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The Hare and the Hortoise: The Potential Versus the Reality of eTP Implementation

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Abstract. In a health system increasingly driven by cost constraints, there is a focus on improved electronic transfer of information to support healthcare delivery. One area of healthcare that has moved more quickly than others to achieve this is prescribing in the primary care environment. Whilst the move to electronic transfer of prescriptions has reduced transcription errors, the regulatory environment persists with handwritten signatures. This constraint, whilst addressed slowly with technology solutions, needs support from legislative change. The ultimate step is to have a secure mobile model, which would support the move to a fully-electronic, paperless transaction model.

Keywords. eTP, electronic Transfer of Prescription, implementing eTP, HL7

Introduction

The National Health and Hospital Reform Commission (NHHRC) recognises that e-health plays a vital role in realising Australia's health reform recommendations [1], and is the key to improving Australian healthcare system whilst supporting a maintainable system [2]. Electronic Transfer of Prescriptions (eTP) is an important contributor in an e-health-enabled healthcare system that ensures medicines information is accurately and securely shared, providing a range of healthcare benefits for both prescribers and consumers [3, 4]. In an environment where 209.8 million prescriptions were filled in the 2013-2014 financial year, an increase of 6.3% on 2012-2013, streamlining the prescription process is vital [5]. This is achieved through sharing of precise patient medication information between prescriber and dispenser [3]. The eTP process allows for electronic generation of a prescription by a prescriber and electronic signature authentication, which is then transmitted securely to a pharmacy.

As the demand for mobile applications to support healthcare provision grows, there is a need to explore opportunities and seek solutions to the issues of secure transmission and use of data for health in a mobile environment. This paper uses eTP as an example of the pathway of technological development from the paper based manual prescription process to a fully mobile, paperless paradigm. It reviews the existing methods of transfer of prescription information including current practice, software capabilities, and regulation and legislative constraints at the Commonwealth, State, and Territory levels. Instead of simply providing a comparative review of various implementations, it presents a snapshot of the current situation in order to provide a context and further it proposes a new mobile fully-electronic solution.

1. Methods for Transfer of Prescriptions

As both hardware and software technology have evolved, there has been a progression in information transfer from a manual prescribing process to a hybrid manual/electronic solution. Figure 1 demonstrates the conventional manual prescribing model with the prescriber writing on a pre-printed prescription pad. Once signed, the prescription is given to the patient, who then presents it to the pharmacy where the prescription details are transcribed into an electronic pharmacy dispensing system for dispensing. This information is also used for Pharmaceutical Benefits Scheme (PBS) claiming and repeat dispensing. This process may include verification of the prescription details with the prescriber, and it is vulnerable to loss of the prescription by the patient, as well as transcription errors in the pharmacy data-entry process.

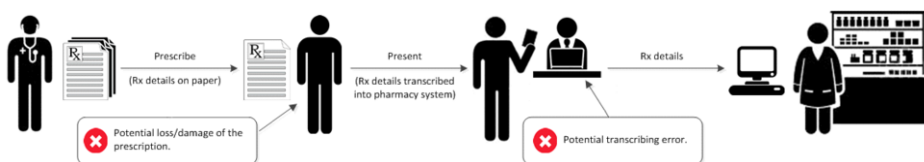


Figure 1. Manual prescribing process.

The introduction of the Practice Incentive Program (PIP) by the Australian Government for desktop computing in general practice in the late 1990’s, saw the transition to printed prescriptions and subsequently electronic process inclusion as part of the prescribing workflow [6].

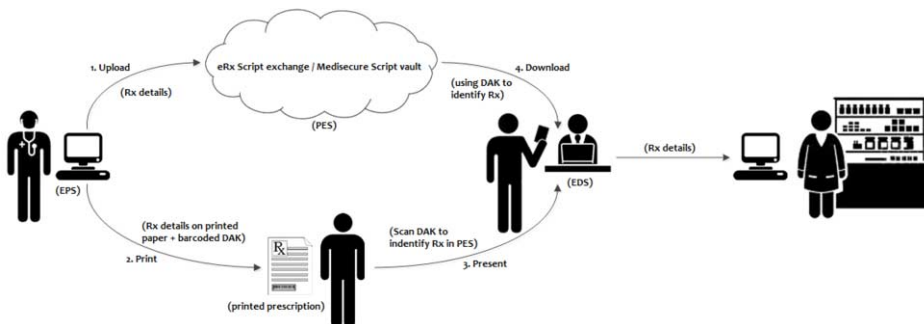


Figure 2. Current electronic prescription transfer process.

Figure 2 describes the prescribing model currently used by 95.7% of GPs in Australia [7]. This model implements eTP technical specification. eTP version 1.1 uses the Prescription Exchange Service (PES), Electronic Prescribing System (EPS) and Electronic Dispensing System (EDS) as key elements:

- The Prescription Exchange Service (PES) is an intermediary service, which enables secure transmission of electronic prescription information between prescribers and dispensers [8].
- The Electronic Prescribing System (EPS) is a component of the prescriber's clinical software package for generating an electronic prescription, digitally signing it and uploading it to the PES [8].
- The Electronic Dispensing System (EDS) is a pharmacy software component, which downloads the electronic prescription from the PES and submits dispense-records to the PES upon dispensing [8].

In this model, GPs use clinical software that has an EPS component for generating prescriptions and upload to one of two script exchanges (PES). Each electronically generated prescription is identified by a unique Document Access Key (DAK), which is provided to the patient encoded as a barcode on the printed and signed Prescription Notification slip. The slip contains information identical to the prescription. When the slip is presented to the pharmacy, the prescription detail is downloaded by the pharmacy's eTP enabled EDS from the PES, using the DAK, as shown in Figure 2. This eliminates the need for verification of the prescription details, and transcription errors. The downloaded prescription is used to dispense the medication and for secondary uses such as PBS claiming. The EDS then provides a record of the dispensed medication to the PES. Whilst existing, the automatic dispense notification service to the originating prescriber is currently disabled at the request of the Royal Australian College of General Practitioners, due to potential implications for clinician duty of care [12].

A mobile application from one PES supplier was released in 2014 to enhance this process model (Figure 2) by allowing patients to scan the DAK barcode from the prescription to their mobile phone, and submit it to their choice of pharmacy, securely for a scheduled pickup. This model still uses the printed Prescription Notification with prescription details as a transfer medium for passing the DAK between the prescriber and dispenser. The prescriber's signature on the printed prescription is mandated by relevant Acts/Regulations (e.g. Poison Regulation 1965 Regulation 51.(1B) in Western Australia). This requirement will be replaced once the use of digitally signed electronic prescriptions has legislative approval.

2. Adoption Potential and Related Issues

Figure 3 depicts the levels of eTP adoption, the extent to which eTP is implemented, and its influence on the information workflow and the form in which the information is communicated. The level of adoption of eTP varies across the different sectors of the healthcare industry, despite being a key government initiative to improve the delivery and quality of healthcare.

	No ETP	ETP Adoption Level 1	ETP Adoption Level 2	ETP Adoption Level 3
Patient or agent carries:	Legal paper prescription	Legal paper prescription	Paper notification of prescription	<div style="border: 1px solid black; padding: 2px;">Paper notification of prescription</div> <div style="border: 1px solid black; padding: 2px;">Electronic notification of prescription</div>
Hospitals and RCFs carry:	Legal paper prescription	Legal paper prescription	Electronic notification of prescription	<div style="border: 1px solid black; padding: 2px;">Electronic notification of prescription</div>
PES carries:		Electronic copy of prescription information	Digitally-signed electronic prescription	<div style="border: 1px solid black; padding: 2px;">Digitally-signed electronic prescription</div>

Legal document: Supporting information:

Figure 3. Level of eTP adoption [9].

In Level 1 the printed prescription is both the legal prescription for dispensing and the transfer medium for delivering the DAK identifier to the dispenser. Having the prescription details printed with the DAK benefits the patient, as the printed prescription details may be used for dispensing if the pharmacy’s EDS is not eTP enabled or access to PES is not available. However, this requires the printed prescription to have the prescriber’s handwritten signature on it as mandated by the s. 51(1B) of the Poisons Regulations 1965 in WA and similar legislation in other States. However, using a data storage device as the transfer media for the electronic prescription, instead of the printed paper version, means the written signature of the prescriber is no longer required as it is exempted by the s. 51 (1A) and s. 51(1C) of the Poisons Regulations 1965, and s. 9(1) and s. 9(3) of the Electronic Transaction Acts 1999.

Level 2 adoption uses the printed prescription notification as a transfer medium for delivering the identifying DAK to the dispenser. The printed prescription notification also contains the same prescription details as the electronic prescription thus facilitating dispensing if access to PES is not available. However, the same principles and restrictions apply as in Level 1 with regard to the prescriber’s handwritten signature. In the current electronic prescription transfer process, the pharmacy’s eTP enabled EDS downloads the prescription details from the PES using the DAK, upon receiving the printed prescription or the prescription notification submitted by the patient/agent.

Level 3 allows for the same conditions as Level 2 but replaces the paper notification with a fully-electronic notification.

3. Designing Solutions to Meet Compliance

Whilst the Australian Government has removed Commonwealth legislative barriers to electronic prescribing, by implementing changes to the National Health (Pharmaceutical Benefits) Amendment Regulations 2006, the State and Territory legislative barriers remain. Alignment with Commonwealth amendments is occurring slowly, and this will provide rules for electronic prescribing and dispensing in the respective jurisdictions. Table 1 lists the Commonwealth, as well as State and Territory Acts and Regulations that have been repealed and/or amended to accommodate implementation of eTP.

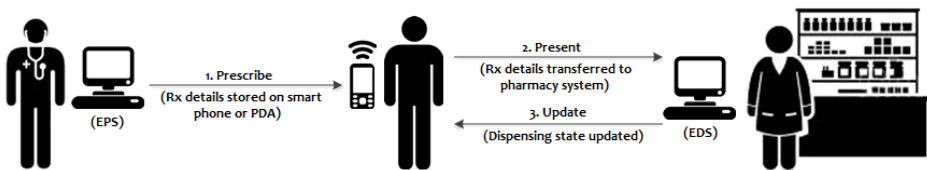
Table 1. Commonwealth, State and Territory Acts enabling the implementation of eTP.

Jurisdiction	Acts/Regulation
Commonwealth	Electronic Transactions Act 1999
Commonwealth	National Health Act 1953; National Health (Pharmaceutical Benefits) Regulations 1960
NSW	Poisons and Therapeutic Goods Regulation 2008
VIC	Drugs, Poisons and Controlled Substances Regulations 2006
QLD	Health (Drugs and Poisons) Regulation 1996
WA	Poisons Act 1964; Poisons Regulations 1965
SA	Controlled substances Act 1984; Controlled substances (Poisons) Regulations 2011
TAS	Poisons Act 1971; Poisons Regulations 2008
ACT	Medicines, Poisons and Therapeutic Goods Act 2008; Medicines, Poisons and Therapeutic Goods Regulations 2008
NT	Medicines, Poisons and Therapeutic Goods Act 2012

Other standards, specifications, and principles that support and govern the implementation of eTP in Australia include: Electronic Transactions Act 1999 (Commonwealth) and Electronic Transactions Act 2011 (WA), Australian Privacy Principles 2014, ATS 4888.1–7 (2013) Electronic transfer of prescriptions using Health Level 7 (HL7) Clinical Document Architecture (CDA), and AS 4700.3-2014 - Electronic messages for exchange of information on medicines prescription using HL7 V2.5. Whilst not exhaustive, this highlight the complexity of designing solutions. In other words, these Acts, regulations, and standards influence the legislative requirements and specifications that must be met in design and development of eTP.

4. A New, Fully Mobile Solution

Whilst the *Electronic Transactions Act 1999* primarily supports the creation, transfer and storage of the electronic prescription, amendments 51(1A) and 51(1C) of the *Poisons Regulations 1965* effectively allows an electronic prescription to be a legal document without the prescriber's written signature. Combined with other changes in governance the Commonwealth and States have made to enable e-health, these two amendments are sufficient to support an ETP Level 3 model.

**Figure 4.** Proposed fully-electronic mobile prescription transfer process.

A fully-electronic mobile prescription transfer model is proposed (Figure 4). The EPS generates an electronic prescription, encrypts it using the DAK as per the data

security conformance guidelines in ATS4888.2, signs the DAK with the prescriber's Medicare digital certificate, and then transfers it to the patient's mobile device. The use of digital certificates not only provides a way to authenticate the prescriber but also assures the confidentiality and integrity of the information transferred. The encrypted electronic prescription is stored on the mobile device in the same way it is stored within the PES in the current prescribing model. When presented at the pharmacy, the encrypted prescription and DAK are transferred to the pharmacy system, the prescriber's digital certificate is verified, and then the prescription is decrypted using the DAK. This model bypasses the PES entirely by using the mobile device as the transfer medium for the electronic prescription. Once dispensed, the pharmacy's EDS uploads the dispensing information into the NPDR. In this model, the prescription is issued and transferred in fully-electronic form, thus removing the requirement for the prescriber's written signature in accordance with section 51(1A) of the Poisons Regulations 1965.

This proposed eTP transfer model supports eTP adoption stages Levels 1 to 3 as long as there is a mechanism to transfer the electronic prescription from the prescriber's EPS to the mobile storage device and from the mobile storage device to the dispenser's EDS securely. This model is envisaged to use Near Field Communication (NFC) technology as the preferred transfer mechanism. NFC is designed for use in close proximity (i.e. up to a few centimetres) for secure data transfer and supports strong security features that facilitate highly secure transfer and storage of data. The NFC technology's reliability and practicality is evident by its use in the banking industry (e.g. Commonwealth Bank for its product, Tap & Pay). Nevertheless, this preference of employing NFC for data transfer is not based solely on the technical viability but also on the consumer acceptance and confidence in the technology. NFC's simplicity from a user perspective, enables easy information sharing. NFC is now available on all recent model mobile phones. In the current hybrid transfer model, the PES makes uploaded prescriptions available to dispensers as well as preventing access to those that have been cancelled, are expired or fully dispensed. For that purpose, PES updates the dispensing state of each prescription after each dispense. In the proposed model, the smart phone utilised as the mobile storage device makes the prescription available to the dispensers and the dispensing state of the prescription is updated by the dispenser's EDS directly to the mobile storage device. Due to the connectionless nature of the proposed model, cancelling the prescription by the prescriber requires additional services such as SMS to update remotely the dispensing state of the prescriptions stored on the mobile device.

5. Conclusion

The Commonwealth, States, and Territories have repealed and/or amended Acts and Regulations, and developed and adopted many standards and specifications in order to pave the way for implementing eTP. The legislative approval for the legal use of digitally signed electronic prescription is one of the last steps supporting the efficient use of electronic information communication in electronic prescribing. The proposed model can be implemented within the existing legislative framework, reduces complexity, and removes the need for ongoing major supporting infrastructure with its associated cost. In addition, users will be empowered and reassured that their sensitive medication data is not available to third parties. The model is very efficient and does not

require internet connectivity for basic functionality. Therefore, it provides an effective solution in all areas including remote locations with poor or no connectivity.

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