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FUTURE OF AUSTRALIA'S ETP: SCRIPT EXCHANGE, SCRIPT VAULT OR SECURE MOBILE ALTERNATIVE

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Abstract

Electronic transfer of prescriptions is an essential element of electronic medications management. Unfortunately, current manual and preliminary electronic transfer of prescription methods are not patient focussed, leading to a suboptimal solution for the patient. This is increasingly relevant in the push for more patient engagement in their own healthcare. The area is highly controlled by legislation and regulation. Through research and an analysis of the possible methods to improve and personalise electronic transfer of prescriptions, this paper provides an overview of these conclusions, and presents an alternative technical solution. The solution has been derived from a number of experiments in data transfer techniques using a mobile phone. The paper explains how this meets the current regulations and legislation, as well as providing a patient centred approach to the problem. Ultimately, healthcare outcomes will improve where patients are given the opportunity and the tools to better engage in their own healthcare management, and secure electronic transfer of prescriptions with patient access to their own medication lists may improve compliance and reduce healthcare costs.

Keywords

ePrescription transfer, ePrescription security, mobile transfer of ePrescription, eTP, mobile eTP

INTRODUCTION

The use of electronic prescription (eTP) is the lifeblood of eHealth and in improving quality of care through better medication compliance, improved prescribing accuracy and efficiency while reducing the adverse drug events. In fact, electronic prescribing is an essential initial step of the electronic Medication Management (eMM) program which primarily focuses on improving medication-related outcomes through better quality and availability of medications-related healthcare information ("NEHTA Blueprint V2", 2011). Having an effective medication management system in place improves medication compliance and reduces adverse drug events. A recent study indicates almost 70,000 hospital admissions per year are associated with adverse drug events and poor medication compliance/adherence. This significantly contributes to having undesirable patient outcomes such as hospital readmission or even loss of life (White, 2015). The use of eTP enables eMM to reduce these undesirable outcomes and to prevent excessive use of healthcare expenditure while providing better patient safety.

Current eTP implementation converts the conventional manual prescription process/model to a digital equivalent using two Prescription Exchange Services (PES), *Script Exchange* from *eRx* and *Script Vault* from *MediSecure* (Htat, Williams, & McCauley, 2015a). Using these PES services, prescribers can upload the electronic copy of the prescription for later download and dispense by the pharmacies. The use of electronic prescription exchange not only connects the two major healthcare providers such as clinicians and pharmacists, but it also paves the way to create a national medication repository. Such a repository would allow clinicians, pharmacists, aged care facilities and hospitals to see a combined list of prescribed and dispensed medications regardless of how many different doctors and pharmacies the patient has visited. However, current implementation of eTP is an expensive operation to maintain as an ongoing process for the nation. The associated electronic prescription fees for each prescription downloaded from PES used to be as much as AU\$ 0.85 prior to achieving the interoperability between the two PES services. Some negotiations and cooperation between the Commonwealth, the Pharmacy Guild and the two PES operators managed to reduce the electronic prescription fees to AU\$ 0.15 per eligible prescription. This electronic prescription fees has, so far, been subsidised by the Commonwealth through a series of Community Pharmacy Agreements (CPA). However, the section 6.1.3 and Appendix-B of the current agreement, Sixth Community Pharmacy Agreement (6CPA), states that funding from 1st July 2016 and onwards will be subject to a cost-effectiveness assessment by an independent health technology assessment body as determined by the Minister ("The Pharmacy Guild of Australia", 2015). Since the eligibility criteria for this subsidy can be tightened or amended to the disadvantages of the pharmacies (i.e. current eTP implementation being a pharmacy user-pay system) ("FAQs", 2016), exploration of cheaper alternatives with comparable security measures to the current use of eTP is commendable.

WHAT ETP STANDARDS AND SPECIFICATIONS MANDATES VS CURRENT ETP IMPLEMENTATION

There are numerous standards and mandates regulating the management of medications in Australia. These include the Electronic Transaction Act (ETA) and various Acts and Regulations governing the Poisons and Therapeutic Goods. They have been repealed and/or amended at the Commonwealth as well as State and Territory level to accommodate the implementation of eTP in Australian healthcare. Figure 1 briefly depicts how these Acts and Regulations fit together to enable the current eTP implementation. It also demonstrates how the legislation and regulations in Australia are constructed and the complexity of this construction for eTP. The outermost circle represents the encompassing regulation for the entire nation. The next inner circle defines the regulations for each State and Territory amended as per jurisdictional legislative requirements. These two circles enable the use of electronic transactions at national, state and territory levels thus making the use of eTP and other electronic transactions possible. The third circle lists Acts and Regulations governing the Poisons and Therapeutic Goods for each jurisdiction which play a major role in enabling the use of eTP. The centre circle contains various standards and specifications developed reflecting those national and jurisdictional legislative requirements. It is named Dante's 4 circles of eTP as the closer the circle is to the centre the more eTP specific it becomes in a similar way the 14th century poet Dante Alighieri's depiction of nine circles of hell (i.e. lower circles are for more severe sins).

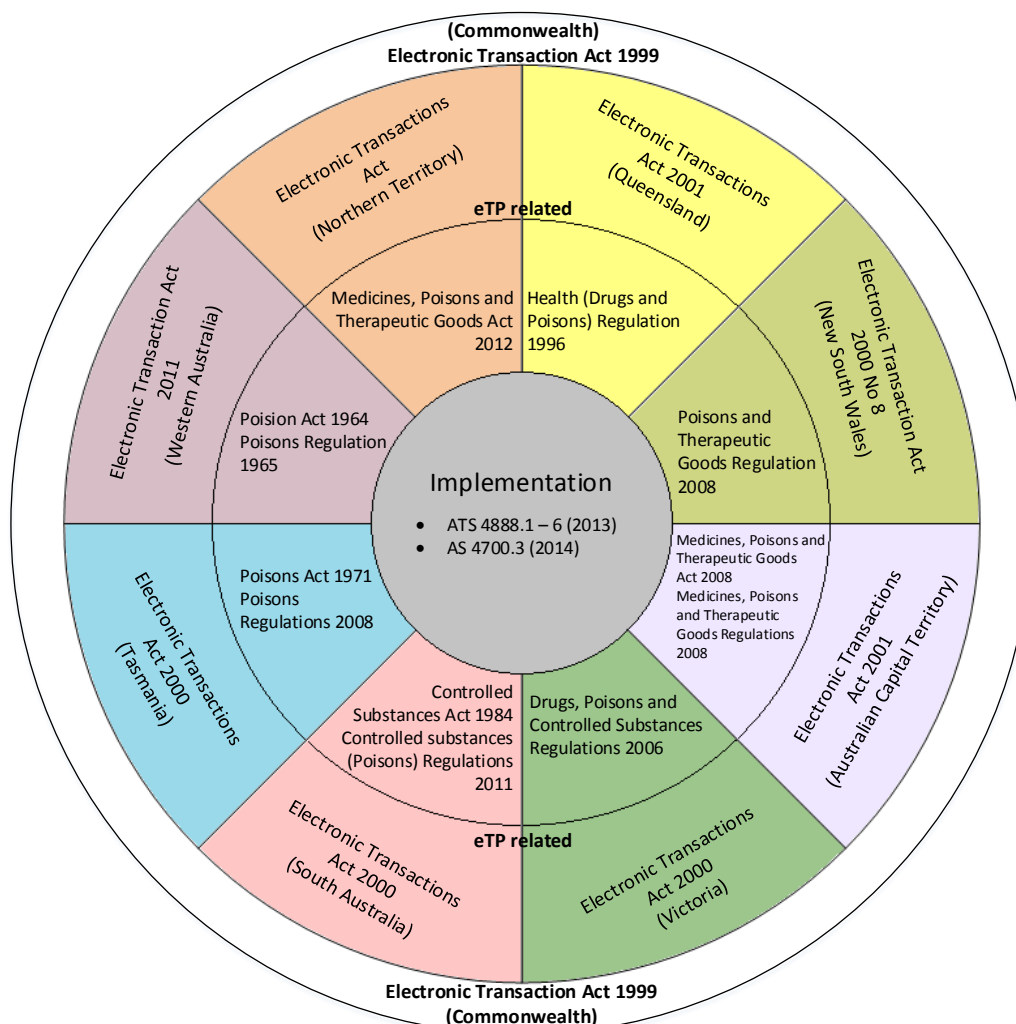


Figure 1. Dante's 4 circles of eTP

The Commonwealth Electronic Transaction Act 1999 facilitates the use of electronic means and enables the use of electronic communications in dealings with government, business and community for the future economic and social prosperity of Australia. Various States and Territories amend/adopt this overarching Act to suit their jurisdictional legislative requirements. This jurisdictional ETA and various Acts and Regulations governing the Poisons and Therapeutic Goods for each jurisdiction dictate the requirements for eTP implementation in that jurisdiction. After all the eTP requirements of all jurisdictions have been considered, various standards and

specifications have been developed reflecting those requirements. Among these related standards and specifications, ATS4888 series and AS4700.3 primarily govern the implementation of eTP. Current eTP implementation developed in compliance with these standards and specifications is briefly depicted in Figure 2.

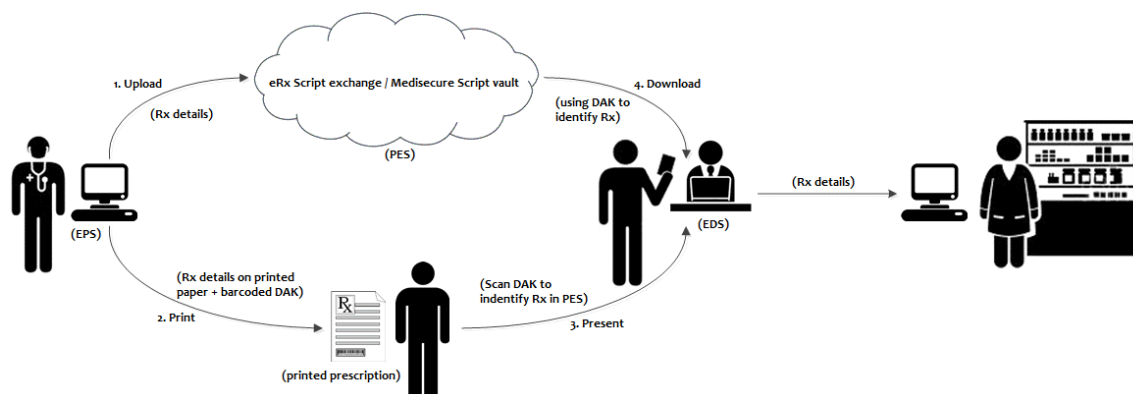


Figure 2: Current electronic prescription transfer model using PES (Htat, Williams, & McCauley, 2015a)

Although ATS4888.2 of the ATS4888 series particularly emphasizes on the platform independent model, it also includes specific details on securing electronic prescription information from the security of the data-at-rest perspective. It mandates that the electronic prescription to be encrypted using a symmetric key derived from the Document Access Key (DAK) before being stored on PES. DAK is the barcode printed on the paper prescription created by any eTP enabled electronic prescribing system. The current eTP implementation also makes use of DAK for authorizing access to the prescription stored on the PES and decrypting it after being downloaded from PES. In addition, section 7.3.3 of the ATS4888.2 strictly prohibits storing of DAK or any of its derived key on any stable storage (i.e. non-volatile storage) unless they have been encrypted using 128 bit encryption. Further details on securing electronic prescription from the security of data-at-rest perspective can be found in sections 5.3.3 - 5.3.4, 5.3.6 - 5.3.7 and 7.3.3 of the ATS4888.2. These sections provide an overview of the security mechanism implemented using the DAK for safeguarding prescription information. Figure 3 briefly illustrates how this security mechanism works.

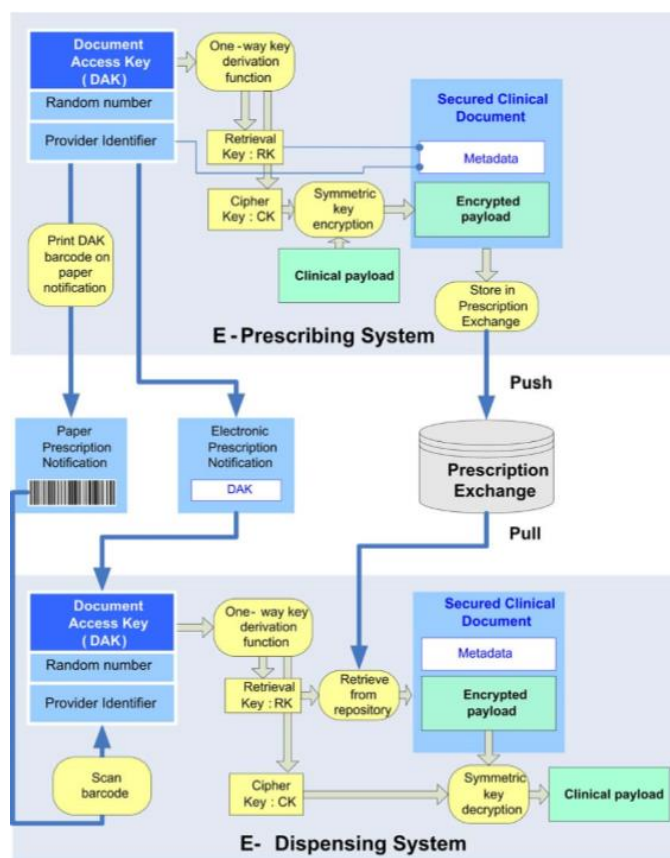


Figure 3: DAK usage for storage and retrieval of prescription with PES (Standards Australia, 2013, Figure 19)

On the other hand, although ATS4888.2 contains specific details on securing prescription information from security of data-at-rest perspective, it mentions very little on securing the prescription information from data-in-transit (i.e. data in motion) perspective. Both sections 5.3.5 and 7.3.3 of ATS4888.2 mention that securing prescription information from data-in-transit perspective entirely relies on the security and encryption mechanism of the implementation platform and the eTP technical specification for that platform. Research on eTP to date has not encountered any other standard or specification which includes further details on securing prescription information from data-in-transit perspective. Security in this context appears to be solely relying on existing industrial standards and best practices. Current implementation of eTP (i.e. both PES services) implements the simple Subscriber-Provider pattern instead of publishing their service endpoints using Endpoint Location Services (ELS) service infrastructure (Htat, Williams, & McCauley, 2016). Moreover, current eTP implementation does not utilize other eHealth infrastructural components such as Health Identifiers (HI) Services. Unfortunately, this leaves current eTP implementation considerable room for future improvement from security perspective.

Another disadvantage of the current eTP is its associated ongoing cost, the electronic prescription fees. Although the combined effort of the Commonwealth, the Pharmacy Guild and the two PES operators could reduce the fees to AU\$ 0.15 per eligible prescription, it is still a taxing expenditure for the nation on the long run. A recent survey by eRx found that pharmacies using eRx are dispensing 753,000 electronic prescriptions per day with up to 25 prescriptions per second during peak periods. When dispensing 753,000 prescriptions per day, it will cost the nation AU\$ 112,950 a day for electronic prescription fees alone.

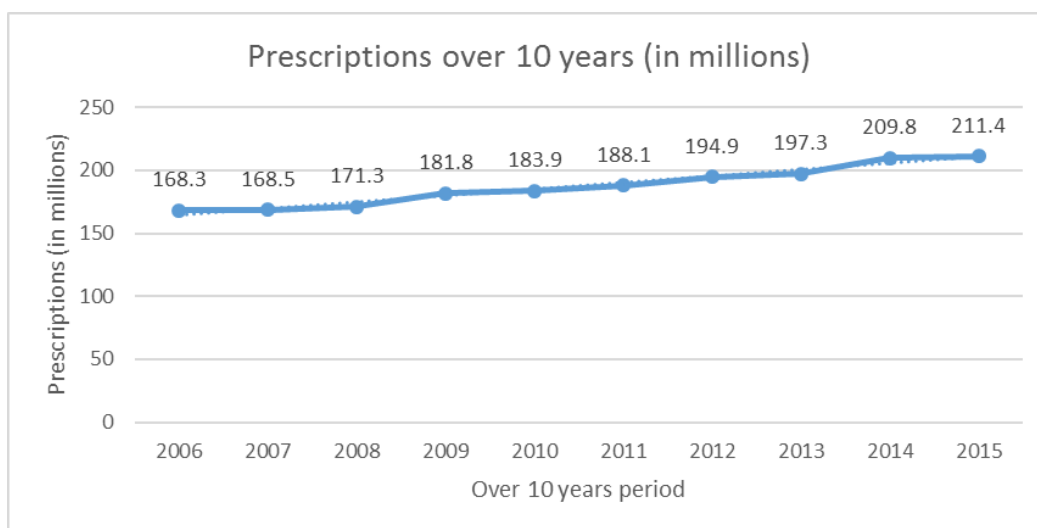


Figure 4. Number of prescriptions over 10 year's period

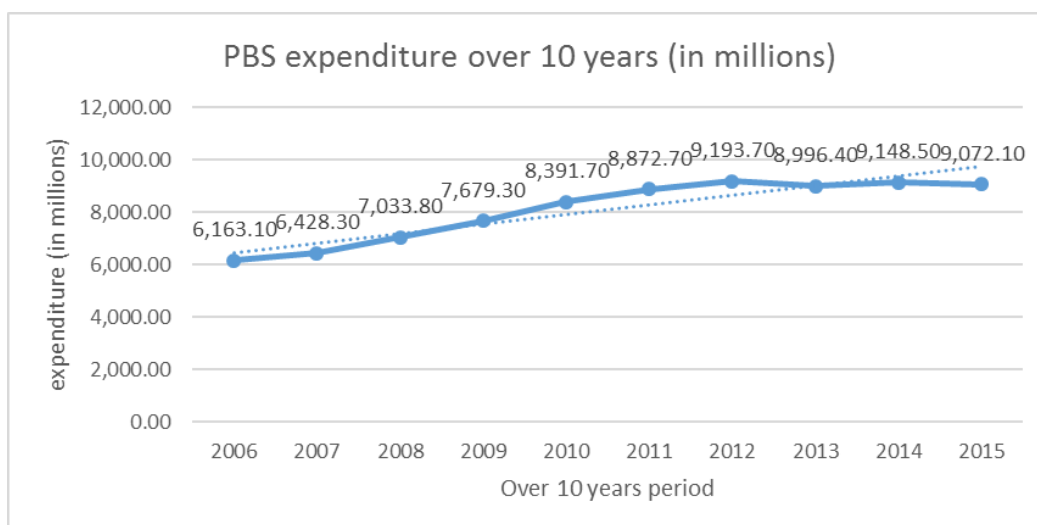


Figure 5. PBS expenditure over 10 year's period

Using statistics from the Pharmaceutical Benefits Scheme website, figure 4 and 5 depicts the number of prescriptions and PBS expenditure over the past 10 years. Based on figure 4 and 5, it is evident that although the PBS expenditure fluctuate slightly, the number of prescriptions increased steadily over the decade. Unfortunately, this indicates that unless less expensive alternatives are explored and utilized, the on-going expense associated with the use of electronic prescription will only cost more in future with increase in volume. At present, electronic prescription fees has been subsidised by the Commonwealth through a series of Community Pharmacy Agreements. However, despite the fact that current eTP implementation being designed as a pharmacy user-pay system ("FAQs", 2016), which party (among prescriber, dispenser and patient) will actually be liable to pay for this on-going cost when it is no longer subsidised by the Commonwealth and the ramification of this potential change is yet to be witnessed.

PROPOSED ALTERNATIVE MOBILE SOLUTION

The proposed mobile electronic prescription transfer application was designed to be a cheaper, if not completely cost-free, alternative with comparable security measures to the current eTP implementation using PES. This proposed solution makes use of the patient's smartphone as the secured transfer mechanism for transferring electronic prescription instead of using PES. Figure 6 roughly depicts how this model works and its simplified operations using the patient's smartphone in place of PES services whilst the rest of the operations remain the same as in the current eTP system.

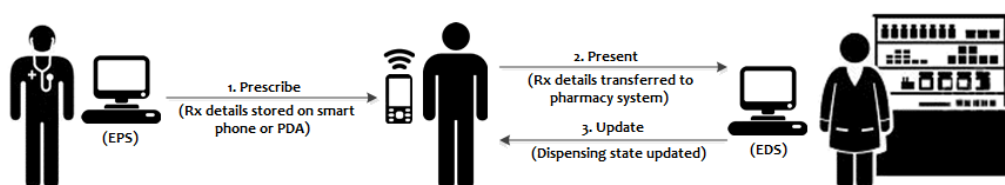


Figure 6: Electronic prescription transfer model using smartphones (Htat, Williams, & McCauley, 2015a)

In securing the prescription information from the security of data-at-rest perspective, this model also makes use of DAK for encrypting the electronic prescription prior to transfer (i.e. to the patient's mobile device) and decrypting at the pharmacy end. However, in this model, the prescriber's Electronic Prescribing System (EPS) also transfers the DAK together with the electronic prescription to the patient's smartphone for storage and transportation instead of using PES. The DAK is then encrypted using a 128 bit symmetric encryption, in compliance with the section 7.3.3 of the ATS4888.2, by the mobile electronic prescription transfer application prior to being stored on the smartphone. Upon arriving at the pharmacy, the mobile electronic prescription transfer application on the smartphone decrypts the DAK and transfers it together with the electronic prescription to the pharmacy's eTP enabled Electronic Dispensing System (EDS). This transfer is to be done via Bluetooth communication although earlier research was conducted with the intention of using NFC technology instead. Once both the DAK and electronic prescription have been transferred to the pharmacy's EDS system, the rest of the eTP operations such as decrypting the prescription using DAK, dispensing the medication and updating the National Prescriptions and Dispense Repository (NPDR) will continue in the same way as if in the current eTP implementation (Htat, Williams, & McCauley, 2015b). For the repeat prescription scenario, the pharmacy's EDS will update the prescription information on the smartphone via the mobile electronic prescription transfer application. This model is designed to have minimal impact on the prescriber's EPS and dispenser's EDS systems in straightforward operations (i.e. simple prescribe and dispense scenario with no script-owing or script-request). How this proposed model's security mechanism works and how it differs from the one using PES can be seen in Figure 7.

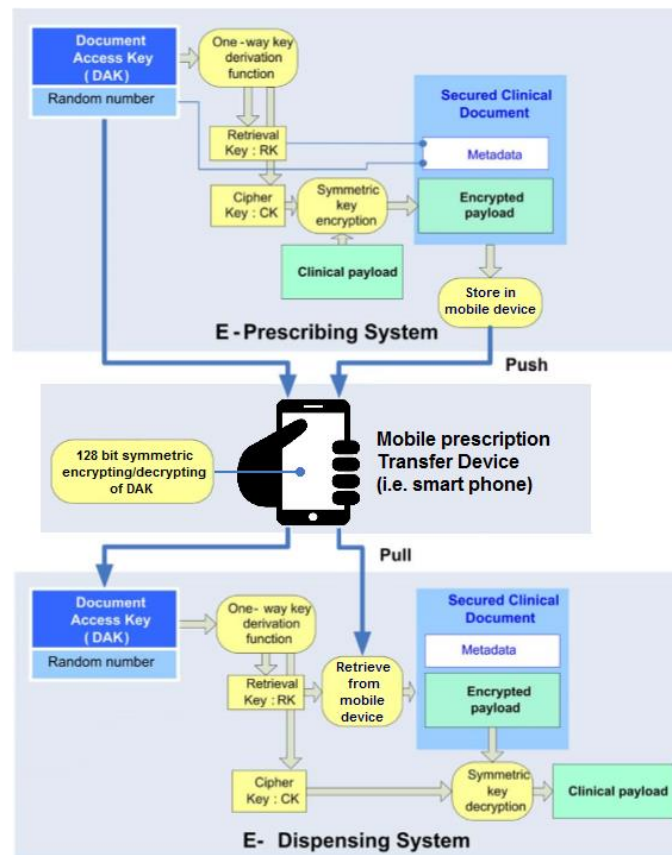


Figure 7: DAK usage for storage and retrieval of prescription in proposed approach (Htat, Williams, & McCauley, 2015b)

Since the prescription information is stored on the patient's smartphone, despite both the DAK and the electronic prescription being securely encrypted, it is still vulnerable to loss due to loss of the device on which it is stored. To ensure this sensitive information does not fall into the wrong hand, the remote data-wipe feature can be implemented as part of the mobile electronic prescription transfer application using Cloud-to-Device-Messaging (C2DM) from Google on Android platform, Google Cloud Messaging (GCM) on iOS platform and Windows Push Notification Services (WNS) on Windows phone platform. This will enable the device owner to remotely delete the prescription data stored on the device. Currently all major mobile OS platforms such as Android, iOS and Windows support remote wipe features for scenario like this.

From the security of the data-in-transit perspective, this proposed model relies on the Bluetooth's inbuilt security measures and governing standards for securing the prescription information in a very similar way current PES implementation relies on the implementation platform and its relevant standards for the security of the data in transit (Htat, Williams, & McCauley, 2015b).

DISCUSSION

The primary objective of the proposed mobile solution is to provide a cheaper, if not completely cost-free, alternative with comparable security measures. Therefore, the proposed alternative mobile solution intends to achieve the same level of security assurance as the current eTP implementation using PES by fulfilling the same security requirements mandated by the same standards and specifications.

Being a national eHealth facility, current implementation of eTP using PES is considered to have complied with the legislative requirements of all the jurisdictions within Australia. However, the study on how it complies with those requirements and to which extent it complies with those requirements leads to interesting findings. For instance, whilst sections 32A, 32B and Appendix-K of the Western Australia's Poisons Regulation 1965 describes the fairly detailed criteria of an approved electronic prescribing system by CEO, the clause "in a manner of writing approved by the Secretary." in section 26 (1) (b) of the Victoria's Drugs, Poisons and Controlled Substances Regulations 2006 implies the use of electronic prescribing without further details on it.

Moreover, whilst the sections 37 (1A) (1B) and 51 (1A) (1B) (1C) of the Western Australia's Poisons Regulation 1965 explicitly state the exemption from the requirement of prescriber's signature on electronic prescriptions, sections 33 (5) and 34 (3) of the South Australia's Controlled Substances (Poisons) Regulations 2011 only mention that prescribers with adequate arrangements for the electronic transmission of prescriptions are permitted to transmit prescriptions electronically and it will be deemed to have been signed. Whilst one Act or regulation dictates something explicitly, the others imply the same meaning using somewhat catch-all statements and vice versa. Therefore, from the legislative approval/acceptance perspective, it is expected that the proposed mobile solution will be accepted as a viable alternative if it complies with all the same standards and specifications as the current eTP using PES.

From the security of the data-at-rest perspective, the proposed solution also makes use of the symmetric encryption key derived from the DAK for securing the electronic prescription in the same way current eTP implementation using PES services does. This limits the impact of the change in transfer mechanism (i.e. patient's smartphone instead PES) on other components of the eTP process such as prescribing, dispensing and updating NPDR etc. Then, in the proposed solution, the DAK is encrypted using a 128 bit symmetric encryption according to section 7.3.3 (i.e. Data Security Conformance Points) of the ATS4888.2 before being stored on the mobile device (Htat, Williams, & McCauley, 2015b). Since the proposed solution uses the same DAK for securing the electronic prescription and the DAK itself is stored encrypted according to the relevant security mandates, the proposed solution's security measures are so far comparable to those of the current approach using PES. Moreover, in the same way the DAK scanned from the paper prescription is used for authorizing the pharmacy access to the prescription stored on the PES in the current eTP implementation, the DAK transferred from the mobile electronic prescription transfer application (i.e. the application from patient smartphone to the pharmacy's EDS) authorizes the pharmacy to access the electronic prescription stored on the patient's smartphone. Therefore, this authorisation mechanism of the proposed solution is also comparable to the current one being used.

From the security of the data-in-transit perspective, the Bluetooth's inbuilt security measures and governing standards upon which this proposed model depends on for securing the prescription information are well accepted by the industry and strictly governed by the Bluetooth Special Interest Group (SIG) and IEEE standard 802.15.1-2005. With strict governance by these two reputable authority bodies (i.e. Bluetooth SIG and IEEE), the implementation platform specific security measures of the proposed model (i.e. using Bluetooth) can be considered comparable to those of the current eTP implementation using the Internet.

Current eTP implementation using PES does not use any of the existing eHealth infrastructural components such as SMD, ELS and HI services although they can be effectively incorporated for better security, identification mechanism, consistency and reliability. Since the current approach using PES does not set very high standards for the proposed prescription transfer approach to live up to, this makes the proposed solution easier to implement and more acceptable to the industry. Although the primary objective of the proposed solution is to be a cheaper alternative with comparable security measures to the current approach using PES, it also has a few additional advantages over the current approach. First, this proposed solution puts the user in control of their sensitive information and allows them to prevent undesirable secondary use of that information by third parties. In addition, some useful features such as prescription expiration alert, last repeat alert, drug allergy alert and alert for harmful doses can also be implemented as part of the mobile electronic prescription transfer application. The ability to transfer the full history of patient's medication from the patient's mobile phone directly into the hospital system (i.e. once the interface has been implemented to integrate this mobile solution with the hospital information system) is just another benefit of this solution. Furthermore, without the requirement for the supporting network infrastructure this proposed solution will also be suitable for the remote regions of Australia where the network availability is limited or unreliable.

CONCLUSION

Before the 6CPA was officially signed, there were concerns and various speculations regarding what the new eligibility criteria will be for electronic prescription fees and how the subsidy will continue. Among them, eRx persuaded users with the no cost policy even for non-eligible scripts. But, some of its publications mention that it may not be able to maintain the cost neutral policy indefinitely but users would be given at least two month notice prior to any change being implemented to the price structure ("eRx slashes e-script pricing", 2010; O'Donoghue, 2012). So, effectively it does not even promise the users that it will remain cost neutral even with the current Commonwealth's AU\$ 0.15 contribution for each electronic prescription. How the use eTP will continue without the Commonwealth subsidy is rather an alarming thought. On the other hand, MediSecure seems to try using a scare tactics on users by implying that the eligibility criteria for electronic prescription fees will likely to be stricter in future ("How electronic prescription fee payment works?", 2015). For instance, from

certain point in time during the 6CPA agreement period, the Commonwealth's AU\$ 0.15 subsidy will only be applicable if the PES can share data with other eHealth components such as PCEHR and NPDR. From that aspect, only their product, Script Vault, is capable of such enhancement with minimal disruption to the services as it is the only PES service that fully complies with various eHealth and HL7 standards. When the 6CPA was officially signed, the section 6.1.3 and Appendix B of the agreement state that from 1st July 2016 and onwards this funding will be subject to a cost-effectiveness assessment by an independent health technology assessment body as determined by the Minister ("The Pharmacy Guild of Australia", 2015). Therefore, instead of living in fear of the potential change in the Commonwealth's subsidy for the electronic prescription fees, this paper proposed a cheaper (i.e. potentially cost-free) alternative with comparable security measures to the options currently available.

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