



White Paper

Closed Loop Electronic Medication Management (CLEMM)

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1. EXECUTIVE SUMMARY

1.1 CLEMM

This White Paper investigates the general market attractiveness, demand drivers and potential benefits of the Closed Loop Electronic Medication Management system (CLEMM). This breakthrough clinical and business solution with integrated packaging, electronic reporting and sophisticated clinical capabilities provides point-to-point medication reconciliation, risk and process control—to ensure that the right drug at the right dose reaches the right patient at the right time.

This investigation reveals the shortcomings of current technologies and approaches to closed loop medication management. Furthermore it challenges the nature of what customers have typically expected a closed loop medication management solution to do. As a result the market segment for such products remains ill-defined. Because of the highly fragmented nature of the global healthcare marketplace customers are turning to a multitude of technological solutions in an effort to improve patient care and accommodate cost increases. This makes to intended market niche less attractive than a larger, more rewarding segment that is emerging as customers have known clinical and implementation problems CLEMM will solve.

The key findings from the research are therefore very much about providing a targeted solution to users who want improved quality of care, and less complexity and cost associated with adoption of information and communication technology (ICT).

1.2 METHODOLOGY

Phoenix Corporation Pty. Ltd. engaged with the lead researcher Dr Marcus Bowles from the University of Tasmania under the Researcher in Business (RiB) initiative. RiB is an element within Enterprise Connect (www.enterpriseconnect.gov.au) and supports the placement of researchers from universities or public research agencies with innovative firms.

The study was conducted in an international context and examined data and research affecting the varying aspects associated with validating CLEMM's commercial value in the marketplace. This included studying the solution design quality, product features and benefits, market attractiveness, competitive positioning and appropriateness given existing healthcare ICT initiatives. More detailed investigation was conducted on specific countries to inform market entry strategies likely to be developed in support of the initial business strategy.

1.3 STUDY OBJECTIVES

Through this research Phoenix sought to:

- help build a collaborative research partnership with University of Tasmania on taking e-health applications 'to market' in a robust business model and development paradigm;
- collate expert insights and knowledge from the latest international research on medication management practices, shortfalls of current applications and the potential benefits to be derived from adopting CLEMM;
- an 'in-principle' design for evaluating pilots and reviewing data from trials being conducted by early adopters of CLEMM;
- secure data and information necessary to refine the features of this system and quantify its health benefits; and
- provide a single, academically and commercially robust document able to inform marketing and encompass the features and business advantages of CLEMM.

1.4 FINDINGS

Implementing new information and communication technology in healthcare is often a delicate balancing act between the promise of significant quality and efficiency improvements^{1 2 3} and the difficulties of executing the transformation.

The impact of information and communication technology (ICT) has dramatically changed the landscape of healthcare around the globe. By and large the promise of cost reduction and improved access and quality of services has been heavily offset by the difficulties associated with technology adoption. These difficulties include financing innovative solutions, integrating different technologies and networks, unwanted changes to accepted work practices, extensive reskilling of users and, ultimately, highly visible examples of the failure to deliver initiatives on budget or on time. All these factors reinforce a dark side to ICT adoption that tends to make all stakeholders in healthcare increasingly cautious.

Closed Loop Electronic Medication Management (CLEMM) leaps ahead of early medicine management solutions, which were costly and complex and typically required long lead times to achieve effective deployment.

Around the globe healthcare providers face the challenge of providing effective medication management in ever-extending supply chains that span disciplines, service providers, and even geographic locations. This has significantly increased the complexity of service delivery and accounted for accelerated costs. The ability to provide equity of access to medication and quality healthcare services is under threat, especially in regional areas.

CLEMM is a breakthrough in how ICT can improve healthcare delivery associated with medication management. As with many important breakthroughs CLEMM is an elegant solution that draws on existing global practices and employs a compelling business model. Using smart, mobile technology and communication networks CLEMM returns control to those directly responsible for delivering healthcare to the patient. Moreover, it is a 'turnkey' solution requiring no upfront capital expenditure or reinvestment in new skills or technology.

In the world of e-health there is often a significant disconnect between the imperative of those funding ICT initiatives and medical professionals responsible for implementing the technology.

CLEMM not only was developed to solve the closed loop medication management requirements sought by funding bodies, but was designed by people who have worked in or been responsible for implementing ICT in medication management processes around the globe. CLEMM is therefore designed to improve access anywhere at any time and to ease adoption without sacrificing the very improvements to quality or efficiency all stakeholders demand.

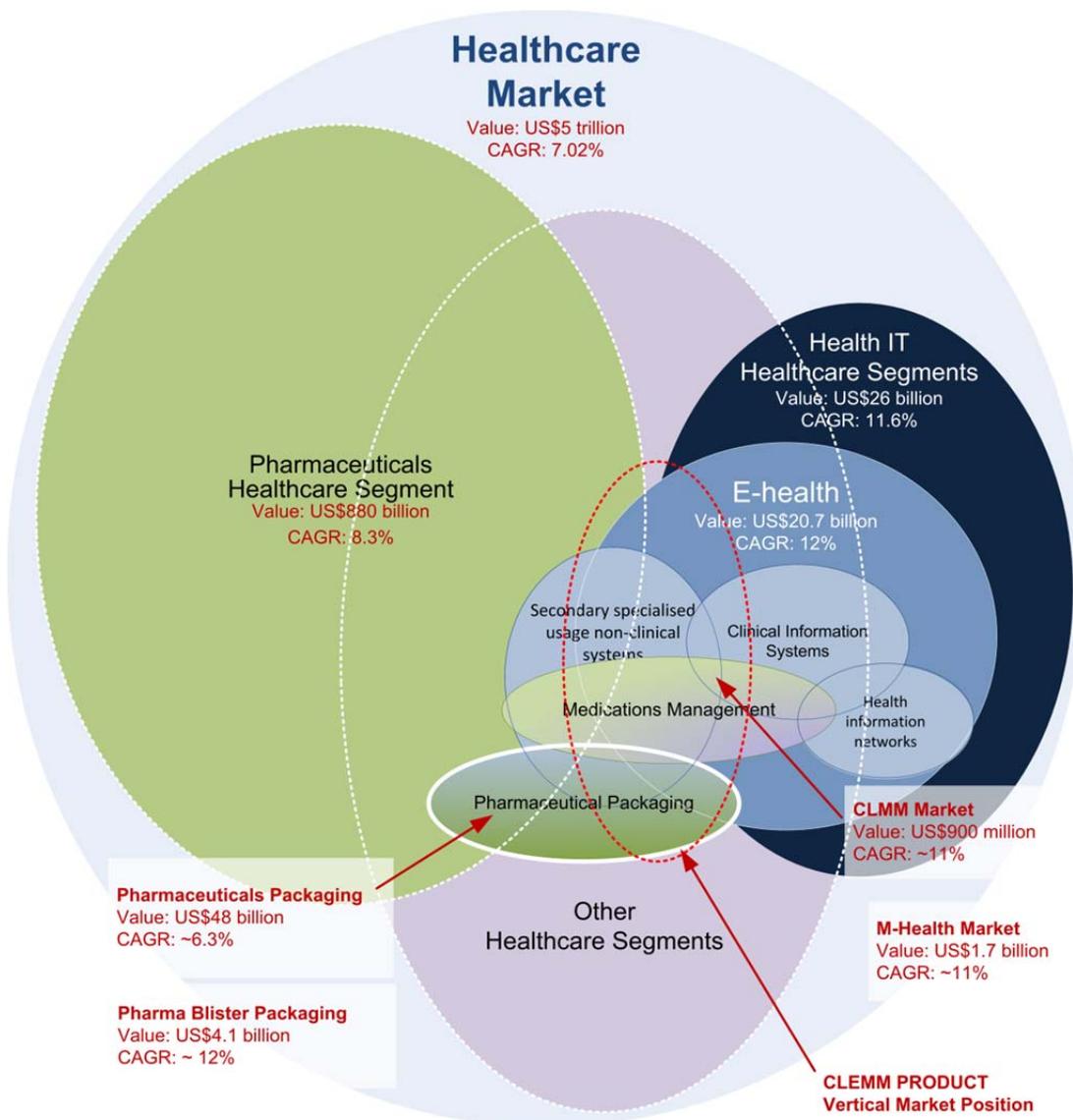
Figure 1: CLEMM attributes



The healthcare market is extremely fragmented. This often makes it hard to position technology into a market, let alone accurately determine the customer or commercial benefits.

CLEMM straddles various segments within a huge, highly fragmented, US\$5.3 trillion healthcare marketplace. Its design and features extend CLEMM’s market attractiveness beyond the US\$900 million closed loop medicine management niche of the electronic health (e-health) market segment. As represented below, CLEMM integrates packaging, supply chain management, clinical information systems, medication management and electronic reporting capabilities that individually and collectively hold significant market attractiveness in the broader healthcare, pharmaceutical, medicines packaging, medicine management, mobile health (m-health) and e-health segments. To existing and emerging companies in all these growing market segments CLEMM offers a differentiated product and a business solution that combines both clinical and commercial appeal.

Figure 2: CLEMM straddles high-growth segments in a fragmented healthcare marketplace



The market occupied by CLEMM has strong growth within and across all core segments. Further, the market encompasses developed and developing countries. A review of healthcare and ICT development in selected countries confirms a compelling set of market performance index data within the global marketplace. The data from different parts of this White Paper is provided in summary form below.

Table 1: Health ICT market data by countries of interest

Country Indicators	Australia	Brazil	China	France	Germany	Hong Kong (SAR)	India	Japan	Singapore	UK	USA
Total healthcare expenditure 2010* (US\$ billion PPP)	96.7	201.6 ⁴	240	245.3	358	13.68	77.3	345	8.98	205.2	2,300
Health CAGR 2010*	5.2	6	17	2.9	2.8	11.2	12	4.7	7	1.8	4.4
Actual GDP (US\$bill 2010) [#]	1,220	2,230	2,998	2,555	3,306	226	1,430	5,391	292	2,259	14,624
Total health expenditure as % of GDP 2010	9.8	9.0	4.6	11.7	11.3	5.2*	4.2	8.3	3.9	9.3	16.2
GDP Growth ⁺	1.3	-0.6	9.1	-2.6	-4.7	-2.8	9.1	-5.2	-1.3	-4.9	-2.6
Health expenditure per capita (\$us Purchasing power parity)	3,867	3,867	177	4,798	4,629	1,582*	45	3,321	1,501	3,285	7,410
Public health as a % of total health expenditure	65.4	45.7	50.1	76.6	75.7	57.2*	32.8	80.0	41.1	83.6	48.6
Demand for healthcare [^] (proportional ranking out of 10)	5.7	5.1	1.6	5.1	4.7	-	1.4	3.7	-	4.7	8.3
Mobile phone subscribers per 100 people	111	90	56	95	128	174	45	90	133	130	97
Internet users per 100 people	72.0	39.2	28.8	71.3	79.5	61.4	5.3	77.7	73.3	83.2	78.1
Availability of latest technologies (1=not available to 7 = widely available, mean = 4.9) [^]	8.7	4.5	1.0	8.0	8.0	8.4*	5.2	8.0	8.2	7.6	9.0
Ease of doing business ranking (1=best to 183 lowest)	10	127	79	26	22	2	134	18	1	4	5

Source: World Bank⁵; World Health Organization⁶; US Dept Health & Human Services⁷; and UK Office of National Statistics⁸.
⁺Annual percentage growth rate of GDP at market prices based on constant local currency. [^] Source: PwC, 2011⁹ * Estimated, based on WHO 2009 data (<http://www.who.int/countries>) and extrapolated estimates of 2010 total population and 2009-2013 CAGR. [#] Source: Global Finance¹⁰

Medication management is a growing problem in healthcare delivery in all nations of the world. Put simply, a direct relationship exists between the quality of medication management systems (MMS), numbers of errors and adverse drug events, quality of patient outcomes, and healthcare costs.

Previous solutions have required a large upfront investment in infrastructure, delivery management, training and improvements for the integration of electronic reporting with the management of medications from point of prescription to the patient. Characteristics of a top-down (the current) approach to e-health include:

- Patient records the focus and driver;
- Compliance with national e-health or electronic health records (EHR)/electronic medical records (EMR) initiatives, and efforts to standardise data and implementation;
- Centralised database model;
- Multiple outputs – COWS (computers on wheels), iPad, handheld devices, and such like;
- Information overload for staff trying to make sense of disaggregated information and data that flows from a spiralling number of applications, networks and professional involved in patient care;
- Critical success factor of change management;
- Dominance of silos within ancillary services, e.g. x-ray, pathology, pharmacy;
- More funds shifting away from primary care delivery to improving communication and management due to growing complexity.

Problems with existing approaches include the following:

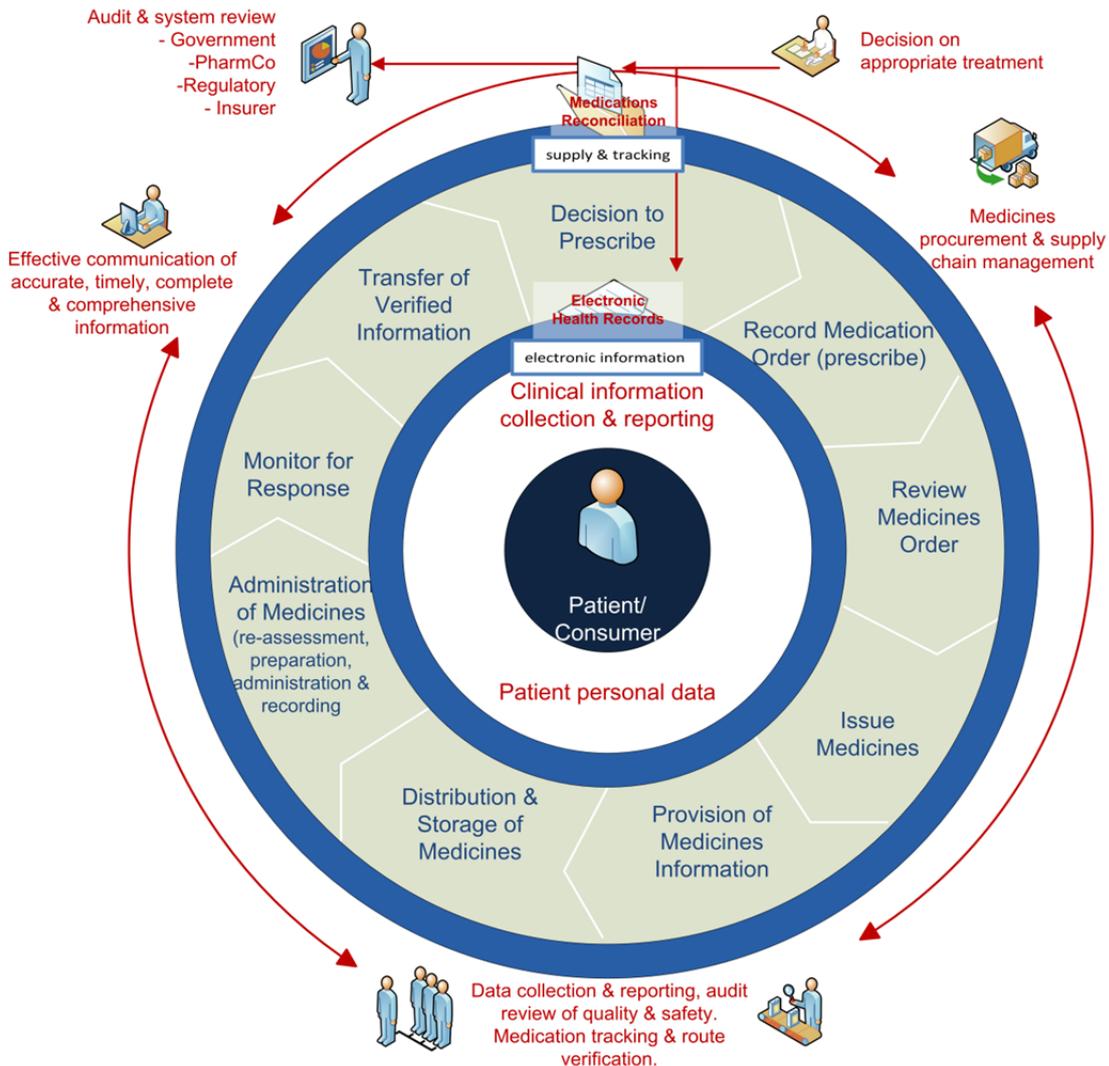
- Current health applications are generally expensive and require large capital outlays.
- In-house infrastructure requires additional maintenance.
- Government procurement processes often require long lead times and limit scalability or the capacity for institutional innovation.
- Regional delivery suffers from the ability of a central system to ‘reach’ the regions or regional health budgets are simply too thin to sustain the overheads.
- Increasing demand for health services has resulted in fewer skilled professionals to manage a large number of low-skilled health workers.
- National initiatives promoting shared health records and medication management rarely succeed as well as organic, local initiatives that originate at the junction of those providing healthcare with local demographic requirements.

Current efforts to close the loop in medication management also have a single, pervasive flaw: The loop does not encompass the lifecycle of the medication management requirement or provide a systems-level view on each medication management episode of care. As a result most existing closed loop medication management (CLMM) technologies fail to manage the pre-pharmacy packaging and supply from the manufacturer. Equally, the follow-up and prescription renewal stages after delivery of the medication to the patient are omitted. These omissions respectively limit the ability to reduce errors and costs introduced into the clinical loop through fraud (counterfeiting, diversion and substitution) or waste.

All parts of the process must be addressed before a single component of the medication management process (MMP) can be fully improved. To truly close the loop the complete medications lifecycle (loop) has to be under control. This requires a fundamental extension of current technologies and the current paradigm associated with the medications management process to encompass the supply chain management conceptualisation of ‘closed loop’. This concept accepts it is equally important to manage the problems introduced into the process prior to or even after the clinical ‘loop’ that has traditionally spanned from prescription to patient receipt of medications.

The image below depicts this reconceptualization of a closed loop medication management process that spans the lifecycle of a medication supply chain. Its layers include both clinical reporting and an audit trail for medications reconciliation across all points in the movement of medications from manufacture through to monitoring and follow-up after a patient receives the medication.

Figure 3: A complete closed loop medication management process



1.5 STRUCTURE OF THE WHITE PAPER

As with any report covering both information and communication technologies (ICT) and global healthcare this White Paper commences by defining the parameters of our study. To do this we first investigate the global healthcare market and conceptually place a closed loop medication management (CLMM) solution into a market segment. The collection of data on markets is then deliberately refined as understanding improves and assumptions are challenged as to the market segment and customers of CLEMM.

After an investigation into the global healthcare market and CLEMM's market position, an investigation is conducted of the key factors driving the demand. In section 3 a study is conducted on the cost of adverse drug events (ADEs) and why medication management systems (MMS) are so important. Coupling this section with the previous on markets the White Paper then uses insights gained to analyse the features of the CLEMM technology, product and clinical benefits.

Based on previous data and findings the White Paper concludes with two sections specific to development of and the commercial future CLEMM. Section 5 addresses the pathways to commercialisation and section 6 concludes by proposing how future research and testing can both refine and confirm the clinical and commercial benefits to all stakeholders.

1.6 CONCLUSION

Evidence suggests CLEMM is more attractive to a larger market segment than suggested in the commercial documents provided to the research team. But the market is fragmented and distracted by the noise and hype surrounding less effective technologies and poorly conceived theories of ‘closed loop’ approach to medication management. This represents an ideal opportunity—a quality solution that removes complexity from the user experience—while reinforcing the importance of correctly planning how CLEMM is be ‘taken to market’.

In addition CLEMM incorporates technology and business principles that suggest ancillary opportunities exist in terms of emerging markets. For instance, CLEMM should not be considered as residing only in the closed loop medication management (CLMM) niche. This niche is too small and restrictive in terms of functionality presented to users. The report depicts the opportunity for sales of CLEMM to pharmaceutical manufacturers, packaging companies, e-health vendors, telecommunications providers, regulators, or governments seeking systems-level electronic reporting. Such findings shift the possible market opportunity from hundreds of millions of dollars to multi-billions of dollars. This is extended upon even further with investigation that confirms unidentified opportunities for sales in emerging segments. For instance, the growing use of nanotechnology in packaging has been determined to position CLEMM as a solution able to assist customers searching for technologies or applications that can support the removal of counterfeiting in the supply of medications from point of manufacture through to point of delivery to a patient.

This White Paper contains a positive narrative and supporting information on the market attractiveness and competitive position of CLEMM. However, it also has been able to provide original data on the market situation and opportunities. While intended to be a report to Phoenix that can be made available for public use, research has provided insights owners and investors in CLEMM may seek to deliberate upon before a published version is released.

