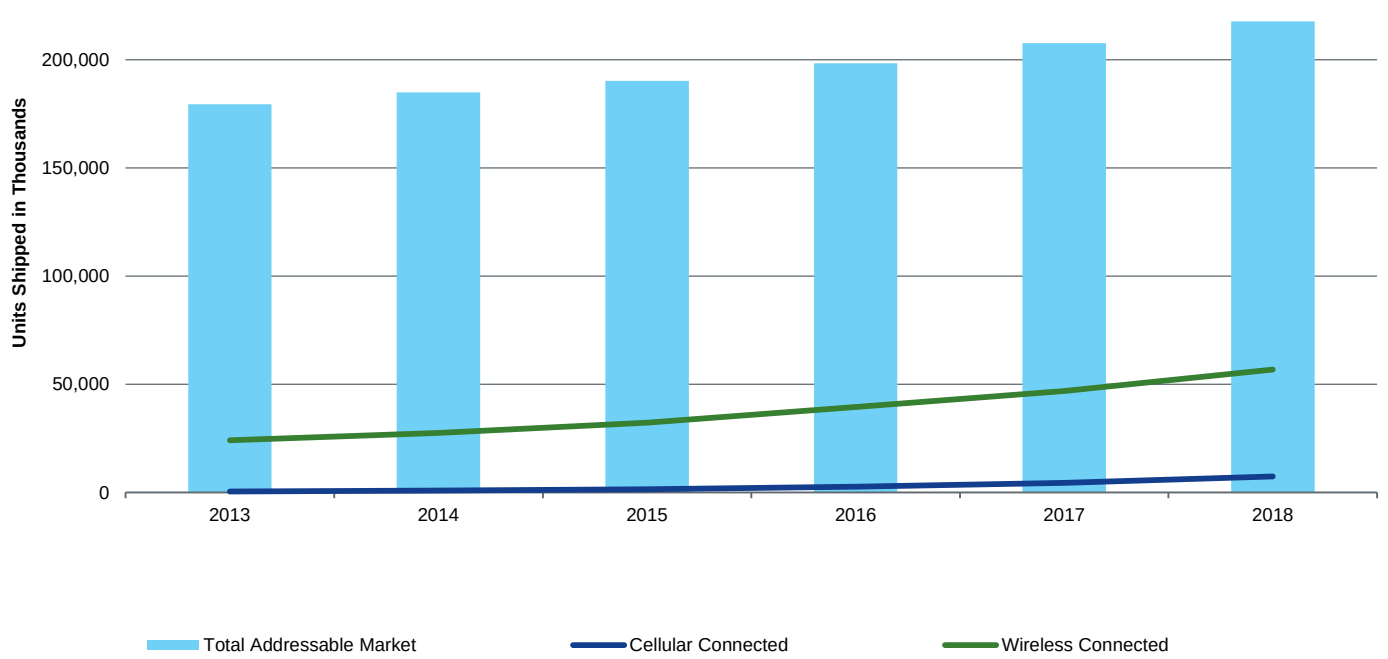
The significantly higher cost of embedding cellular versus a short-range technology is also noteworthy. IHS estimates that based on the bill-of-materials (BOM) costs alone, this gap is $20-$70 (depending on the specific type of cellular technology used). The more complex design and certification requirements of cellular technology further increase the cost of bringing such devices to market. This cost disparity is problematic in the healthcare market in which increased competition and economies of scale have led to dramatic declines in the average sales price (ASP) of most devices.

As this market becomes increasingly saturated, it is expected most manufacturers will be hesitant to embed cellular and increase the ASP of their healthcare devices, especially since short-range technology provides a sufficient level of connectivity for most consumers. Therefore, IHS believes it is primarily in the more limited, high-end segment of healthcare devices where embedded cellular M2M technology will be offered.

It should be noted that there are detractors that point out that the tethering process required when using a short-range technology could be confusing for some users, most notably the elderly who happen to be the key demographic for many healthcare devices. There are also concerns that these applications could drain the battery of phone quickly, and a handset with no power would obviously be unable to transmit the patient's medical information.

While legitimate concerns, IHS believes they are far outweighed by the cost, power consumption and other advantages offered by these short-range technologies. Due to these issues, the use of short-range technologies is expected to far outpace that of cellular in healthcare devices during the forecast period. As seen in Figure 3, IHS forecasts that the annual number of cellular-connected healthcare devices will grow from 500,000 in 2013 to nearly 7.5 million in 2018. During this same time period, healthcare devices with a short-range technology will grow from 24 million to nearly 57 million.

Figure 3. Wireless Technolgies in Healthcare - World - 2013 to 2018



Source: IHS

Shift in global healthcare industry represents unprecedented opportunity

Escalating expenditures along with declining resources worldwide are among the factors converging to drive change in the healthcare industry. A study by the Groupe Spéciale Mobile Association (GSMA) found that worldwide, total healthcare spending now exceeds USD $4.2 trillion, consuming an average of 10% of GDP in OECD countries, and that this figure is increasing at an average of 5% every year. In most countries, spending on healthcare systems is not expected to increase at a sufficient rate to maintain healthcare services. At the same time, it is anticipated there will be a shortage of healthcare personnel in coming years, with the World Health Organization (WHO) estimating that 4.3 million more healthcare personnel will be needed by 2015 to maintain current standards of care.

For these reasons it is generally agreed upon that the cost and resources required to treat patients in a traditional manner is no longer sustainable and that more affordable and efficient models of healthcare delivery must be developed. This is not a simple task to accomplish and will likely entail complex restructuring throughout several areas of the global healthcare industry. However, there is a general consensus that the greater use of technology to treat, diagnose, and monitor patients remotely must be a key component of this transformation to more cost-effective, yet high-quality medical care. IHS believes it is this shift toward remote patient monitoring (sometimes referred to as "telehealth") that provides the best opportunity for the growth of cellular M2M in the healthcare market in the years to come.

While some telehealth and other remote monitoring services have been on the market for over two decades (and the evidence on their effectiveness has been publicly available for a number of years), IHS believes this market has not yet reached its full potential. While interviewees noted multiple reasons for this, the two most commonly cited reasons for this were insufficient levels of reimbursement and low level physician engagement. Each of these issues, however, are showing some signs of progress.

- The fact that reimbursements for remote patient monitoring services are not equivalent to those given for face-to-face care and treatment has long been viewed as the biggest barrier to growth. Although reimbursement for telehealth is still currently considered to be low, it is increasing and there is strong movement in the regulatory environment that suggests this trend will continue. For instance, in the United States, where reimbursement for remote patient monitoring is approximately $10 per day, the Telehealth Enhancement Act would expand reimbursements for services under Medicare and Medicaid. Similar activity is occurring at the state level. In 2013, Arizona and Montana become the latest US states to sign into law requirements for private insurers to cover healthcare services provided via telemedicine comparable to that of in-person services. Nineteen states now have similar laws.

- Physician engagement has been a major barrier for telehealth and there are still some providers who are doubtful of the positive effect remote patient monitoring will have on healthcare quality and costs. However, IHS believes a number of successful telehealth programs have improved the general awareness and perception of telehealth in the healthcare community, which has resulted in more physicians becoming ambassadors for its use.

Additionally, a driver for remote patient monitoring is that many of the large healthcare reforms being proposed by governments around the world are focusing on patient-centered healthcare. These reforms support changing incentives for healthcare providers from quantity towards quality of care. IHS believes there will be strong synergies between the growth of remote patient monitoring and this future direction of healthcare.

- First, most accept that remote patient monitoring improves the care experience because most patients would prefer to be monitored at home rather than at a hospital. Therefore, as patient-centered healthcare reforms are increased, the use of these solutions seems likely to increase.

- At the same time, the ability of telehealth and remote monitoring to decrease readmissions will become increasingly important as many of these new patient-centered reforms severely penalize healthcare providers for patient readmissions within 30 days. For example, as part of the Affordable Care Act in the United States (which took effect on 1st January 2014) an estimated 2,225 hospitals will lose 2% of their reimbursements due to readmissions within 30 days. The penalty will rise to 3% on 1st October 2014 and will cover a wider range of chronic diseases by the end of 2015. The United Kingdom has also implemented a similar readmission reduction program. IHS believes these penalties are likely to compel more healthcare providers to incorporate telehealth or remote patient monitoring solutions after discharge.

Due to a complex mix of drivers and barriers it is extremely difficult to predict the year that remote patient monitoring services will truly emerge and become a mainstream component of the healthcare industry. However, the forecasts provided in this report expect this market to grow considerably beginning in 2016, with its adoption in healthcare sectors around the world accelerating in subsequent years.

IHS believes that the growth of telehealth and remote patient monitoring will present a substantial opportunity for greater use of cellular M2M technology in the healthcare market, particularly in the years beyond the forecast period of this report. Though numerous communication technologies will undoubtedly be used to connect remote patient monitoring devices, cellular is expected to play a significant role, particularly as many of these devices will be used to monitor critical and severe health ailments. With such conditions, the unique ability of cellular to provide real-time, constant monitoring in all locations will be viewed as essential.

The opportunity for M2M in wearable technology

IHS estimates that over 103 million wearable technology devices were shipped in 2013 and that this number will exceed over 200 million by 2018. Much of the next wave of wearable technology will be headwear and wrist-worn devices that support social, gaming and infotainment applications. (It is important to note such devices are not included in the TAMs in this report.) But the market will remain diverse, with a considerable share of devices exclusively providing health-related applications. Just a few examples of such devices include continuous glucose monitors, ECG monitors, patches for drug delivery, personal emergency response systems (PERS), heart rate monitors, and pedometers. Implantable devices that control medication disbursement will further expand the market in years to come.

At the end of 2013, IHS estimates that the wireless attach rate in wearable technology devices was 39%, a figure propelled almost exclusively by the incorporation of *Bluetooth* and ANT+. For the most part, wearable technology devices with embedded cellular are nonexistent, with the most notable exception being PERS devices.

As noted earlier in this report, outside of the added cost, the primary challenge in incorporating cellular into wearable technology devices is supplying sufficient battery power in an aesthetically-pleasing form factor. Despite this challenge, in recent months IHS has noted a series of releases and announcements of cellular-connected wearable devices.

- The Neptune Pine and the Androidly smart watches feature embedded cellular, allowing users to take and receive calls without tethering to a separate handset. To enable this capability, these products feature 900 mAh and 800 mAh batteries, respectively (far larger than the 140 mAh to 315 mAh batteries offered on most smart watches currently on the market). Not surprisingly, these large batteries have resulted in sizable devices that IHS believes are not generally considered aesthetically-pleasing by most consumers.

- At the 2014 Consumer Electronic Show (CES), Intel revealed it is developing a smart watch with embedded cellular and smart geo-fencing. While details are limited, it is expected the product will be released within a year.

Of the wearable technology currently on the market, PERS devices have seen the greatest incorporation of cellular technology. Recent product releases in this category include the AT&T EverThere and Philips Lifeline GoSafe. By embedding cellular, these PERS allow the wearer to notify the emergency responders that medical assistance is needed even in locations outside of the user's residence (traditional PERS are connected only when the patient is in the home).

Throughout the forecast period, IHS assesses that PERS will continue to constitute the largest portion of wearable technology using cellular M2M. Though these devices will represent the high-end of the PERS market, the considerable additional safety and peace of mind they provide over traditional offerings is important enough that many consumers will be willing to pay the higher cost. At the same time, the need for larger batteries to enable cellular connectivity is less of a concern as an appealing form factor is not considered integral for a PERS device.

For cellular M2M to be embedded in other healthcare-focused wearable technology there needs to be a similar demonstration that the technology provides significant advantages over the more common short-range tethering solutions. The most likely instance of this criteria being met is in devices that monitor critical healthcare conditions. Such wearable devices that IHS believes would likely incorporate cellular in the near term include ECG monitors, insulin pumps, and continuous glucose monitors (especially for Type 1 diabetics as they need to test their blood-glucose levels several times a day).

IHS expects that for most other healthcare-focused wearable technology, including sports and fitness devices, embedded cellular will remain limited throughout the forecast period. Despite the above product announcements, the technological advancements (to include efficient displays, energy harvesting techniques, etc.) needed to create aesthetically-pleasing, cellular-connected wearable devices will take several years to refine. The expected higher ASPs of the cellular-connected wearable devices will also pose a challenge in what is already showing signs of becoming a price-competitive market.

Conclusion

At present, the use of cellular M2M in the global healthcare market is extremely limited. While it has generated significant interest from key players in recent years, the core obstacles inhibiting greater uptake, to include the prevalent use of alternate connectivity solutions and the complexity of the healthcare regulatory processes, are substantial. IHS believes overcoming these and other challenges will require considerable time and that it is unlikely that there will be solutions that completely address these issues during the forecast period of this report.

However, as reflected by its considerable addressable market, healthcare represents one of the largest potential markets for cellular M2M. While as of yet this potential has largely gone unrealized, fundamental changes in the global healthcare industry, most notably the growing reliance on remote patient health monitoring, present an unprecedented opportunity for cellular M2M in the healthcare space.

Due to its unique mixture of immense potential yet relatively tepid implementation to date, healthcare is the most debated vertical market in the M2M industry. Views on cellular M2M's future role, or lack thereof, within the healthcare market vary widely. Even for those that share optimism about future growth, there are vastly divergent views about when this uptake will occur. As seen in this report, IHS expects that in the near term the use of cellular M2M in healthcare will remain low, particularly when compared to other key M2M vertical markets such as automotive and utilities. However, in the years beyond the forecast period, IHS believes that the elimination of key barriers and convergence of key drivers will create an environment in which cellular M2M in healthcare can begin to realize its full potential.

