

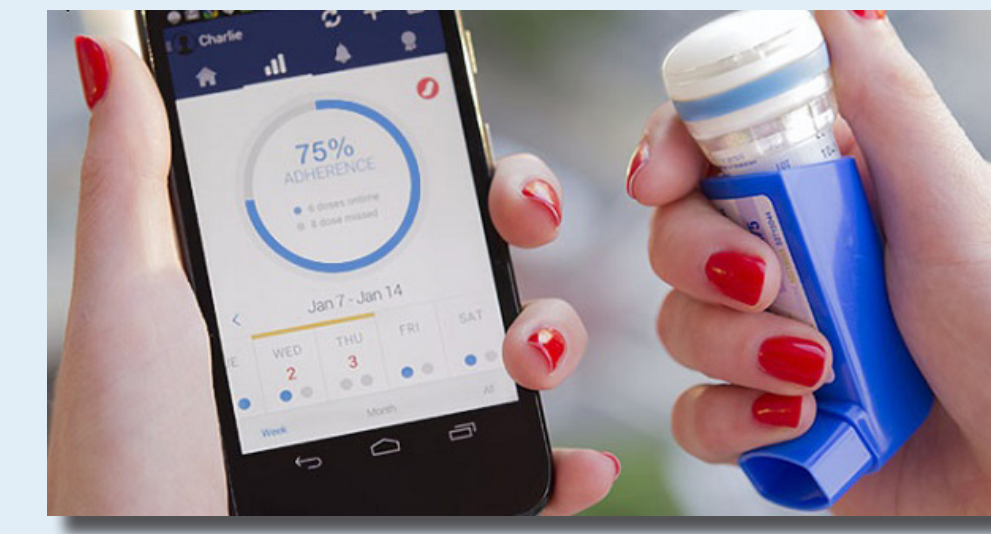
Applying the EpiPen Case Study to Implementation of Smart Medication Telemanagement (SMT)

Common challenges and the strategies and tactics to help overcome them

Challenges



EpiPen Case Study



SMT Take-Aways

Pharma industry and healthcare practitioner conservatism.

Many doubted that emergency self-administration of epinephrine could be successful. Appropriate technology did not exist. Individuals (researchers, practitioners, device developers, component suppliers and many managers) focused and led to push the product forward.

Technology is available to enable SMT. While some still question Pharma's role in providing service, leadership is taking shape. A focus on taking the high ground, on saving lives and improved quality of life builds enthusiasm among all stakeholders, including employees.

Deciding how to "own" the patient relationship.

Initially no one owned the EpiPen relationship with patients. Then, Mylan took ownership in many ways.

Understand and partner with the current pharma product owners, patients themselves, practitioners and PBMs/ pharmacies, and successful consumer-facing companies can drive SMT adoption.

Siloed Pharma industry structure and leadership.



Mylan leadership apparently won the important battles and led all the stakeholders. For example, Mylan's track and trace team proved well informed on SMT at the first FDA conference on pharma serialization.

Build and support your teams developing SMT.

Political risks/uncertainties.

Mylan took the lead in promoting the benefits and broadening the EpiPen user and support bases.

Show that SMT will save money and improve outcomes; follow the U.K. and French mandates for telemonitoring; and encourage payment parity. Emphasize the benefits to chronic care management, transitional care management, and alternative payment systems.

A lack of regulatory clarity, especially from FDA.

Mylan understood how a company can help modify coming regulation to be less burdensome to industry AND provide benefits to patients and further Mylan's interests.

Unified pursuit of clarity and simplicity consistent with the public good can move SMT forward.

The existential threats to any business.

Badly defined, unmeasurable goals; wrong partners; contractual disputes. The EpiPen suffered from most of these and still survived.

Apply today's techniques and experienced stakeholder knowledge.

Changes in direction and leadership.

These plagued EpiPen. Mylan's purchase of EM and focus on treating anaphylaxis resulted in the current success of EpiPen.

Prioritizing and assigning long-term ownership of SMT is key.

Liability and litigation threats.

Some feared introducing the EpiPen, especially giving it to kids. Weighing the benefits led to taking the risks.

Some fear having product information from patients. Understanding that ignorance is an ever weaker defense and that FDA and many others are already gathering data on your products leads to the conclusion that one should position oneself with information from SMT.

Technical risks associated with injection devices and IT.

The EpiPen, not the most advanced device available today, still leads all competitors in its class. It may evolve to maintain leadership. A new competitor will enter. Another company has developed a connected companion product, Veta, for the EpiPen.



Consider the benefits of SMT and the risks of NOT participating.

Little understanding in healthcare outside Pharma about the importance of intellectual property (IP) in emerging technologies.

Mylan and others used EpiPen IP, including a strong brand to develop investor and other stakeholder relationships, and block competitors.

Develop your SMT IP strategy. Consider following models in the electronics industry.

SMT presents challenges beyond those of an unconnected auto injector. Some of these are:

- Security, confidentiality, secrecy, and HIPPA concerns
- Lack of EMR/PMR interoperability
- Following other industries in supporting healthcare improvement initiatives. PERS, banking and aerospace have tools to better manage at low cost.
- Integrating SMT devices and systems into healthcare using professionally staffed monitoring facilities.

The EpiPen case demonstrates some tactics and strategies for Pharma stakeholders partnering to create SMT systems that can improve the quality of life for patients and Pharma profitability. Great opportunities now await those who become part of this industry segment.

Help ensure that SMT is understood within and outside your company. Support: proof of cost-effectiveness; standards and best practices; telemedicine payment reform; informed regulatory IT compliance and regulatory streamlining; human factors design and behavioral analysis; patient stratification to identify those who will most benefit; standardization of sensors, ability to make IT modifications based on experience, scalability and tort reform. Learn from and partner with successful consumer-facing companies. Above all, support stakeholder involvement.



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