

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Standards

# ePrescribing: An International Review

May 2018

Safer Better Care

# **About the Health Information and Quality Authority**

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered. HIQA's ultimate aim is to safeguard people using services and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- Setting Standards for Health and Social Services Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation** Registering and inspecting designated centres.
- Monitoring Children's Services Monitoring and inspecting children's social services.
- Monitoring Healthcare Safety and Quality Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- Health Technology Assessment Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- Health Information Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

# **Overview of the health information function of HIQA**

Healthcare is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is therefore imperative that information is managed in the most effective way possible in order to ensure a high-quality, safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests — if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has a key role to play in healthcare planning decisions — where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under section (8)(1)(k) of the Health Act 2007, the Health Information and Quality Authority (HIQA) has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving the quality and filling in gaps where information is needed but is not currently available.

Information and communications technology (ICT) has a critical role to play in ensuring that information to drive quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to this, it can support a much faster, more reliable and safer referral system between the patient's GP and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in Ireland's health and social care sector is highly fragmented with major gaps and silos of information which prevents the safe, effective, transfer of information. This results in people using the service being asked to provide the same information on multiple occasions.

In Ireland, information can be lost, documentation is poor, and there is over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, understandable and trustworthy information on which to base our decisions.

As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international best practice. A robust health information environment will allow all stakeholders, the general public, patients and service users, health professionals and policy makers to make choices or decisions based on the best available information. This is a fundamental requirement for a high reliability healthcare system.

Through its health information function, HIQA is addressing these issues and working to ensure that high quality health and social care information is available to support the delivery, planning and monitoring of services.

One of the areas currently being addressed through this work programme is the need to develop standards to support the electronic prescribing (ePrescribing) across organisational boundaries. In 2013, HIQA published an international review on ePrescribing to inform the adoption of appropriate standards in Ireland. The focus of the review for each country was mainly on prescribing and dispensing of medication in the community rather than from the hospital setting. This document will provide a timely review of changes to ePrescribing initiatives internationally in order to inform the adoption of appropriate standards in Ireland.

# Contents

About 1	this document	7
Execut	ive Summary	8
Chapte	r 1 Introduction	17
1.1	Background	.17
1.2	Scope	.18
1.3	Methodology	.18
1.4	Expected benefits	.19
Chapte	er 2 Overview	20
2.1	Concepts	.20
2.2	Irish context	.29
Chapte	er 3 ePrescribing in Europe	34
3.1	Nordic countries	.34
3.2	United Kingdom	.51
3.3	Baltic States	.72
3.4	Northern Europe	.79
3.5	Cross-border ePrescribing Programmes	.86
Chapter 4 ePrescribing worldwide		92
4.1	United States	.92
4.2	Australia	.98
4.3	New Zealand	106
Chapte	r 5 Research and analysis1	.11
Chapte	r 6 Conclusion1	.19
6.1	Review of factors that could influence Irish adoption	119
6.2	Review of Irish ePrescribing programme	120
6.3	Further considerations for successful adoption	121
Appendix A — epSOS ePrescription Dataset124		

# **About this document**

This document is divided into the following sections:

- Chapter 1 Introduction This chapter outlines the background to the international review, the scope of the research and the methodology used.
- Chapter 2 Overview This chapter defines the term ePrescribing and explores related concepts, such as the expected benefits and integration with other eHealth systems.
- Chapter 3 ePrescribing in Europe This chapter describes national ePrescribing in nine countries in Europe, in terms of strategy, governance, the history of the programme and any lessons learned. It briefly explores European Union programmes for cross-border ePrescribing and outlines relevant research findings on ePrescribing adoption in Europe.
- Chapter 4 ePrescribing worldwide This chapter describes national ePrescribing programmes in the United States, Australia and New Zealand, again using the themes of strategy, governance, programme history and lessons learned.
- Chapter 5 Research and analysis This chapter summarizes the main findings of research on national ePrescribing programmes and analyzes the implications for the Irish ePrescribing programme.
- Chapter 6 Conclusion This chapter summarizes the main findings of the review, outlines progress on the Irish national ePrescribing programmes and suggests factors to be taken into account for the successful adoption of ePrescribing in Ireland.
- Appendix A epSOS Prescription Dataset This appendix lists the dataset that was developed by the epSOS project for an ePrescription.

# **Executive Summary**

# **Overview**

This review, which focuses on ePrescribing in primary care, revises the *International Review of ePrescribing and Electronic Transfer of Prescriptions* published in 2012. It is based on documentation that was available on national ePrescribing programmes and on interviews with four European programme leads. The review defines ePrescribing as the generation of prescription information, the transfer of prescription information and the dispensing of the prescription electronically using a dedicated system. Itoutlines key areas of national ePrescribing programmes, including the strategy, governance and possible implementation models. Furthermore, it summarizes progress since 2012 on the Irish ePrescribing program.

Having identified nine European countries and three other countries with significant national ePrescribing programmes, it describes each in terms of the main programme areas and any considerations based on lessons learned. It also discusses findings of international research, carried out principally in Europe, highlighting additional considerations. Finally, the conclusion summarizes these considerations, outlining where they have already been incorporated into the Irish programme and providing suggestions for how the remainder may be incorporated.

# ePrescribing in Europe

The review identified nine countries in Europe that have made significant progress towards the adoption of some kind of ePrescribing system.

# Denmark

Denmark is considered the leading country in Europe in terms of eHealth, owing to its long history and significant investment in information and communication technology (ICT).<sup>(1,2,3,4,5,6)</sup> Work began on ePrescribing in the 1990s, and the founding of Medcom in 1994 saw the beginning of a coordinated ePrescribing initiative. A cooperative venture between authorities, organizations and private firms linked to the Danish healthcare sector, Medcom worked with stakeholders to gain consensus and introduce the messages and specifications needed to support projects such as ePrescribing. The ePrescribing system was

a message-broker-based system that used the EDIFACT Med 3 standard for prescriptions based on asynchronous transfer to a secure mailbox. By 2010, ePrescribing rates were reported to be close to 100%.<sup>(7)</sup> In 2014, it became mandatory for all Danish healthcare providers to use the Shared Medication Record, which (some contend) effectively phased out the ePrescribing message broker. Lessons learned include the importance of a single national authority that worked closely with stakeholders to establish infrastructure and define standards, together with the ability to assess compliance with national standards.

#### Sweden

The world's first electronic prescription was sent in Sweden in 1983.<sup>(8)</sup> Messaging began to be used in the 1990s, initially in relatively small volumes. Once common standards for health data exchange were introduced in 2000, electronic prescribing became normal practice.<sup>(9,10)</sup> Sweden adapted the Electronic Data Interchange (EDI) standard, which Denmark had pioneered, together with a secure mailbox.<sup>(10)</sup> Around 2001, the EDIFACT standard began to be replaced by an XML message format based on the European pre-standard ENV 13607 and web-based transfer.<sup>(10)</sup> Following sustained strategic effort to encourage the adoption of ePrescribing, use increased significantly after 2002.<sup>(10)</sup> In 2016, approximately nine million prescriptions were generated monthly in Sweden, with 98% of these estimated to be ePrescriptions.<sup>(11)</sup>

#### Norway

In 2001, the Office of the Auditor General raised concerns about prescription refunds from the Welfare Administration Agency.<sup>(12)</sup> This prompted the Norwegian Ministry of Health to initiate a pilot study on ePrescriptions in 2004.<sup>(12)</sup> The 2008–2013 eHealth strategy included ePrescribing as a priority, covering all aspects of the generation and transfer of prescriptions and the reimbursement of expenses in a comprehensive system.<sup>(13)</sup> Results from the first pilot project in 2008 were not as expected. However, the program continued and was fully implemented by 2013, following extensive engagement with vendors. A major revision of the ePrescribing infrastructure was also approved in 2013.<sup>(12)</sup> This includes updates to messages and a range of modifications based on practical use, such as error corrections and modifications triggered by regulatory changes. New messages and functions were added the ePrescription solution, allowing the solution to be integrated with new secure health information services.<sup>(12)</sup> By the end of 2014, about 75% of prescriptions were generated and transferred electronically.<sup>(12)</sup> The Norwegian experience showed the importance of working effectively with the installed base—that is, with the systems, technologies, and business

processes already in place— and of engaging stakeholders' support.<sup>(12)</sup> For example, Profdoc, the vendor with 70% of the GP market, struggled to develop the ePrescribing capability in its patient record software and considered withdrawing completely from the programme. Developing the ePrescribing functionality as a standalone module lessened the impact of issues with the vendors' practice management software.

# England

In the 1990s, NHS England recognized the potential for the digital delivery of health information and services. In 2001, the National Programme for Health IT (NPfIT) strategy included an ePrescribing service.<sup>(14)</sup> Given the size and complexity, national rollout and implementation of ePrescribing was split into two releases. Each release consisted of a first testing phase followed by a general rollout phase. Beginning in 2005, Release 1 added barcodes to prescriptions and established the fundamental technical infrastructure for message transmission.<sup>(15)</sup> Release 2, involving the full electronic transfer of prescriptions, is in progress. In January 2018, the Electronic Prescription Service (EPS) was reported to be live in 11,672 (99.4%) community pharmacies and 6,869 (91.3%) GP practices in England.<sup>(16)</sup> The English experience showed that a phased approach to implementation gave stakeholders time to provide input to the process and to become accustomed to the new systems, while also providing a window within which to identify and resolve any challenges that only become apparent during implementation.

# **Northern Ireland**

In 2006, the Department of Health, Social Services and Public Safety (DHSSPS) proposed the introduction of an ePrescribing service principally to address prescription fraud, which was estimated to have cost the Department £7.8 million in 2004 and 2005.<sup>(17)</sup> NHS Northern Ireland chose a system where a 2D barcode encodes all information on the paper prescription using XML technologies.<sup>(17)</sup> This solution was also considered to have minimal impact on prescribers and dispensers.<sup>(17)</sup> The Electronic Prescribing and Eligibility System (EPES) has been operational throughout Northern Ireland since 1 May, 2008.<sup>(18)</sup> The former Central Services Agency (CSA) stated that it received 16.8 million prescriptions in 2009, all of which could be viewed electronicallyd.<sup>(19)</sup> The Health and Social Care Business Services Organization processed more than 41 million prescription items in 2016.

#### Wales

The Primary Care Informatics Programme (PCIP) developed the 2-Dimensional Barcoded Prescriptions (2DRx) service in 2007.<sup>(20)</sup> 2DRx is based the ePrescribing service architecture used in Northern Ireland, with some localization to the information, and it was implemented by NHS Wales.<sup>(14)</sup> As in Northern Ireland, this approach was considered to have the least impact on prescribers and dispensers.<sup>(14)</sup> Following a successful trial, the service was authorized for national rollout.<sup>(21)</sup> By 2010, all GP practices in Wales could generate prescriptions with the 2D barcode and community pharmacists were enabled to use scanners to read the barcoded prescriptions.<sup>(20)</sup> In 2016, the NHS Wales Informatics Service reported that 78 million prescriptions has been managed through the 2DRx service.<sup>(22)</sup>

## Scotland

In 2001, the ePharmacy programme began as an IT infrastructure project to support electronic transfer of prescriptions for reimbursement. In 2002, the ePharmacy programme was broadened to cover four supporting services, including the Electronic Acute Medication Service (eAMS), which is the electronic transfer of prescriptions between GP practices and community pharmacies.<sup>(23)</sup> NHS Scotland chose a 2D barcode solution for eAMS, with a claim sent automatically to the payment processing service when the pharmacist scans the prescription barcode. Rollout of eAMS began in 2008, with 1.9 million prescriptions sent electronically in July.<sup>(14)</sup> In July 2009, it was reported that Scotland had become the first country in the UK to deliver an electronic prescription service, with more than 90% of prescriptions submitted electronically.<sup>(24)</sup>

### Estonia

Estonia is considered to be one of the most digitally advanced nations in the EU, if not the world.<sup>(9,25)</sup> All prescriptions are managed electronically and the ePrescribing service is considered to be one of the most successful and widely adopted of Estonia's eHealth services.<sup>(9)</sup> Estonia began the digitization of government services shortly after it achieved independence from Russia in 1991, laying the foundations of the legislative framework and building public trust.

The Estonian Health Insurance Fund manages the reimbursement of all public prescriptions. The fund first developed an electronic reimbursement service for prescriptions, with input from stakeholders, which was significantly more cost effective than the manual process. From 2002, all pharmacists were legally obliged to use the service. Then, the fund

developed the ePrescribing service to monitor consumption and to improve the transparency of the prescribing process. From 2010, all stakeholders were required to use the ePrescribing service. During this year, GPs were instructed to revert to paper prescriptions for six months while capacity issues with the ePrescribing service were resolved.

As some healthcare organizations and pharmacies were reluctant to invest additional resources to enable the service and expressed negative views about the value of the service in the media, stakeholder engagement was shown to be very important. Furthermore, the initial issues with capacity highlight the need for accurate capacity analysis — while ultimately successful, the 'big bang' approach to national adoption initially caused capacity problems.

# Netherlands

All GPs in the Netherlands use an electronic medical record management system, which includes a module to create prescriptions electronically called the Elektonisch Voorshrijf Systeem (EVS).<sup>(26)</sup> Since 2014, prescribers are mandated to use the EVS to generate prescriptions.<sup>(26)</sup> However, while regional networks exist, there is still no national system for the electronic exchange of prescription information.<sup>(27)</sup> GPs send the electronic prescription to the patient's nominated pharmacy as an EDIFACT message using the secure healthcare mail system.

#### **Cross border programmes**

Running from 2008 to 2013, the European Patient Smart Open Services (epSOS) project was an EU-wide pilot project that developed and tested an e-health framework and an ICT infrastructure for secure cross-border access to patient health information between different European healthcare systems.<sup>(28)</sup> Included as part of this project was ePrescribing. The project resulted in the EU member states agreeing a number of semantic interoperability standards for patient summaries and for cross-border electronic transfer of prescriptions.<sup>(28)</sup>

When the epSOS project finished in 2014, work continued through the Connecting Europe Facility (CEF) eHealth Digital Service Infrastructure (eHDSI) programme, developing and implementing the digital services infrastructures for cross-border exchange of patient summaries and ePrescribing. These services are managed by the eHealth Network, a voluntary collaboration of the national authorities responsible for digital healthcare in all EU

countries.<sup>(29)</sup> To connect to the digital service, each European member state makes their implementation available for audit.<sup>(30)</sup> The eHealth Network then reviews the audit report and determines if the member state is eligible to connect.<sup>(31)</sup>

The EU ePrescribing programme is being rolled out as part of three waves of deployments in Europe, between 2018 and 2020. The Irish ePrescribing programme is scheduled to implement the capability to provide the epSOS Patient Summary and ePrescriptions in Wave 3, which is due occur in February 2020.

# ePrescribing Worldwide

## **United States**

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (1993) required Medicare Part D to support an electronic prescription system, with a planned implementation date of April 2009.<sup>(14,32,33)</sup> Over the course of 2008 and 2009, two acts incentivized the use of both ePrescribing and the electronic health record (EHR). In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act provided \$19 billion dollars to incentivize healthcare providers' meaningful use of EHR, with ePrescribing considered a key component of meaningful use.<sup>(32)</sup> The Medicare Improvement for Patients and Providers Act (MIPPA) offered financial bonuses for qualified prescribers who sent prescriptions electronically using a certified system.<sup>(14)</sup> These financial bonuses were available from 2009 until 2013, with the amount decreasing annually.<sup>(14)</sup>

#### Australia

From 2005 to 2016, the National E-Health Transition Authority (NEHTA) Limited was tasked with identifying and developing the necessary foundations for eHealth.<sup>(14)</sup> In 2008, the National eHealth Strategy set out the foundational components for eHealth. A collaborative enterprise by the Australian Commonwealth, State and Territory governments, NEHTA developed these foundational components between 2008 and 2013. Implementation was planned in a staged and incremental fashion, with paper prescribing and direct transfer (without a message broker) supported as interim steps towards full electronic transfer.<sup>(34)</sup> In the proposed implementation, each electronic prescription item merited a separate prescription with a unique DAK barcode.<sup>(35)</sup> As part of the subsequent rollout, two vendors developed prescription exchange services, which were used to transfer the prescription

information asynchronously between prescribers and dispensers. In 2013, the vendors announced that their respective services had finally achieved interoperability. In 2016, the Australian Pharmaceutical Benefits Scheme processed more than 208 million prescriptions for reimbursement.<sup>(36,37)</sup> NEHTA reported in 2016 that the electronic transfer of prescription capability was built on a series of national infrastructure services: terminologies standards, secure messaging standards, identification services, and the National Authentication Service for Health.<sup>(38)</sup>

### **New Zealand**

ePrescribing has been on the New Zealand Health IT agenda since 2005.<sup>(14)</sup> Part of the strategy's proposed eMedicines programme, the New Zealand ePrescription Service (NZePS) was expected to deliver a wide range of benefits to patients, prescribers and organizations. The National Health IT Board (NHITB) was founded in 2010 to provide strategic leadership and funding for information systems in the health and disability sector. It has overall responsibility for the national ePrescribing solution in New Zealand and, following collaboration and extensive public consultation, developed a new information governance framework for all e-health initiatives at a national level. The New Zealand service used a 1D barcode, which stored a unique identifier that idenitified and retrieved the correct prescription from the transaction broker when the pharmacist scanned the barcode. Community trials of the New Zealand ePrescription Service (NZePS) began in March 2011, following by national rollout from July 2012. In June 2017, 66 GP practices were reportedly using New Zealand ePrescription Service (NZePS) to generate 113,000 ePrescriptions while pharmacies used the service to processed 37,000 ePrescriptions.<sup>(39)</sup>

# **Research and analysis**

National ePrescribing programmes have been shown to provide a range of benefits, including time savings and efficiency gains, transparency and fraud detection, health and social benefits, and cost benefits. Most important, ePrescribing can improve patient outcomes significantly. Approximately half of the 17% of patient hospitalizations that are due to medication error are considered avoidable.<sup>(9)</sup> ePrescribing can reduce medication errors, for example, it has reduced errors by an estimated 15% in Sweden.<sup>(9)</sup> It can also make both prescribers and dispensers more accountable through increased transparency, and it can make time-critical medications more readily available to patients.<sup>(9)</sup> Furthermore, ePrescribing costs far less and takes less time than processing the same prescriptions

manually, saving time and money.<sup>(40)</sup> In Estonia, the cost savings from ePrescribing in 2010 almost matched the country's investment in the printing and secure storage of the forms in 2009.<sup>(17)</sup>

Research also showed a number of significant influences on the success of a national ePrescribing programme. A correlation was found between the type of national health system within a country and the successful adoption, or otherwise, of ePrescribing within the country—that is, countries with a centralized (or NHS style) health system were more likely to have a successful national ePrescribing than countries with one of the two other health systems identified.<sup>(3)</sup> Other crucial requirements are a clear ePrescribing strategy and the programme being led by an authority with the ability to agree, and ensure compliance with, appropriate standards and other factors. Countries with successful ePrescribing programmes combined visionary leadership with strong local engagement — effectively combining both 'bottom up' and 'top down' approaches.<sup>(9)</sup> Effective leadership must be combined with the financial resources needed to implement ePrescribing.<sup>(9)</sup> The ePrescribing system needs to be well-designed for the business processes of stakeholders, including GPs and community pharmacists.<sup>(9)</sup>

Countries with a successful ePrescribing programme also tended to have established a national infrastructure that spans eHealth services, which avoids the situation of developing similar services — such as for user identification and authentication — for each individual eHealth service.<sup>(9)</sup> Adoption can be less disruptive where stakeholders are already using other eHealth services and can take advantage of the trust already built. The pre-existing built environment, the standards already adopted and the existing and planned services should also be considered carefully when deciding the technical architecture, standards and other aspects of the final ePrescribing solution.<sup>(12)</sup> A coordinated rollout, including effective piloting, was also shown to be crucial to the success of an ePrescribing programme.<sup>(9)</sup>

# Conclusion

The vision for the Irish ePrescribing program is set out in the *eHealth Strategy for Ireland*.<sup>(41)</sup> The goal of ePrescribing strategy in Ireland is to reduce medication errors, thereby reducing the associated costs and speeding up patient access to medication. The National ePrescribing Programme is using a phased, standards-based implementation. This pilot-based approach is in line with best practice. HIQA has defined and agreed the related

standards for messaging and datasets. Additionally, national health identifier legislation has been passed, permitting the creation and use of the Individual Health Identifier. Two ePrescribing pilot projects have also been undertaken. The model used in the pilots also mirrored stakeholders' current business processes and gave stakeholders time to become accustomed to and provide feedback on their user experience. It also gave time for the legislative and information governance framework to mature.

Successful ePrescribing programmes typically balance local and national needs, continually sharing a clear national vision that also meets important local requirements. To ensure stakeholders' commitment to the programme, GPs, community pharmacists, vendors and others may need to participate more fully in designing and testing the service to ensure their needs are full met. Undertaking further pilot projects may give stakeholders more time to feed back on experiences and allow time to stress test the service. Once service functionality is defined, it may also be useful to initiate wider engagement and training programmes. ePrescribing programmes typically realize the full benefits when integrated with other eHealth services, especially with an electronic medical record (EMR). Therefore, the ePrescribing service should ensure interoperability with other systems, for example, the National Medicinal Product Catalogue and the planned EHR system.

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# **Chapter 1** Introduction

# **1.1 Background**

The international review in this document was performed as per HIQA's legislative remit under the Health Act 2007 and subsequent amendments to the Act. Under the Health Act 2007, HIQA has a statutory remit to develop standards, evaluate information and make recommendations about deficiencies in health information. The responsibilities of HIQA in this regard are outlined in the following sections of the Act:

- Section 8(1)(i): to evaluate available information respecting the service and the health and welfare of the population
- Section 8(1)(j): to provide advice and make recommendations to the Minister for Health and the HSE about deficiencies identified by HIQA in respect of the information referred to in paragraph (i)
- Section 8(1)(k): to set standards as HIQA considers appropriate for the HSE and service providers respecting data and information in their possession in relation to services and the health and welfare of the population
- Section 8(1)(I): to advise the Minister for Health and the HSE as to the level of compliance by the HSE and service providers with the standards referred to in paragraph (k).

Under Section 8(1)(i) of the Health Act 2007, HIQA is charged with provide advice and make recommendations to the Minister for Health and the HSE about deficiencies identified by HIQA in respect of the service and the health and welfare of the population. In 2012, HIQA conducted its first review of international experience of electronic prescribing (ePrescribing) and the electronic transfer of prescriptions. In 2017, HIQA carried out a follow up review, the results of which are presented in this document. This document describes progress in ePrescribing practices in the countries covered by the original review and any changes that are relevant from other countries. Its findings are intended to inform the discussion around ePrescribing in Ireland.

# 1.2 Scope

This review investigates changes that have happened in international ePrescribing initiatives and practices since the original review in 2012. It concentrates on ePrescribing in primary care, that is, ePrescribing as it occurs typically between GPs and community pharmacists. ePrescribing (and dispensing) can take also take place in secondary or tertiary care — such as hospitals — where it is often known as medication management. However, secondary or tertiary care presents a different set of challenges and is, therefore, largely outside the scope of this review.

While every effort has been made to review all pertinent materials and include all relevant facts, this review was limited by the availability of English-language materials and by widely varying availability of information on each aspect of national ePrescribing programmes. It was also limited by the paucity of research on national ePrescribing programmes outside Europe compared with the significant body of available research on national ePrescribing programmes in Europe.

# 1.3 Methodology

At the time of the original review, national ePrescribing programs were well underway in many countries.<sup>(14)</sup> These programs provided a wealth of data and prompted much subsequent research on the factors that led to (in some countries) and hindered (in others) the successful adoption of ePrescribing.<sup>(9,12,40,42,43,44,45)</sup>. Research found that other aspects, including governance, strategy and stakeholder engagement, of a national ePrescribing program are equally important to successful adoption and, if neglected, can derail the programme.<sup>(9)</sup> Therefore, this review seeks to locate the technical standards adopted by each national ePrescribing program in the wider context in which they were developed and implemented.<sup>(9)</sup>

First, a desktop investigation of ePrescribing-related materials was undertaken. It identified reports, articles, and other materials from countries that had achieved, or had made significant progress towards, full national adoption of ePrescribing. It also included materials from countries where full adoption at regional level had not led to full adoption at national level.

From these resources, the investigation identified key aspects of governance (including stakeholder groups), national strategy and programme history that were considered to influence the development and success of each national ePrescribing programme. It also noted, where available, the lessons that either researchers or programme participants considered to have been learned over the course of the programme's development. Four participants from three European national programmes were also interviewed.

Finally, as this review seeks to inform the debate on ePrescribing in Ireland, information about ePrescribing programmes in Europe was given particular consideration as was research on European Union research and programmes. The review also outlines progress made to by the Irish national ePharmacy initiative, which encompasses ePrescribing, and the future steps that may be taken in light of the review findings.

# **1.4 Expected benefits**

National ePrescribing programmes have been shown to provide a range of benefits including time savings and efficiency gains, transparency and fraud detection, health and social benefits and cost benefits. Most important, ePrescribing can improve patient outcomes significantly. Approximately half of the 17% of patient hospitalizations that are due to medication error are considered avoidable.<sup>(9)</sup> ePrescribing can reduce medication errors, for example, by an estimated 15% in Sweden.<sup>(9)</sup> It can also make both prescribers and dispensers more accountable through increased transparency.<sup>(9)</sup> ePrescribing can make time-critical medications more readily available to patients, and it costs far less and takes less time than processing the same prescriptions manually, saving time and money.<sup>(40)</sup> In Estonia, the cost savings from ePrescribing in 2010 almost matched the country's investment in the printing and secure storage of the forms in 2009.<sup>(17)</sup>

# **Chapter 2 Overview**

The original international review introduced the main concepts of ePrescribing and looked at international practices in the area, with a view to informing the discussion about ePrescribing standards for Ireland. It outlined the benefits that ePrescribing and the electronic transfer of prescriptions were expected to bring and examined the relevant aspects of implementation in six countries. It also provided a brief overview of the epSOS project, which was running at the time and created a common framework for an EU ePrescribing infrastructure, as well as other relevant projects.

This review looks again at international practices and adoption, which have moved on significantly in the six years since the original review was published. It also reviews materials that examine the factors that contribute to the success, or otherwise, of ePrescribing initiatives. And finally, it outlines the EU standards that have been adopted, which are directly relevant to the Irish context. The following section defines ePrescribing and reviews the main concepts associated with it.

# 2.1 Concepts

# 2.1.1 Definition of ePrescribing

The United States Centers for Medicare and Medicaid Services states that 'ePrescribing is a prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care, an important element in improving the quality of patient care.<sup>(46)</sup> This definition captures the generation of the prescription, the transmission of the prescription from prescriber to pharmacy and the pharmacy's dispensing of the prescription.

The original Fifth Community Agreement between the Australian Department of Health and the Pharmacy Guild of Australia includes the following concepts: the prescriber's ability to generate an accurate prescription electronically, the electronic transfer of the prescription to the dispenser and the dispenser's ability to receive and dispense the prescription. However, it also states explicitly that the prescription must be signed digitally, transmitted securely and integrate with the pharmacy billing system.<sup>(47)</sup>

The European Patient Smart Open Services (epSOS) initiative, which sought to develop an eHealth infrastructure that would enable seamless and secure access to patient health information across borders for European citizens, defined the ePrescribing process as having two parts:

- ePrescribing is defined as a prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point of care.<sup>(3,48)</sup>
- eDispensing is defined as the act of electronically retrieving a prescription and reporting on giving the medicine to the patient as indicated in the corresponding ePrescription.<sup>(48)</sup>

These international programmes reflect the general understanding that the term ePrescribing is used to describe all aspects of the generation and transfer of prescriptions electronically using a dedicated system, whether in paper or electronic from, rather than faxing or emailing the prescription.<sup>(40)</sup> The same sources consistently identify ePrescribing as taking place in primary care, which involves the generation of the prescription by GPs, the transmission of prescriptions electronically from GP to pharmacy over national networks and the pharmacy dispensing the prescription. The term ePrescribing can also include the transmission of dispensing records from dispensers to prescribers and to national reimbursement services. However, recent research has also found that the crucial technical requirement for an effective ePrescribing program is a reliable, real-time electronic transfer of prescriptions (ETP) process.<sup>(40)</sup>

The review continues to differentiate between the generation of electronic prescriptions and their subsequent transfer and dispensing. It uses the three-step model identified in the original review, which, in some sources, are described collectively as ePrescribing:

**Step 1. ePrescribing**, where the prescriber generates the prescription electronically.

**Step 2. Electronic transfer of prescription (ETP)**, where the prescription is transmitted electronically to the dispenser.

**Step 3. eDispensing**, where the dispenser retrieves the prescription (and optionally reports on the medicines given to the patients).

This review focuses on ePrescribing as a primary care process, using GPs as examples of prescribers and community pharmacists as examples of dispensers. Finally, it pays particular attention to the transfer of the electronic prescription or prescription information, which has been identified as the most potentially challenging of these three steps. However, before looking at any of these aspects, it looks at the reasons for introducing a national ePrescribing system.

# 2.1.2 Wider goals and perceived benefits

A national ePrescribing system can deliver significant benefits for patients, prescribers, dispensers and others involved in the process.<sup>(40)</sup> In particular, ePrescribing can improve patient safety considerably by reducing errors of mistaken identity, incorrect dosage, incorrect medication, adverse drug interactions, and so on.<sup>(40)</sup> It can also resolve challenges concerning overlapping medications and improve medication practices.<sup>(40)</sup> It can also reduce the number of pharmacist interventions significantly.<sup>(40)</sup> ePrescribing costs far less and takes less time than processing the same prescriptions manually, saving time and money.<sup>(40)</sup>

As far back as 1999, the United States Institute of Medicine's report, *To Err is Human*, outlined the role of ePrescribing in improving patient safety while reducing costs.<sup>(49)</sup> The resulting Medicare Prescription Drug, Improvement, and Modernization Act (MMA) in 2003 required Medicare Part D to support an electronic prescription system, while in 2010 the Health Information Technology for Economic and Clinical Health (HITECH) Act provided substantial incentives for prescribers to adopt ePrescribing as a module in an electronic health record system.<sup>(33)</sup> EPrescribing is also one of the key action items in the government's plan to expedite the adoption of electronic medical records and build a national electronic health information infrastructure in the United States.<sup>(33)</sup>

In the European Union, the epSOS project expected ePrescribing to deliver benefits for patients, for healthcare providers and for each EU health system as a whole. Expected benefits for patients included faster and easier access to more competent health services and higher patient mobility across Europe. Healthcare providers would be able to provide better and more efficient care through timely interventions and cost savings. Finally, extending ePrescribing across EU borders was expected to reduce medication errors and, therefore, improve the overall efficiency of the system.

The goal of ePrescribing strategy in Ireland is to reduce medication errors, thereby reducing the associated costs of  $\in$ 10-15 million per year, and speed up patient access to medication.<sup>(41)</sup> In Estonia, ePrescribing was seen as a useful means for monitoring medicine consumption and for improving the transparency of prescribing. In Northern Ireland, ePrescribing was introduced principally to reduce the incidence of prescription fraud.<sup>(17)</sup> ePrescribing was considered the highest priority of Australia's early efforts to establish an eHealth programme, in that it would provide an early opportunity to connect a significant group of healthcare providers at national scale.<sup>(50)</sup>

The considerable benefits in terms of patient safety and patient care, as well as the time and cost efficiencies resulting from it, make ePrescribing an attractive option for many stakeholders. Responsibility for an ePrescribing system usually rests with the national health authority, while other stakeholders include national and regional bodies representing prescribers, dispensers and other groups. In fact, the expected benefits of ePrescribing often inform the country's national programme strategy.

## 2.1.3 Strategy and governance

ePrescribing is usually an early component of a national eHealth strategy, which typically outlines the expected benefits for the country as a whole as well as the governance model for the program and the implementation approach. The implementation often uses a phased approach, with interim steps allowing for use of both electronic and paper prescriptions. This phased approach gives time for key stakeholders and patients to become accustomed to the system, for the legislative and governance framework to evolve and for the technical capacity to be built.

The technical implementation of an ePrescribing system must ensure that prescription information is handled according to national regulations and guidelines for information governance. The supporting national legislative framework to recognize the validity of the different components of ePrescribing process must also be considered. Research has identified authentication, electronic signature, patient consent and access to the paper prescription among important legal considerations.<sup>(51)</sup> Many countries use smart cards for identification and authentication within national ePrescribing systems.<sup>(51)</sup> For example, digital signatures must usually be recognized in national law before electronic prescriptions can be recognized as a legal form. By law, a prescriber must authorize a paper prescription with

their written signature. Similarly, if the electronic form is to be considered a legal prescription, an electronic prescription must usually be authorized with the prescriber's digital signature.

Depending on the governance, technical and legislative framework, a national ePrescription program may recognize both paper and electronic prescriptions. Initially, a national ePrescribing programme may support the parallel electronic transmission of prescription information while the signed paper prescription remains the legal document. This takes account of the phased upgrade of prescribing and dispensing software and gives prescribers and dispensers time to become accustomed to the new system. It is often used as an interim step towards the introduction of a paperless system.

A national ePrescribing programme may support the parallel electronic transmission of prescription information when the legislative and information governance framework does not yet recognize an electronic prescription as the legal document. For example, the United States mandated the use of written prescriptions for controlled substances,<sup>(52,53)</sup> and such legislation may need to be updated to allow the use of electronic prescriptions for controlled substances. Some ePrescribing systems are hybrids, with patients able to choose a paper or an electronic prescription, with both recognized as legal documents. Other systems are almost completely paperless, with prescribers legally permitted to use paper prescriptions only in exceptional circumstances, such as system outage.

Legislation can support the adoption of ePrescribing in various sectors and accelerate the obsolescence of paper prescriptions. ePrescribing can be introduced as a voluntary program, with incentives for adoption, then becoming mandatory as the legislative framework matures and as a critical mass of users is reached. Or in other cases, it can be introduced as a mandatory process in state health schemes, with later implementation in private practice.

For example, in Estonia legislative changes supported the transition in public schemes first.<sup>(43)</sup> In 2002, all pharmacies were obliged by law to transmit prescription information for reimbursement electronically to the single public payer, the Estonian Health Insurance Fund.<sup>(43)</sup> By 2005, all reimbursement claims and prescription data were submitted electronically.<sup>(43)</sup> In 2007, legislation obliged all healthcare providers to send medical data to the Estonian National Health Information System (EHIS), including ePrescriptions.<sup>(43)</sup> By

2010, all prescriptions had to processed electronically using the newly launched digital prescription service.<sup>(43)</sup>

In Finland, legislation on the use of ePrescribing was passed in 2007.<sup>(40)</sup> In 2010, the Finnish Client Data Act mandated all public healthcare organizations to store all health records in electronic form by 2011.<sup>(40)</sup> In 2014, new laws made ePrescribing mandatory in all sectors in Finland from 2017.<sup>(40)</sup>

Changes to legislation and information governance as well as to the technical implementation of the prescribing system have a huge impact on stakeholders, in particular, GPs and community pharmacists. As a consequence, a successful national ePrescribing strategy often include significant efforts to engage and educate stakeholders and to make decisions informed by their experience and expertise.<sup>(40)</sup> For example, NHS England worked with stakeholder organizations to develop a phased approach to implementation, with tightly controlled pilot implementations involving GP and community pharmacy pairs, and also developed a comprehensive training programme ahead of the nationwide implementation.<sup>(54)</sup> The GP community pharmacy pair is also useful for illustrating the basic model for transferring prescriptions electronically.

# 2.1.4 Models for the electronic transfer of prescriptions

This section looks at how prescriptions can be transferred electronically between prescriber and dispenser.

# ePrescribing with signed paper prescription as legal document



# Figure 1. ePrescribing with signed paper prescription as legal document

In this scenario, ePrescribing mimics the paper-script-based business practice and the paper prescription remains the legal document, indicated in red with an asterisk (\*):

- 1. **ePrescribing:** The prescriber generates a paper prescription with a barcode, which the prescriber signs:
  - **1D barcode** the barcode uniquely identifies the prescription with an identifier.
  - **2D barcode** the barcode contains all the prescription information.
- 2. **Electronic transfer of the prescription:** The electronic prescription is sent to the prescription exchange, where it is stored until it is downloaded and dispensed.
- 3. **eDispensing:** The dispenser scans the barcode on the paper prescription, which:
  - **1D barcode** identifies the prescription information in the prescription exchange, then downloads it to the dispensing system.

2D barcode — loads all the information from the paper prescription onto the dispensing system.

The dispenser can optionally send an acknowledgement that the prescription items have been dispensed.

# ePrescribing with electronic prescription as legal document



# Figure 2. ePrescribing with electronic prescription as legal document

Where the electronic prescription is the legal document, (indicated in red with an asterisk (\*)), the prescriber signs the electronic prescription digitally.

- 1. **ePrescribing:** The prescriber generates an electronic prescription, which is signed digitally by the prescriber. Patients may also be receive a paper notification, with a barcode contains a unique identifier for the prescription. In completely paperless processes, patients may use smartcards or some other means to identify themselves.
- 2. **Electronic transfer of the prescription:** The electronic prescription is transferred to the prescription exchange, where it is stored until it is dispensed.
- 3. **eDispensing:** The dispenser scans the barcode on the paper notification (or the patient's smartcard), which contains an identifier that uniquely identifies the electronic prescription in the prescription exchange, then downloads it to the dispensing system.

The dispenser can optionally send an acknowledgement that the prescription items have been dispensed.

#### ePrescribing model with prescription repository

The ePrescribing system may also be extended to include the dispensing of multiple prescriptions, repeat prescriptions and the capacity to handle billing. It may also be extended to make secondary use of the prescription information that it handles. In both scenarios described, where the message containing the electronic prescription information is sent to a message broker, the message broker can optionally forward message content to a clinical repository site.



# Figure 3. ePrescribing model with prescription repository

This clinical repository can be used to store information about the patient's current medications and to provide historical data to the patient, to healthcare providers, and to other systems such as an electronic health record. It can provide feedback to patients and to commissioners about their prescribing patterns. The repository can be integrated into decision support systems. For example, in 2017 the Estonian ePrescribing service was upgraded to include the SFINX database covering drug interactions.

# 2.1.5 Integration with other eHealth systems

An electronic prescription service may also need to interoperate with other national eHealth services. Examples of such services include:

- National medicines reference database to verify the medicines listed in the prescriptions and typically using a clinical terminology such as SNOMED.
- National prescription database to provide information on all prescriptions that a
  patient has received from different primary and secondary sources, as well as
  making anonymized data available for statistical and research purposes.
- Medication list to provide a longitudinal record of a patient's current and previously prescribed medications for each patient, often within an electronic health record.
- National identity service to verify the identity of patients accessing the ePrescribing service and other eHealth services, usually based on a national health identifier.
- National authentication service to verify the digital signatures of prescribers.
- National healthcare providers registration service to verify the identity of prescribers and dispensers.

This integration with other systems relies on the ability of all systems to understand and process information in the same way, which is known as semantic interoperability. Conforming to the relevant national standards, for example, messaging standards, facilitates this integration. Developing a standards-based approach to the security infrastructure will also help. By its nature, this information is sensitive and must be handled within a secure framework, of which the patient ID is also a core element. At national and international level, this requires significant effort and collaboration. The European Union has provided significant resources to projects that develop the interoperability standards and models that would enable cross-border transfer of electronic prescriptions within the EU.

# 2.2 Irish context

The aim of both this review and the original review of ePrescribing is to inform the development of ePrescribing in Ireland.

# Scale

According to the latest national census, in 2016, Ireland had a population of over 4.7 million.<sup>(55)</sup>

## Governance

The Irish Department of Health has the overall responsibility for leadership and policy direction of the Irish health sector while the Health Service Executive is tasked with providing all of Ireland's public health services in hospitals and communities across the country.<sup>(56,57)</sup> The Department of Health published its *eHealth Strategy for Ireland* in 2013 and set up eHealth Ireland to realize this vision.<sup>(41)</sup>

As part of this strategy, the Office of the Chief Information Officer (OCIO) was established in 2014. OCIO has responsibility for delivering the technology to support and improve healthcare in Ireland.<sup>(58)</sup> The Health Service Executive's *Knowledge and Information Strategy* outlines its plan for realizing the eHealth strategy.<sup>(59)</sup> Key strategic programmes supported by the OCIO and eHealth Ireland included the Individual Health Identifier programme and the ePharmacy programme.<sup>(60)</sup> Its ePharmacy programme supported a number of initiatives, including an electronic prescriptions in primary care initiative and a National Medicinal Product Catalogue.<sup>(60)</sup>

# Strategy

The eHealth strategy noted that medication errors cost the Irish health system between  $\in 10$ and  $\in 15$  million per annum.<sup>(41)</sup> The goal of ePrescribing strategy in Ireland is to reduce these errors, thereby reducing the associated costs, and speed up patient access to medication.<sup>(41)</sup> The strategy also suggested that a phased approach to the introduction of ePrescribing has proven successful in other countries, starting with ePrescribing in the community, and acknowledged as a significant enabler the work of the Irish Medicines Board in establishing a medicines formulary and products database.<sup>(41)</sup>

Finally, ePrescribing is considered a core operational solution within an electronic health record, which is the ultimate goal of the eHealth Ireland strategy.<sup>(61)</sup> A national electronic health record (EHR) is seen as a comprehensive solution that supports the creation and sharing of key patient information.<sup>(41)</sup> The EHR is identified as a key capability requirement for the future delivery of healthcare.<sup>(41)</sup>

At the first eHealth Ireland summit in June 2015, the National ePrescribing Programme was announced. Two of the eight projects within that programme related to HIQA's work —

ePrescribing in primary care and a National Medicinal Product Catalogue. This programme supported eHealth Ireland's high level roadmap for ePrescribing, which emphasized the need for a phased, standards-based implementation.

The programme's phased approach included the development of the initial building blocks (phase 1), leading to an ePrescription phase (phase 2), followed by the roll out of ePrescribing in primary care (phase 3).



# eHealth Ireland ePrescribing Programme Roadmap

This roadmap is consistent with the international evidence and implementation of national ePrescribing solutions in other jurisdictions. Key components of the programme are outlined below.

#### National health identifier

An individual health identifier (IHI) is required to safely identify patients, their prescriptions and their dispensing records, as well as for health and social care professionals and organizations.<sup>(14)</sup> The National Identifiers Act was signed into Irish law in 2014.<sup>(62)</sup>

## **National Medicinal Product Catalogue**

The original review noted the importance of developing a data model to support the implementation of a national medicinal product reference catalogue, which would uniquely identify all products that can be prescribed or dispensed.<sup>(14)</sup> The National Medicinal Product

Catalogue is a key deliverable of the Irish ePharmacy Programme.<sup>(63)</sup> To date, input has been sought from individuals, organizations and agencies with expertise in the area about a standards-based model that would be managed centrally but available to all care areas.<sup>(63)</sup>

# National interoperability framework and messaging standards

The original review noted the need for a standards-based interoperability framework and supporting infrastructure to facilitate the secure electronic transfer of prescriptions between prescribers and dispensers, including the messaging standards and clinical datasets. Since 2012, HIQA has developed a number of technical standards to support ePrescribing in Ireland:

- *ePrescription dataset and clinical document architecture standard* (March 2015)
- Data model for an electronic medicinal product reference catalogue a National Standard (March 2015)
- National Standard for a Dispensing Note including a Clinical Document Architecture specification (January 2017)

In November 2016, Ireland acquired a national licence for SNOMED when it became the 29<sup>th</sup> member of SNOMED International.

# Integration with the national message broker, HealthLink

eHealth Ireland notes that the full national electronic prescription program will be implemented in accordance with national standards and using the National Message Broker, HealthLink.<sup>(64)</sup> This will ensure a standardized transportation mechanism and supporting infrastructure for the safe electronic transportation of a prescription from a prescribing site to a dispensing site.<sup>(64)</sup>

# Electronic prescribing and dispensing capabilities in GP and pharmacy systems

To date, two ePrescribing pilot projects have been undertaken. Run in conjunction with Health Innovation Hub, the first pilot, eScript, involved a small group of GPs and pharmacies in Cork. GPs sent a notification of a prescription directly to the patient's preferred pharmacy before the patient left the GP practice. One lesson learned from this pilot was that sending the prescription notification to an intermediary, instead of directly, was preferred as it would allow patients to fill the prescription in any participating pharmacy. In the second pilot project, again involving a small group of GPs and pharmacies in Cork, GPs sent prescription information to the cloud, where it could be downloaded by pharmacists. GPs also generated

the legal paper script, with a barcode that identified the prescription in the cloud. Pharmacists then scanned the barcode, ensuring the correct prescription information was downloaded.

# **Chapter 3** ePrescribing in Europe

Since the original review, additional research has been carried out on ePrescribing in Europe. In 2013, research found adoption rates of 80% or higher in all the Nordic countries — Denmark, Sweden, Norway, Finland and Iceland — as well as in Estonia, Croatia, and the Netherlands.<sup>(40)</sup> For example, in 2015, 98.8% of Croatian prescriptions were processed electronically, with 2,300 GP offices and 1,300 pharmacies connected to the ePrescribing system.<sup>(65)</sup> Romania, Spain, France, Greece and the United Kingdom were also found to be making progress. The remaining EU member states surveyed were at the very early stages of their respective ePrescribing programs.

This section focuses on Denmark and Sweden as they are long-time EU leaders in the ePrescribing field. It also describes the challenges that Norway (not an EU member) faced and resolved when integrating a message-broker-based ePrescribing system with an electronic health record system. Moreover, it covers progress in ePrescribing in the United Kingdom (England, Scotland, Wales and Northern Ireland), which was described in the original review. It looks at Estonia, a world leader in digital services including ePrescribing, and at the Netherlands, which has well-developed regional ePrescribing systems but is still working towards national interoperability. Finally, it provides a brief overview of European Union programmes to establish infrastructure for cross-border ePrescribing with the EU.

# 3.1 Nordic countries

The five Nordic countries — Denmark, Sweden, Norway, Finland and Iceland — are considered to be the leaders in Europe in the field of ePrescribing. As early as 2013, all five countries had adoption rates of 80% or higher, thanks largely to years of investment in eHealth and health information technology.<sup>(40)</sup> This review focuses on three of those countries: Denmark, Sweden and Norway.

# 3.1.1 Denmark

Denmark is considered the leading country in Europe in terms of eHealth, owing to its long history and significant investment in ICT.<sup>(1,2,3,4,5,6)</sup> By 2010, ePrescribing rates were reported to be close to 100%.<sup>(7)</sup>

# Scale

Denmark is a parliamentary democracy with a constitutional monarchy. The population of Denmark was estimated at just over 5.75 million on 1 January 2017.<sup>(25)</sup>

# Governance

The Danish health system operates across the three political and administrative levels: national, regional and municipal.<sup>(5)</sup> The Ministry of Health has overall responsibility for coordinating and supervising health and elder care.<sup>(5)</sup> The five regions are responsible for hospitals, GPs and psychiatric care.<sup>(5)</sup> The 98 municipalities are responsible for primary healthcare services and elder care.<sup>(5)</sup>

Danish healthcare is universal, compulsory and funded from central taxation.<sup>(45)</sup> All registered residents are entitled to healthcare services, with medication prescribed in hospitals free but medication prescribed by GPs subject to a small fee that is known as a copayment.<sup>(45)</sup> Supplementary private health insurance can be purchased to reduce these copayments and to access services in private hospitals.<sup>(45)</sup> GPs are gatekeepers to specialist and hospital services, except for acute illness, while Danish hospitals are publicly owned and administered by the regions.<sup>(45)</sup>

Founded in 1994, MedCom is the publicly-funded, non-profit cooperative body that develops standards and profiles for the exchange of healthcare-related data in the healthcare sector, liaising with national and international stakeholders.<sup>(66)</sup> Financed and owned by the Ministry of Health, the Danish regions and local governments, MedCom is a cooperative venture between authorities, organizations and private firms linked to the Danish healthcare sector.<sup>(67)</sup> It also manages the operation of the Danish Healthcare Data Network (SDN), a secure virtual private network (VPN) for data communications in the Danish healthcare sector, private and public sections, supplementing the commercial VANS network.<sup>(14)</sup>

Other stakeholder organizations include:

- The Danish Organization of General Practitioners (Praktiserende Loegers Organisation, PLO)<sup>(68)</sup>
- The Association of Danish Pharmacies (Danmarks Apotekerforening).<sup>(69)</sup>

Pharmacies are legally obliged to dispense the cheapest generic version of any prescribed medication. If the patient wants a more expensive product, the patient must pay the difference.

# Strategy

The Danish Government's objective is to make Denmark a world leading ICT-driven nation.<sup>(45)</sup> To fulfil this objective, the Danish Government has published and carried out six national health-IT strategies:

- Handlingsplan for Elektronisk Patient Journal (HEP), 1996-1997, an action plan for the electronic patient journal.
- National strategi for IT i sygehusvaesenet, 2000-2002, the national strategy for IT healthcare services.
- National IT-strategi for sundhedsvaesenet, 2003-2007, the national IT strategy for public health.
- National strategi for digitalisering of sundhedsvaesent, 2008 2012, the national strategy for the digitalization of public health.
- Making eHealth work (2013-2017).
- National Strategy for Personalised Medicine (2017-2020).<sup>(70)</sup>

This reflects the long-term focus on health data networks and on eHealth, with a view to providing efficient access to healthcare information. Since its establishment in 1994, MedCom has developed and carried out strategic work plans to achieve these eHealth objectives. MedCom creates a new strategic work plan every two years, corresponding to its funding cycle. It also developed two key building blocks for eHealth delivery, including ePrescribing:

- the Danish Health Data Network, which was developed in 1994
- the Sundhed.dk healthcare portal, which was developed in2003.

All GPs, pharmacists and other healthcare providers must use software approved and certified by MedCom.

# History

Work began on ePrescribing in the 1990s, and Denmark is considered to have pioneered the electronic transfer of prescriptions using the Electronic Data Interchange (EDI) standard as
part of a wider drive to adopt the Electronic Data Interchange For Administration, Commerce, and Transport (EDIFACT) standards.<sup>(10)</sup> The founding of MedCom in 1994 saw the beginning of a coordinated ePrescribing initiative.

#### Phase 1 — 1994 to 2002

Initially, MedCom worked to establish the transaction broker-based ePrescribing system, defining relevant standards, and encouraging adoption.

### 1994 to 1996 (MedCom I)

Initially funded as a one-off healthcare project running from 1994 to 1996, MedCom I led the development of national EDI standards for frequently exchanged communications and Electronic Patient Records.<sup>(67,71)</sup> MedCom worked with stakeholders to gain consensus and introduce the messages and specifications needed to support projects, including ePrescribing. Messages were sent predominantly using the EDIFACT standard, with a later migration to the XML standard. HL7 v2 was evaluated in the early 2000s, but rejected largely because of poor vendor support at the time.

## 1997 to 1999 (MedCom II)

MedCom ensured that the EDI messaging standards developed previously were disseminated widely and that pilot projects were carried out.<sup>(67,71)</sup> In 1999, the organization was made permanent with formal funding of approximately  $\in$ 3 million annually and a remit to contribute to the development, testing, implementation and quality assurance of electronic communication with the purpose of supporting 'good patient flow'.<sup>(14)</sup>

# 2000 to 2001 (MedCom III)

MedCom worked to consolidate and improve the quality of communication across healthcare data network, including those between GP practices, hospitals and pharmacies.<sup>(67)</sup> By the end of 2001, more than 22 million EDI-based messages had been sent in the healthcare network, including prescription messages.

### Phase II - 2002 to 2014

Between 2002 and 2014, MedCom concentrated on implementing web-based technologies in national and local projects.<sup>(67)</sup> It also worked intensively to introduce electronic health records, together with the associated infrastructure.<sup>(67)</sup> Some of the developments that took place during this period are outlined below.

#### 2002

MedCom reported that an average of 63% of all prescription items were transferred electronically, varying across counties.

#### 2003

MedCom launched the National eHealth Portal, sundhed.dk, which acts as an interface between patients, healthcare practitioners and institutions.<sup>(72)</sup> The portal links existing data sources and is used across all regions and municipalities in Denmark.<sup>(72)</sup> It provides a range of eHealth services, for example, citizens have access to their own prescription data while pharmacies can see what medication has been dispensed at other pharmacies.<sup>(9)</sup> Danish GPs had the option to send e-prescriptions to specific pharmacies or to submit an open eprescription, which could be filled at any pharmacy in the country.

The ePrescribing system was a message-broker-based system that used the EDIFACT Med 3 standard for prescriptions — a standard also used in Sweden. The model was based on asynchronous transfer to a secure mailbox. The prescriber/GP sent the prescription to the server using the EDIFACT message standard. The pharmacist could then retrieve the prescription from the mail server.

The eHealth strategy made provision for implementing and upgrading electronic health records (EHRs).<sup>(7)</sup> As part of this upgrade, the ePrescribing system was extended to include a personal medication profile on a national prescription server, which was set up by the Danish Health and Medicines Authority.<sup>(1,73)</sup>

# 2004

Since 2004, GPs have been mandated to use MedCom-compliant electronic record systems.<sup>(45)</sup>

#### 2007

The Association of Danish Pharmacies began development of a new medicines database. This medicines database was expected to provide patients with a view of their medication and to provide the latest pricing for medications automatically to pharmacists, improving their ability to identify the most cost-effective generic medication.

# 2009

The National eHealth Portal, sundhed.dk, was upgraded and relaunched on a new technical platform, after which citizen views increased by 45%.<sup>(72)</sup>

# 2010

The Danish National Board of eHealth along with the responsible vendor Trifork started to roll out and test the new medication database.

# 2011

The Danish EHR system contained data on more than 85% of the population. Denmark was then the only country in Europe to have a health portal that allowed patients to have access to their medication profiles and to re-order certain repeat medications themselves. That same year, MedCom's remit was widened to improve the efficiency of healthcare delivery.<sup>(5)</sup>

During 2011, the Danish National Board of eHealth and Trifork reviewed the national rollout of the Shared Medication Record and identified the need for a scalable database that makes critical health data highly available.<sup>(74)</sup> They decided to move from an SQL query database to a secure, private cloud-based solution for storing health data.<sup>(74)</sup>

# 2012

The final version of the national medication database was launched. The Danish Health Data Authority took over management of the database.

### 2013

Denmark was ranked first in the use of ICT in general practice in Europe.<sup>(4)</sup> 99% of prescriptions were sent electronically to pharmacies.<sup>(5)</sup>

### 2014

In September, the Shared Medication Record was made mandatory for all doctors, thus effectively phasing out the previous message-broker-based ePrescribing system.<sup>(75)</sup> The record gives patients online access to view their purchases of prescription medicine in the preceding two years and an updated list of their current prescriptions.<sup>(9,73)</sup>

### Phase III — Current system

Intended for use by all GPs, hospitals, and municipalities, the Shared Medication Record uses the Danish national health ID to provide Danish citizens with information about all medications prescribed and dispensed to the patient for the last two years. Pharmacies download the updated version of the national medicines database every two weeks to ensure their systems have the correct information.

In the Shared Medication Record implementation, ePrescribing does not involve sending the prescription via a message broker. To prescribe medication, the prescriber updates the patient's Shared Medication Record directly in the Shared Medication Record database. When the pharmacist dispenses the prescribed medication, they also update the record. Dispensers can also update the dosage and indications, as required. In the previous system, neither could be altered.

The record is paused if a patient is admitted to hospital then restarted when the patient is discharged. The discharging healthcare provider is also obliged to update the record with any medications that the patient has been prescribed for use after discharge. The Shared Medication Record database uses the national XML standard and can be queried each time medication is prescribed or dispensed. Use of the Shared Medication Record is now mandatory and all GPs, specialists, private hospitals and home care services have access to the record.

### Success factors and lessons learned

Other initiatives which facilitated ePrescribing in Denmark include:

- The existence of an unique health identifier for patients in Denmark since 1966.
- The coordination of all ePrescribing and eHealth IT related programs by MedCom, which has the authority to approve and certify systems and to mandate use.
- MedCom's ability to regulate the GP management systems, into which the ePrescribing system is integrated.
- The Danish Medicines Agency's national medicines file. The agency, which regulates the used of medicines in Denmark, produces a single national file of all medicines every two weeks, and this is distributed to software suppliers. The file contains information about drugs, including name, content, substitutions, price, mapping to ATC codes and codes for dosage. There is almost 100% adoption of this file by

vendors of GP and pharmacy systems, thus facilitating interoperability and ePrescribing.

- The national eHealth portal launched in 2003 designed to provide patients with services such as viewing of their hospital records, booking of appointments, ordering medications and renewing prescriptions.
- Proactive approach by MedCom to train software suppliers in the specifications developed by MedCom.

Two factors contributing to the successful digitization of healthcare generally, and ePrescribing in particular, were:

- MedCom's close work with key stakeholders, gaining consensus on the standards to be implemented. This helped ensure the successful adoption of MedCom standards, for example, MedCom gained consensus on the EDIFACT messaging standard for the original ePrescribing system and developed the necessary messages and specifications.
- the establishment of a health data network for secure electronic communication between healthcare providers.

For both the current and previous systems, MedCom worked closely with experts from the pharmacy association(s), GP association(s), and the EMR vendors to develop standards. MedCom provided training to those groups as part of preparation for implementation. Many of the relationships are longstanding, with some EMR vendors working in the market since 1994.

However, Denmark's 'aggressive push for eHealth systems' has had some negative consequences.<sup>(4)</sup> In spite, or perhaps, because of this strong drive for a digitized healthcare system, the main systems have difficulties exchanging data. At the time of writing, work continues to make the link between the various IT solutions in the Danish healthcare system 'more seamless'.<sup>(5)</sup>

# 3.1.2 Sweden

Sweden transferred the world's first ePrescription in June 1983.<sup>(76,77)</sup> It is recognized as a leader in Europe in the area of ePrescribing and, after Denmark, Sweden is considered to be the most e-health oriented nation in Europe.<sup>(12,40)</sup>

# Scale

The population of Sweden was estimated to be just under 10 million on 1 January 2017.<sup>(25)</sup>

# Governance

The Government of Sweden sets the political agenda for health and medical care through laws and ordinances or by reaching agreements with county councils and municipalities.<sup>(12)</sup> Sweden is divided into a non-hierarchical structure of 290 municipalities and 21 county councils.<sup>(12)</sup> Municipalities and county councils are autonomous and make their own investments in ICT, and they also pay for the bulk of health and medical costs.<sup>(12)</sup> National government acontribute some funding while patients pay a small percentage of costs.<sup>(12)</sup> Patients can choose the hospital or specialist they attend but must be referred by their GP.<sup>(12)</sup>

The county councils, regions and municipalities collaborate on the development of digital services through the limited company, Inera AB, which they own and manage.<sup>(78)</sup> The Swedish Association of Local Authorities and Regions (SALAR) also collaborates through Inera AB, which was originally known as the Center for eHealth.<sup>(12,78)</sup> Apoteket AB is a state-owned pharmacy business that was founded in 1971.<sup>(79)</sup>

The Swedish Pharmacy Association represents the interests of pharmacists, while the Swedish Association for General Practice represents physicians.<sup>(80,81)</sup> Key stakeholders include:

- Swedish Association for General Practice (Svens forening for allmanmedicin)<sup>(80,82)</sup>
- Swedish Pharmacy Association (Sveriges Apoteks Forening)<sup>(81)</sup>
- Apoteket AB, the state-owned pharmacy business<sup>(79)</sup>
- Swedish Association of Local Authorities and Regions (Sveriges Kommuner och Landstig, SALAR)<sup>(83)</sup>
- Inera AB, a limited company owned by SALAR.<sup>(78)</sup>

# Strategy

In 2005, the National IT Strategy first proposed the development of a Swedish eHealth architecture.<sup>(12)</sup> It was intended to:

- provide patients with comprehensive information on health in general and on their own health
- provide healthcare professionals with access to information across organizational boundaries that would ensure patient safety and facilitate their daily work
- provide healthcare decision makers with access to relevant information to monitor and follow up on patient safety, quality of care and healthcare performance.<sup>(12)</sup>

These objectives were expanded in subsequent strategies and action plans, namely:

- National EHealth the Strategy for Accessible and Secure Information in Healthcare (2010)<sup>(84)</sup>
- National Action Plan for eHealth (2009-2012)<sup>(12)</sup>
- National Action Plan for eHealth (2013-2018)<sup>(12)</sup>.

The two initial strategies provided a vision of potential eHealth use while the two action plans contained a clear statement of what needed to be achieved and when.<sup>(12)</sup>

# History

Sweden was one of the first countries in the world to explore the possibility of transferring prescriptions electronically.<sup>(76,77)</sup> Some the developments that took place during the development of ePrescribing are outlined below.

# 1980s/1990s

In 1981, a working group of computer experts, physicians and pharmacists was tasked with exploring the possibility of transferring a prescription from a GP's office to a pharmacy using a computer.<sup>(77)</sup> This work resulted in the world's first electronic transfer of a prescription in 1983 from a doctor's office to a nearby outpatient pharmacy.<sup>(77)</sup> An online pilot in 1984 saw physicians connected to their local pharmacy system. Messaging began to be used in the 1990s, in relatively small volumes, until common standards for health data exchange were introduced in 2000 and electronic prescribing became normal practice.<sup>(9,10)</sup> Sweden adapted the Electronic Data Interchange (EDI) standard, which Denmark had pioneered, for its own use.<sup>(10)</sup>

#### 2001

Around this time, the EDIFACT standard began to be replaced by an XML message format based on the European pre-standard ENV 13607.<sup>(10)</sup>

#### 2002

The use of ePrescriptions in Sweden increased rapidly from this year on.<sup>(77)</sup> Though it occurred approximately 20 years after the first pilot project, this tipping point is considered to have originated from the decisive strategic action taken in the late 1990s by the National Corporation of Swedish Pharmacies (Apoteket AB), in cooperation with different regional healthcare bodies and national players.<sup>(77)</sup>

#### 2004

Patients could have their medication dispensed at any pharmacy and access their prescriptions using an online portal. Known as 'eRecept', the electronic prescription could be transferred in one of two ways — the prescription could be sent from a primary care electronic medical record system or GPs could generate ePrescriptions using a secure webbased prescribing package, which forwards the prescription securely to a designated pharmacy or to the centralized national ePrescription database.<sup>(85,86)</sup> The message-brokerbased ePrescribing system used an EDIFACT Med 3 standard. Sweden developed this standard, which was subsequently adopted in Denmark and Finland. Only prescribers and dispensers have access to the database. Patients could collect their medications at any pharmacy in Sweden.

### 2005

Legislation was changed to allow the establishment of an online prescription repository, and the National Pharmacy Register was established.<sup>(77)</sup>

#### 2006

Citizens had the option to store their prescription information for up to 15 months in the repository, with only the prescribing GP and pharmacy personnel allowed access.<sup>(6)</sup>

### 2007

Inera AB developed the first Swedish National Reference Architecture Framework.<sup>(12)</sup> The framework defines the set of architecture principles, architecture patterns and guiding examples that govern projects, whether nationally- or regionally-funded, in the Swedish eHealth ecosystem.<sup>(12)</sup> This coordinated strategy included the launch of a national reference architecture for eHealth by the national eHealth standardization body, Carelink, and the establishment of a new national eHealth programme office, called the Center for eHealth.<sup>(12)</sup>

# 2008

By September 2008, 70% of all new prescriptions were transferred electronically.<sup>(2,76,77)</sup>

# 2011

The national reference architecture was updated to improve patient empowerment.<sup>(12)</sup>

# 2014

More than 90% of prescriptions were sent electronically.<sup>(87)</sup>

### 2016

Approximately nine million prescriptions were generated monthly in Sweden, with 98% of these estimated to be ePrescriptions.<sup>(11)</sup>

# **Lessons learned**

One of the six architecture principles that Inera developed was allowing the organic development by county councils (and therefore by many stakeholders) without relying on central direction. This is considered to have played a key role in the development of the Swedish eHealth ecosystem.<sup>(12)</sup> This ecosystem includes ePrescription as part of its care services and electronic health record system.<sup>(12)</sup>

When ePrescriptions were introduced, Sweden had a single, state-owned pharmacy chain (Apoteket AB). Stockholm County Council collaborated with the state-owned chain to introduce ePrescriptions in the region around Stockholm. Later, ePrescriptions were rolled out to other regions. Healthcare is organized at regional level in Sweden; however, the Swedish eHealth authority retains organizational responsibility for e-prescription. This decentralized rollout model, with introduction planned locally and evaluation meetings held every three to six months as operations began, was considered to be a factor in the program's success.

From 1970 to 2009, the National Corporation of Swedish Pharmacies was the sole pharmacy retailer in Sweden. This enabled the development of pharmacy ICT much earlier than other European counterparts.

However, in 2016, the Swedish national ePrescription service failed for seven hours.<sup>(11)</sup> Emergency procedures had been put in place and implemented, for example, pharmacies reverted to paper prescriptions and were able to assess anyone requiring medication urgently and dispense appropriate medication. Non-urgent cases were advised to return the following day.

# 3.1.3 Norway

Like Denmark and Sweden, Norway is considered to be a leader in Europe in ePrescribing. Electronic prescription capabilities were finally installed in all GP surgeries and pharmacies in February 2013.<sup>(88)</sup>

### Scale

The population of Norway was estimated to be just under 5.26 million on 1 January 2017.<sup>(25)</sup> Norway is split into four regions and 428 municipalities.<sup>(12)</sup>

### Governance

The Norwegian Ministry for Health and Care is responsible for setting overall health policy, while the Directorate of Health is responsible for carrying out this policy since 2008.<sup>(12,89)</sup> The regional authorities manage the hospitals in their respective regions, while primary care is managed at municipal level.<sup>(12)</sup> Roughly half of GPs are employed by the municipalities, with the other half in private practice.<sup>(12)</sup> Since the privatization of the pharmacy sector in 2001, pharmacies are managed by five pharmacy groups.<sup>(12)</sup> The primary care sector issues 70% of prescriptions, with hospitals issuing the remainder.<sup>(12)</sup> Norwegian healthcare is largely publicly funded by a national insurance scheme.<sup>(12)</sup>

The Norwegian Directorate of eHealth (NDE) established on 1 January 2016 as a subordinate institution of the Ministry for Health and Care Services, replacing the Ministry's

former eHealth division.<sup>(89)</sup> The NDE coordinates the development and delivery of eHealth services, including ePrescribing. Key stakeholders include:

- the National Pharmacist's Union
- the National Insurance Administration
- the Norwegian Medical Association
- the Norwegian Medicines Agency
- vendors for EPR solutions
  - three vendors for GP solutions: ProfDoc (approximately 70% market), InfoDoc (25%), Hove (5%)
  - three vendors for hospital solutions
  - one vendor for pharmacy solution: NafData

# Strategy

In 2004, existing regional health networks were consolidated into a dedicated secure network called the Norwegian Health Network (NHN).<sup>(12)</sup> All GP offices, hospitals and nursing homes have electronic patient record (EPR) systems and can communicate using this network.<sup>(12)</sup> Within the Directorate of Health, a permanent organization was established for the development, maintenance and governance of the network.<sup>(12)</sup> The governance structure included a Change Council, with representatives from stakeholder groups such as vendors, and a Change Forum.<sup>(12)</sup>

The 2008–2013 eHealth strategy included ePrescribing as a priority, covering all aspects of the generation and transfer of prescriptions and the reimbursement of expenses in a comprehensive system.<sup>(13)</sup>

In 2010, HealthNorway was established to provide secure digital services to citizens, which would help strengthen citizens' role in healthcare.<sup>(12)</sup> The organization devised and delivered a strategy around health information and services.<sup>(12)</sup>

In 2012, the Government white paper *One citizen, one record* outlined the aim to give healthcare professionals and patients easy and secure access to appropriate information and services and to make the data, which should be registered automatically, available for monitoring, quality assurance, governance and research.<sup>(12)</sup>

#### History

Key steps in the development of ePrescribing in Norway are outlined below.

### 2004

Following a report in 2001 from the Office of the Auditor General, which raised concerns about prescription refunds from the Welfare Administration Agency, the Ministry of Health initiated a pilot study on ePrescriptions in 2004.<sup>(12)</sup> Managed by the Ministry, the pilot project included representatives for the four main stakeholders — the National Pharmacists' Union, the National Insurance Administration, the Norwegian Medical Association and the Norwegian Medicines agency.<sup>(12)</sup>

#### 2005

All pharmacies in Norway were using NAF-Data's FarmaPro solution.<sup>(12)</sup> NAF-Data had decided to develop an electronic prescription module as part of their new version of FarmaPro and announced that the new module would be released in 2008.<sup>(12)</sup>

#### 2006

The Norwegian Directorate of Health published detailed requirements and specifications, including an architectural document, for a fully integrated ePrescribing solution.<sup>(12)</sup> The solution included 31 standardized messages carrying information between the applications, emphasising exchange of messages that conform to approved standards.<sup>(12)</sup>

The six main electronic patient record (EPR) solution vendors were invited to participate in pilot projects.<sup>(12)</sup> Only the largest vendor for the GP market, Profdoc, participated.<sup>(12)</sup> (The other two GP solution vendors, Infodoc and Hove, joined later.)<sup>(12)</sup> Profdoc had two existing EPR solutions, but was developing a third version to replace both.<sup>(12)</sup> It decided to developed a new ePrescribing module for the new EPR solution only.<sup>(12)</sup>

#### 2008

The first small pilot implementation, between GPs and the local pharmacy in a small town in Eastern Norway, performed very poorly and eventually failed.<sup>(12)</sup> GP vendor Profdoc's new EPR solution was at fault as it was highly unstable; however, the electronic prescription element was blamed in the media.<sup>(12)</sup> NafData also announced that release of their new ePrescription module, scheduled for 2008, would be delayed.<sup>(12)</sup>

# 2009

The ePrescription exchange message broker was tested and accepted.<sup>(12)</sup>

# 2010

Pilot testing started as planned in two locations: the first covered two GP offices and one pharmacy, while the second covered two pharmacies and a handful of GP offices.<sup>(12)</sup> All the GPs used the Infodoc EPR system, the only EPR vendor solution ready for testing at the time.<sup>(12)</sup>

During the first pilot, ProfDoc's management was so unhappy with progress on the new ePrescription module that they informed the ePrescribing program management that they were considering abandoning work.<sup>(12)</sup> However, with 70% of the GP market, ProfDoc was essential to the success of the ePrescribing initiative and was encouraged to continue.<sup>(12)</sup> During the second half of 2010, Profdoc developed GPM, which ran in parallel with Profdoc's two existing EPR systems and handled all prescription information separately (rather than developing the module for the new product as planned).<sup>(12)</sup> This was intended to be a temporary workaround that decoupled the ePrescribing module from the new EPR solution release schedule.<sup>(12)</sup>

# 2011

The third GP EPR vendor, Hove, completed the updates to its medication module and started to roll out the updated product to GPs.<sup>(12)</sup> Profdoc also rolled out the standalone ePrescribing module, GPM, that could be used with its two existing EPR systems.<sup>(12)</sup>

In June, pharmacy software vendor, NafData, was still uncertain of when their ePrescribing module (originally scheduled for release in 2008) would be ready for deployment.<sup>(12)</sup> After the Minister for Health and the national initiative management indicated that they were considering adapting ProfDoc's GPM solution for pharmacy use, NAF-Data raced to complete their new version.<sup>(12)</sup>

A PricewaterhouseCoopers report showed that the two ePrescribing pilots were considered successful, with high user satisfaction.<sup>(12)</sup> However, the report also highlighted challenges, for example, all GPs would need to upgrade their ICT infrastructure to run the solution but it was unclear who would pay these costs.<sup>(12)</sup>

#### 2012

Profdoc started to roll out its new EPR version, CGM Journal, with an integrated ePrescription/medication module.<sup>(12)</sup> By March, the new solution was deployed to about 280 GP practices and 134 pharmacies in 67 of 428 municipalities.<sup>(12)</sup> More than 1 million prescriptions were sent.<sup>(12)</sup> It was expected that the ePrescribing solution would be deployed to GPs and pharmacies in all municipalities by the end of 2013.<sup>(12)</sup>

In 2012, work also started to adapt the Prescription Exchange, GP systems and pharmacy systems to support multi-dose dispensing.<sup>(12)</sup> Additionally, work intensified to integrate hospital EPRs with the ePrescribing solution.<sup>(12)</sup> These developments are not covered in this review.<sup>(12)</sup>

### 2013 and after

A major revision of the ePrescribing infrastructure was also approved in 2013.<sup>(12)</sup> This includes updates to messages and a range of modifications based on practical use, such as error corrections and modifications triggered by regulatory changes. New messages and functions were added the ePrescription solution, allowing the solution to be integrated with new secure health information services.<sup>(12)</sup>

The new secure health information service, My Health, was also launched.<sup>(12)</sup> My Health was an online portal where citizens could find information about their GP, expenses and prescriptions.<sup>(12)</sup> Access to the Shared Care Summary Record was added to the My Health portal.<sup>(12)</sup>

These two infrastructures — the ePrescription infrastructure and the Summary Care Record infrastructure — are under different jurisdictions, with different governance. For example, the ePrescription infrastructure is only allowed to store prescriptions while they are valid while the Summary Care Record infrastructure can store them for up to three years.<sup>(12)</sup> Prescription information from the ePrescription infrastructure is mirrored in the Summary Care Record infrastructure, with updates made to the ePrescription Exchange during the preceding 24 hours are copied to the Summary Care Record database.<sup>(12)</sup>

#### **Lessons learned**

The ePrescribing information infrastructure has been widely adopted and is considered a success. The solution was developed with a strong focus on the everyday practices of GPs (prescribing) and pharmacies (dispensing).<sup>(12)</sup> The initial pilots were developed based on the existing EPR and pharmacy systems being linked through a message broker and the secure network.<sup>(12)</sup> This led to challenges when developing ePrescribing in other areas (hospitals) or for more complex processes (multi-dose dispensing).<sup>(12)</sup>

From a technical point of view, the workaround module for ePrescribing decoupled progress on the ePrescribing infrastructure from the EPR systems' development schedules and eased the challenges mentioned.<sup>(12)</sup> Finally, from a governance point of view, the initial ePrescribing strategy assumed (incorrectly) that all the stakeholders involved — vendors, GPs, pharmacists, municipalities and so on — had both the means and the motivation to implement the changes required for the ePrescribing strategy to succeed.<sup>(12)</sup>

# 3.2 United Kingdom

This section describes the development and implementation of ePrescribing in each of the countries in the United Kingdom. It provides a detailed account of the development of ePrescribing in primary care in England, which has the largest share of the British population, then summarizes the development in Scotland, Wales, and Northern Ireland.

### Scale

The United Kingdom is a parliamentary democracy with a constitutional monarchy.<sup>(90)</sup> The population of the United Kingdom was estimated to be just over 65.8 million on 1 January 2017.<sup>(25)</sup>

### Governance

Established in 1948, the National Health Service (NHS) manages the day-to-day delivery of free healthcare to the all UK residents.<sup>(14,91)</sup> The NHS is a publicly funded healthcare system, financed mainly from general taxation but with a small proportion coming from national insurance and other sources.<sup>(91)</sup> Private health insurances schemes also exist.<sup>(91)</sup>

In 1999, the national parliament of Scotland and the national assemblies of Wales and Northern Ireland took over responsibility for health policy, as well as other policy areas, in their respective jurisdictions.<sup>(90)</sup> NHS Scotland, NHS Wales and NHS Northern Ireland are

correspondingly responsible for the delivery of health services in their respective regions.<sup>(90)</sup> The UK Department of Health retains responsibility for health policy in England, and NHS England manages the delivery of health services.<sup>(90)</sup> All four organizations have a framework for cooperation, which is reviewed regularly.<sup>(92)</sup> The NHS organization also reports on healthcare in the United Kingdom as a whole, for example, comparing metrics in the four jurisdictions and producing statistical analyses for the whole of the UK.

In all four jurisdictions, primary care is delivered largely through GPs, who refer patients to secondary care such as specialists and hospitals.<sup>(91)</sup> Patients usually register with the local GP practice, though some walk-in clinics that do not require registration exist.<sup>(91)</sup> The Community Pharmacy Contractual Framework (2005) stated that all community pharmacies in England and Wales would be provided with a new Electronic Transfer of Prescriptions (ETP) service, for the safe, secure transfer of patient prescription information from GP practices.<sup>(21)</sup>

Stakeholders include:

- the British Medical Association, which represents doctors working in all areas of the UK
- the General Pharmaceutical Council, which regulates pharmacists in the UK.

# 3.2.1 England

### Scale

In 2016, the population of England was estimated to be just over 55.2 million.<sup>(93)</sup>

### Governance

The UK Secretary of State for Health has a legal obligation to ensure the provision of a free healthcare system, apart from specified fees.<sup>(91)</sup> Led by the Secretary of State for Health, the Department of Health provides strategic leadership for healthcare in the UK.<sup>(91,94)</sup> NHS England is responsible for the day-to-day delivery of health services across England. From 2001 to 2013, NHS England was organized into 10 Strategic Health Authorities (SHA), each of which was responsible for implementing Department of Health policy.<sup>(14)</sup> Each SHA supervised a number of primary care trusts that responsible for commissioning and running health services in their areas.<sup>(14,94)</sup>

Following a reorganization in 2013, Primary Care Trusts ceased to exist and NHS England was organized into a number of Clinical Care Groups (CCGs), each of which is responsible for the commissioning and running of health services in their respective area.<sup>(95)</sup>

Stakeholder groups included:

- GP groups: Royal College of General Practitioners, the British Medical Association (BMA) and other primary care specialist groups.
- community pharmacy groups: Royal Pharmaceutical Society
- NHS strategic health authorities (SHAs) and primary care trusts (PCTs)
- NHS Business Services Authority
- patients and user groups
- vendors.

To harness the power of information technology, the Department of Health has established a number of institutions and NHS England has undertaken a number of projects.

# **Projects and institutions**

- The National Programme for Health IT (2002) project was launched as part of the Department of Health strategy for digitalization of health service delivery, principally through an EHR system but later including an ePrescribing service.
- NHS Connecting for Health (2005) was established as the directorate responsible for delivering the National Programme for Health IT (NPfIT), including the ePrescribing service.<sup>(14)</sup> Initially expected to run until 2010 at the latest, its termination was announced in 2011 and it ceased to exist in 2013.<sup>(15)</sup>
- The Health and Social Care Information Centre (2013) was established to take over responsibility for the ePrescribing service and other parts of the NPfIT from NHS Connecting for Health on 31 May 2013.<sup>(96,97)</sup> The name was changed to NHS Digital in 2016.<sup>(98)</sup>

### Infrastructure and components

- The Dictionary of Medicines and Devices (2004) was adopted to ensure a single standard for representing medicines.
- The Care Records Guarantee (2005) was introduced to safeguard electronic patient data.<sup>(15)</sup>
- NHS Spine (2007/2008) was trialled and launched, providing a database of patient demographic information and patient summary for each UK resident that NHS Connecting for Health maintained. The service was migrated to an open source base in 2014.<sup>(99)</sup> NHS Digital now maintains the NHS national IT infrastructure.<sup>(100)</sup>

### Strategy

As early as the 1990s, the UK recognized the potential for the digital delivery of health information and services, creating strategies to exploit these capabilities:

 Information for Health and Information for Strategy for the Modern NHS from 1998-2005 outlined the aim to provide NHS staff with the most modern tools to improve the treatment and care of patients.

- Equity and Excellence: Liberating the NHS (2010) placed even more emphasis on the importance of health information for patient-centric care.
- The Power of Information (2012) was the 10-year strategy aimed at harnessing new technologies and information to improve healthcare services and outcomes, produced in response to consultation documentation.<sup>(14)</sup>
- The Five Year Forward View (2014) strategy restated the NHS commitment to harness information technology to improve the delivery of health services and listed ePrescribing as one of the digital services to be delivered.<sup>(101)</sup> It noted that, while the NHS had invested significantly in digital health services, interoperability issues remained and progress was slower than expected.<sup>(101)</sup>

When developing the Electronic Prescription Service, the NHS carried out an extensive engagement programme.<sup>(15,54)</sup> In fact, the EPS stood out among NPfIT programmes for the range of stakeholders it needed to engage and for how closely it worked with these stakeholder groups throughout the development and implementation of the service and creating appropriate training programmes— for example, GP practices, community pharmacies, the Pharmaceutical Services Negotiating Committee (PSNC), Royal colleges, professional associations, and software vendors.<sup>(15,102)</sup>

The NHS Electronic Prescription Service (EPS) required prescribers and dispensers to register to use the service. Once registered, they were issued with smartcards to control their access to the service. The service was introduced using an incremental approach:

# Electronic Prescription Service Release 1 (ETP R1)

Release 1 added barcodes to prescriptions and established the fundamental technical infrastructure for message transmission.<sup>(15)</sup> The standard paper prescription form, FP10, was changed to include a space for a barcode, which had a universal unique identifier.<sup>(15)</sup> The unique identifier ensured the correct prescription was retrieved from the NHS Spine.<sup>(15)</sup> The paper prescription remained the legal entity, while an electronic version of the prescription was uploaded to the NHS Spine.<sup>(15)</sup> The NHS Spine is a centrally managed reference database that stores the electronic prescription as well as the demographic information.<sup>(15)</sup>

Community pharmacists could scan the barcode to identify and retrieve the patient's prescription from the NHS Spine.<sup>(15)</sup> This phase provided dispensers with a chance to test

information retrieval from the NHS Spine and to ensure that every patient had only one record in the NHS Spine.<sup>(15)</sup>

Implementation of Release 1 was split into two phases:

**Phase 1** Release 1 pilots were set up at specified sites only.<sup>(14,15)</sup> A series of pairs of GP practices and community pharmacies tested Electronic Prescription Service Release 1 Phase 1 (EPS R1 P1) modules.<sup>(15)</sup> Once the modules met acceptable standards for message exchange and were accepted by the test sites, the modules were given to the NHS for deployment.<sup>(15)</sup>

**Phase 2** National implementation of Release 1 began, with the goal of installing the accepted Electronic Prescription Service for all.<sup>(15,103)</sup> Primary care trusts were responsible for applying for Directions from the Secretary of State for Health, authorizing them to implement the service in their respective areas.

### **Electronic Prescription Service Release 2**

In this release, the electronic prescription was sent to the NHS Spine, where it could be downloaded by any pharmacist or the patient's nominated pharmacist.<sup>(15)</sup> The electronic prescription, which was signed digitally, was the legal document, and the patient receives a paper notification with barcoded identifier.<sup>(15)</sup> When the patient presented the notification, the dispenser scanned the barcode to identify the prescription in the NHS Spine then download the prescription to the dispensing system.<sup>(15)</sup>

The following capabilities were also included:

- Nomination of dispenser, where the patient can nominate the dispenser.
- Cancellation of prescription, which allows for the prescriber (or any authorized staff in their practice) to cancel the prescription up until it is dispensed.
- Repeat prescribing/dispensing, where prescribers can sign a number of prescriptions electronically.<sup>(104)</sup>

Some provision remains for paper prescriptions—for example, in case of EPS outage.<sup>(15)</sup> Again, implementation of Release 2 was split into two phases:

**Phase 3** A restricted number of prescribing-dispensing pair sites took part in live testing of prescribing and dispensing using Release 2.<sup>(15)</sup> Prescriber entry was tightly controlled — prescribers could connect to R2 functionality only if their primary care

trusts had been authorized by Secretary of State Directions.<sup>(15)</sup> Dispensers/pharmacies did not require identification.<sup>(15)</sup> Any pharmacy could dispense an R2 prescription.<sup>(15)</sup>

**Phase 4** This phase is the national implementation of Release 2, providing full electronic prescribing capability.<sup>(15)</sup>

# Timelines

The core goal of R1 was to set up and test the underlying infrastructure, for example, to ensure only one Spine record existed per patient.<sup>(15)</sup> While some clinical benefits were expected to arise during R1, the main benefits were expected during R2.<sup>(15)</sup>

Originally, the expected date for the deployment of Electronic Transfer of Prescriptions service was 2007.<sup>(15)</sup> The service has followed this implementation schedule:

Release	Phase	Purpose	Start dates
ETP R1	<b>Phase 1</b> For initial implementersStarted in 2005		Started in 2005
	Phase 2	For nationwide deployment	Started in 2005
ETP R2 Phase 3 For		For testing in limited locations	Started in 2008
	Phase 4	For full ETP nationwide	Planned for 2018 or later

### Architecture

The EPS release 1 retained the paper script as the legal prescription and transferred the prescription information in parallel via the NHS Spine, with the following architecture:<sup>(14)</sup>

# EPS release 1 used the following architecture:<sup>(14)</sup>



#### Figure 4. EPS Release 1 architecture

	Name	Examples
1	Prescribing Systems	Examples include GP practice management systems
2	NHS Network N3	NHS national broadband network
3	Dispensing Systems	Examples include pharmacy dispensing systems
4	Commercial network	Contracted network services for pharmacies
5	Transaction messaging service (TMS)	Spine service routing messages
6	Electronic prescription service (EPS)	Spine transient store for prescription messages
7	Identity agent (IA)	Spine service to check user credentials for access
8	Personal demographics service (PDS)	Spine service with data for each registered NHS user
9	NHS Choices	NHS website providing information to patients and others
10	NHS prescription service	NHS service for pharmacy reimbursement

### History

Key steps in the development of ePrescribing in England are outlined below.

# 1997 to 2002

In 1997, the Department of Health published a series of principles for use of ETP and, in 2000, announced trials of ETP.<sup>(105)</sup> Three pilot ETP implementations began in 2002 but finished in 2003 without providing a model for national implementation.<sup>(15)</sup>

# 2003

The Minister for Health announced that the Electronic Prescription Service would be delivered as part of the National Programme for Health IT (NPfIT).<sup>(15)</sup> The programme was intended to develop the IT infrastructure needed for health services.<sup>(105)</sup> ETP related procurement was also undertaken, with PCTs procuring GP practice management systems in response to requests. Community pharmacies received two payments for deployment of EPS R1 and R2 and a monthly payment for connecting to the NHS Spine.<sup>(15)</sup>

### 2004

The Dictionary of Medicines and Devices (2004) was adopted to ensure a single standard for representing medicines in the Electronic Prescription Service.

### 2005

The newly-established NHS Connecting for Health took over management of NPfIT programme, including the Electronic Prescription Service.<sup>(105)</sup> NHS Connecting for Health was an executive agency with a five year remit to manage delivery of digital services.<sup>(105)</sup> NHS Electronic Prescription Service Release 1 Phase 1 was deployed in series of GP– pharmacy pairs (one GP and one community pharmacy) using specific systems for testing. Once testing was successful, the modules were distributed nationally.<sup>(15)</sup>

### 2007

Pharmacy systems were updated to enable access to the NHS Spine.<sup>(15)</sup> The paper script remained the legal document but prescription information could be sent in parallel from GP practices to pharmacies via the Spine. In July, one estimate was that EPS R1 was live in 66% of GP practices and 48% of pharmacies.<sup>(106)</sup> Another estimate held that 70–80% of GP practices sent prescription information electronically to the Spine but only 10% of the

prescription information was being downloaded electronically from the Spine at pharmacies.<sup>(106)</sup>

#### 2008

The Department of Health gave the formal go-ahead for EPS Release 2.<sup>(15)</sup>

#### 2009

Secretary of State Directions were issued to 17 initial implementer primary care trusts, with plans for two waves of deployment.<sup>(15)</sup> This authorized prescribers in those trusts to connect to R2 functionality, where both paper and electronic prescriptions are legal documents.<sup>(15)</sup> Testing began in Leeds.<sup>(15)</sup>

#### 2010

Testing of the Electronic Prescription Service continued in other sites.<sup>(15)</sup>

# 2011

The NPfIT ceased before completion due to spiralling costs and a lack of value for money, and the NHS Connecting for Health organization was abolished.<sup>(15)</sup>

#### 2012

The new NHS strategy, Power of Information, was released, emphasising the patient's management of their own data.

#### 2013

The Health and Social Care Information Centre was established as part of the new strategy, taking over management of the NHS Spine and other infrastructure components from NHS Connecting for Health, which ceased to exist.<sup>(15)</sup> The original HIQA review identified 137 primary care trusts (PCTs) as authorized to use the R2 functionality in February 2013.<sup>(107)</sup>

#### 2016

An estimated 43% of prescriptions were transmitted electronically, as Release 2 prescriptions, in April.<sup>(9)</sup>

#### **Current state**

By January 2018, the Electronic Prescription Service (EPS) was live in 11,672 (99.4%) community pharmacies and 6,869 (91.3%) GP practices in England.<sup>(16)</sup> More than 588 million Release 2 prescriptions have been sent and more than 26.1 million patients have nominated a dispenser.<sup>(16)</sup> During November 2017, an estimated 25,044,235 prescriptions were claimed by EPS Release 2.<sup>(16)</sup>

As described earlier, the EPS is a national system implemented within the NHS Spine, which provides a transitory store of prescription data for prescriptions that are still in the dispensing process. The NHS Business Services Authority (NHSBSA) is responsible for the long-term storage of prescribing and dispensing data. The NHS Business Services Authority (NHSBSA) receives 54 million dispensed medication items per month, receiving 63.7% of all prescriptions electronically in July 2017.<sup>(108)</sup> The service must handle over a million transactions per day, with peak periods during and after GP surgery hours.<sup>(108)</sup> It is designed to handle these peak loads with minimal impact on service response times.<sup>(108)</sup>

It is estimated that Release 2 Phase 4 will increase this figure to 90% of all prescriptions. Phase 4 will be launched as a pilot at a small number of GP practices across England once General Medical Services (GMS) Regulations are amended as needed.

The Phase 4 pilot is in progress and NHS Digital is focussing on enhancements such as the prescribing and dispensing of Schedule 2 and 3 Controlled Drugs and developing the EPS Prescription Tracker.

### **Lessons learned**

Several reasons were identified for the incremental approach to ePrescribing implementation. First, the scale of the implementation created logistical challenges that were best resolved by an incremental approach, for example, deploying locally and coordinating this deployment with other services such as the Personal Demographics Service, the Identity Agent service and the NHS website. Second, implementing the ePrescribing service while retaining the paper-based prescription allowed patients to become familiar with the electronic service while retaining the choice of pharmacist and of paper or electronic versions.

NHS Digital estimated that, over the three years from 2013 to 2016, the 'transformative' electronic prescription service saved the NHS £130 million.<sup>(109)</sup> Prescribers saved £327 million, while dispensers saved nearly £60 million over the same period.<sup>(109)</sup> NHS Digital also reported significant time savings for prescribers, dispensers and patients.<sup>(109)</sup>

# 3.2.2 Northern Ireland

### Scale

In 2016, the population of Northern Ireland was estimated to be just over 1.8 million.<sup>(93)</sup>

### Governance

As in England, healthcare services in Northern Ireland are free at the point of delivery.<sup>(14)</sup> However, in Northern Ireland, healthcare services are also integrated with social care services such as home care and social work.<sup>(14)</sup> Formerly known as the Department of Health, Social Services and Public Safety, the Department of Health in Northern Ireland has overall responsibility for setting policy in these areas: health and social care, public health and public safety.<sup>(110)</sup>

Health and Social Care, the NHS organization for Northern Ireland, is responsible for implementing the Department's policy on health.<sup>(111)</sup> The Health and Social Care organization is comprised of several Northern-Ireland-wide bodies, such as the Northern Ireland Ambulance Trust and five regional trusts.<sup>(111)</sup> The regional trusts provide and manage a wide range of health and social care services in their communities, including primary care.<sup>(111,112)</sup> The Regulation and Quality Improvement Authority (RQIA) regulates the delivery of these services.<sup>(113)</sup>

The Data Protection Act 1998 provided the eight fundamental principles for the use of personal data, including healthcare data.<sup>(114)</sup> Health and Social Care's Standard on Information and Communications Technology also requires providers to use a consistent, comprehensive and systematic approach to managing electronic information and systems.<sup>(14)</sup> All health and social care providers must adhere to the Code of Practice on protecting the confidentiality of service user information, which the Department of Health published to ensure that the privacy and confidentiality of individuals are safeguarded.<sup>(14)</sup> The ePrescribing system was seen as improving the safety of communications between care providers and pharmacists.<sup>(14)</sup>

# Strategy

In 2005, the Department of Health, Social Services and Public Safety (DHSSPS) published the *Information and Communications Technology Strategy* for consultation, which first mentioned the ePrescribing as part of a wider move towards structured care communications.<sup>(115)</sup> In 2006, the DHSSPS proposed the introduction of an ePrescribing service principally to address prescription fraud, which was estimated to have cost the Department £7.8 million in 2004 and 2005, with £7.41 million (95%) attributed to patientinitiated fraud.<sup>(17)</sup> However, many patients suspected of this fraud alleged that the pharmacist had made the mistake.<sup>(14)</sup>

Both paper-based and paperless systems were investigated, informed by experiences in setting up ePrescribing services in Spain and the Netherlands.<sup>(17)</sup> The proposed ePrescribing service was paper-based, with 2D barcodes to be added to paper prescriptions.<sup>(17)</sup> Using XML technology, 2D barcodes encode all information on the prescription, that is, a unique prescription identifier, patient information, prescriber information and prescribed medication information.<sup>(17)</sup>

Unlike paperless solutions, this proposed solution was considered to have minimal impact on prescribers and dispensers.<sup>(17)</sup> The only change required was updating the GP prescribing software with the ability add the barcode to the existing paper prescriptions.<sup>(17)</sup> Pharmacists could use a commercially available barcode scanner to load information from the 2D barcode to their dispensing systems.<sup>(17)</sup>

The eHealth and Care Strategy for Northern Ireland was reviewed during 2015 and published in 2016.<sup>(116)</sup> The key objectives of the revised strategy include:

- supporting people by allowing electronic ordering of repeat prescription
- modernizing eHealth infrastructure, including an Electronic Prescribing and Eligibility System (EPES) to be supported by the implementation of an Electronic Prescribing and Medicines Administration (EPMA) solution at relevant locations.

# History

The Electronic Prescribing and Eligibility System (EPES) has been operational throughout Northern Ireland since 1 May 2008.<sup>(18)</sup> The system provides the ability to view electronically each of the 16.8 million prescription forms returned annually to the Central Services Agency (CSA).<sup>(18)</sup> The following architecture was used:<sup>(17)</sup>



# Figure 5. Electronic Prescribing and Eligibility System (Northern Ireland)

When the patient presents the prescription at the community pharmacy, the pharmacist scans the barcode to automatically download the information to the pharmacy system.<sup>(14)</sup> The pharmacist can alter the prescribed medication details according to their judgement and record details of the patient's payment or eligibility for reimbursement.<sup>(14)</sup> The pharmacist sends the updated record to the central EPES database for reimbursement, which includes a check against social security records for fraudulent claims, and print a paper copy for the patient.<sup>(14)</sup> The pharmacist can also send the paper copy to the Prescribing Pricing Division of the NHS Business Services Authority, to be scanned into the central EPES database where it can verify the electronic record and rule out any alleged mistakes by the pharmacist.<sup>(14)</sup>

The former Central Services Agency stated that it received 16.8 million prescriptions in 2009, all of which could be viewed electronically.<sup>(19)</sup> The Health and Social Care Business Services Organization processed more than 41 million prescription items in 2016.

Page 64 of 152

# 3.2.3 Wales

# Scale

In 2016, the population of Wales was estimated to be just over 3.1 million.<sup>(93)</sup>

# Governance

In keeping with the founding principle of the National Health Service (NHS), healthcare services are free at the point of delivery in Wales.<sup>(117)</sup> The Welsh government is responsible for setting policy for NHS Wales and for funding health services.<sup>(118)</sup> NHS Wales is responsible for the commissioning and delivery of these health services.

Following a reorganization in 2009, seven NHS boards and three NHS Trusts were set up to deliver healthcare.<sup>(119)</sup> The Primary Care Informatics Programme was also merged with Informing Healthcare.<sup>(120)</sup> In 2010, the NHS Wales Informatics Service (NWIS) was established from a merger of Informing Healthcare (including the Primary Care Informatics Programme), Health Solutions Wales, the Business Services Centre IM&T element and the Corporate Health Information Programme.<sup>(121)</sup> NWIS brought together responsibility for the strategic development of information communications technology (ICT), the delivery of operational ICT services and information management.<sup>(121)</sup>

The NHS Wales Shared Services Partnership (NWSSP) was founded in 2011 to develop and manage a range of high-quality, customer-focussed professional, technical and administrative services on behalf of all Health Boards and Trusts in NHS Wales.<sup>(122)</sup> NWSSP's Primary Care Services division is responsible for the timely and accurate capture of data from every prescription dispensed in Wales for reimbursement purposes.<sup>(123)</sup> It also runs related services, including the eReturns service that enables community pharmacists to return unused medicines.

Stakeholders include:

- the British Medical Association's General Practitioners Committee Wales, which represents GPs in Wales<sup>(124)</sup>
- the Royal College of General Practitioners Wales<sup>(125)</sup>
- Community Pharmacy Wales, which represents more than 700 community pharmacists.<sup>(126)</sup>

#### Strategy

In 2003, the Welsh Assembly Government published the *Informing Healthcare Strategy*<sup>1</sup>, outlining how new information and communication technologies would transform the delivery of health services. <sup>(127)</sup> This transformation included the introduction of a single electronic record, increased patient involvement in decision-making, improvements in safety through service automation and better knowledge management.<sup>(127)</sup>

The General Medication Services IM&T Programme Board commissioned *the GP Clinical Systems: A Strategic Framework*, which was published in 2006.<sup>(128)</sup> This strategy outlined a mechanism for introducing national standards for interoperability in GP systems, the Minimum System Specification (MSS).<sup>(128)</sup> The MSS was considered successful in the rollout of 2D barcoded prescriptions to all GP clinical systems.<sup>(128)</sup>

The strategic programme for the newly formed NHS Wales Informatics Service, *Delivering a Five-Year Service Workforce and Financial Strategic Framework for NHS Wales*, was published in 2010.<sup>(129)</sup> Priorities included defining healthcare standards and improving medication management during transitions from secondary to primary care.<sup>(129)</sup>

The Welsh Government published *Informed Health and Care: A Digital Health and Social Care Strategy for Wales* in 2015.<sup>(130)</sup> The strategy aimed to improve interoperability between systems and services and to make better use of data through the adoption of national standards, as well as to introduce a national demographics service.<sup>(130)</sup> Priorities included the development of a digital health ecosystem as well as the publication of technical standards.<sup>(130)</sup> The *Managing medicines in primary and secondary care* strategy, published in 2016, reiterated the importance of the GP record system in improving medication management during the transition from secondary to primary care.<sup>(131)</sup> The system was particularly useful for pharmacists when they reconciled a patient's medicines after discharge from hospital.<sup>(131)</sup>

### History

Key steps in the development of ePrescribing in Wales are outlined below.

<sup>&</sup>lt;sup>1</sup> The *Informing Healthcare Strategy* document is no longer available online. The Healthcare Alliances organization produced a summary of the strategy, referenced here.

# 2007

The Primary Care Informatics Programme (PCIP) developed the 2D Barcoded Prescriptions (2DRx) service.<sup>(20)</sup> The PCIP noted that, as NHS Wales did not have a Welsh version of the NHS England Spine, the NHS England Electronic Prescription Service (EPS) could not be adapted for use.<sup>(20)</sup> Therefore, the NHS Wales ePrescribing service, 2DRx, was based Northern Ireland's ePrescribing service architecture, with some localization to the information contained in the 2D barcode.<sup>(14)</sup> 2DRx also used a different algorithm to generate the unique identifier.<sup>(14)</sup> As in Northern Ireland, this approach was considered to have the least impact on prescribers and dispensers.<sup>(14)</sup> Following a successful trial, the service was authorized for national rollout.<sup>(21)</sup>

### 2008

In January, work began with GP suppliers to add barcodes to paper prescriptions.<sup>(20)</sup> Work with pharmacies to enable the use of barcode scanners began in September.<sup>(20)</sup>

### 2010

All GP practices in Wales could generate prescriptions with the 2D barcode, and community pharmacists were enabled to use scanners to read the barcoded prescriptions.<sup>(20)</sup>

The Northern Ireland prescription was localised as follows:

- the Prescription type field allowed different values
- new fields were added for the number of medicines and the age of the patient
- some optional fields were made mandatory, namely, middle name, title, patient's gender.<sup>(14)</sup>

### 2012

NHS Wales Informatics Service reported that community pharmacists across Wales could now scan the 2DRx barcoded prescriptions.<sup>(132)</sup>

# 2016

In their annual review for 2016, the NHS Wales Informatics Service reported that 78 million prescriptions has been managed through the 2DRx service.<sup>(22)</sup>

#### A note on medication management

In 2014, NHS Wales began to pilot a GP record system that contained a medication record, which pharmacists could also access.

In 2014 and 2015, the GP record system was piloted at Aneurin Bevan and Cardiff and Vale University Health Boards before being rolled out to other health boards. The system contains a summary of the information help by GPs about each patient. Pharmacists can use the system to access GP-held information about a patient's medicines directly without having to call the GP surgery. However, in December 2016 the system was still only being used for patients admitted as emergencies.

The NHS Wales Informatics Service (NWIS) was implementing a national audit tool, designed to monitor use of the GP Record in health bodies and in community pharmacy. Following successful implementation, the NWIS planned to extend the GP Record to a greater number of registered pharmacy professionals.

In the report from December 2016, the Auditor General for Wales reiterated the huge benefits that a single electronic system would bring to the management of medicine and criticized delays in implementing such a system.<sup>(131,133)</sup> Late in 2017, the Cabinet Secretary for Health, Wellbeing, and Sport, announced that, by March 2018, all community pharmacies using the Choose Pharmacy IT system would have access to the GP Record system.<sup>(134)</sup>

# 3.2.4 Scotland

### Scale

In 2016, the population of Scotland was estimated to be just over 5.4 million.<sup>(93)</sup>

### Governance

The Scottish Government Health and Social Care Directorate is responsible for the development and implementation of health and social care policy.<sup>(135)</sup> It allocates funds to and sets strategic direction for NHS Scotland.<sup>(135)</sup> NHS Scotland is divided into 14 regional NHS boards, seven Special NHS Boards and one public health body.<sup>(136)</sup> Regional NHS

Boards are responsible for public health in their areas, while Special NHS Boards provide a range of specialist and national services.<sup>(136)</sup>

In February 2007, NHS Scotland published a framework for handling information in a confidential and secure manner in accordance with ethical and quality standards.<sup>(14)</sup> The ePrescribing initiative in Scotland was considered to represent an improvement to patient safety in terms of information governance by reducing the numbers of medication errors, transcription errors and incorrect identity errors.<sup>(14)</sup>

Stakeholders include:

- Community Pharmacy Scotland, which represents community pharmacists in Scotland<sup>(137)</sup>
- British Medication Association, General Practitioners Committee, Scotland.<sup>(138)</sup>

# Strategy

In 2001, work began on an IT infrastructure to support the electronic transfer of prescriptions, which would make prescribing and payment processing more efficient.<sup>(14,139)</sup> Following publication of *The Right Medicine* pharmacy strategy in 2002, the ePharmacy programme was broadened to include the development of e-applications that would support the future delivery of community pharmaceutical services and improve communications across the healthcare team.<sup>(14,140)</sup> The programme aimed to improve patient care and to reduce GPs' workload by making better use of pharmacists' skills and expertise, especially for minor ailments and chronic conditions.<sup>(139)</sup>

The expanded ePharmacy programme aimed to deliver three services:

- the Minor Ailment Service (MAS), which enabled patients with minor ailments to register with, and be treated at, a community pharmacy without a visit to a GP
- the Electronic Acute Medication Service (eAMS), which is the electronic transfer of prescriptions between GP practices and community pharmacies<sup>(23)</sup>
- the Chronic Medication Services (CMS), where pharmacists identify and address current or potential adverse effects from medicines prescribed to patients with chronic conditions.<sup>(139,141)</sup>

eAMS supported both electronic and paper prescriptions to facilitate the full testing of the IT infrastructure.<sup>(14)</sup> NHS Scotland worked closely with GP and pharmacy stakeholder groups,

such as Community Pharmacy Scotland, throughout the development and implementation of the programmes, for example, creating training packs, communicating timelines clearly and providing financial incentives.<sup>(142)</sup>

The eHealth Strategic Programme 2014–2017 noted that electronic prescribing was nearly universal among GP practices and community pharmacists, who also had access to the Chronic Medication Services for managing patients' repeat prescriptions.<sup>(143)</sup> Any recommendations related to electronic prescribing in secondary care settings.<sup>(143)</sup>

In August 2017, the Scottish Chief Pharmaceutical Officer, Rose Marie Parr, outlined the strategy for ePharmacy.<sup>(144,145)</sup> Parr noted that, while the ePharmacy programme had focused primarily on underpinning GP prescribing activity, which represented the vast majority of all activity, a growing number of new prescribers would benefit from using ePharmacy.<sup>(145)</sup> The strategy also noted the benefits from moving incrementally to paperless prescribing across primary care; however, it acknowledged this to be a wide-scale change requiring new legislation and new IT functionality.<sup>(145)</sup> The Scottish eHealth strategy has the following aims for 2020 to integrate ePharmacy into the overall electronic medicines management structure, and to eliminate any manual re-entry of prescription data.<sup>(145)</sup>

### History

### 2001 to 2002

In 2001, the Scottish Government's ePharmacy programme began work on an IT infrastructure that allowed prescriptions to be sent electronically between GPs and community pharmacists.<sup>(14)</sup> The IT infrastructure was designed to make prescribing and payment processing more efficient. The program was broadened to enable electronic transfer of prescriptions (ETP), that is, to enable prescriptions to be generated, transmitted, dispensed and processed electronically.<sup>(14)</sup> The aim was to make prescribing and payment processing more efficient.<sup>(14)</sup> The government launched a pilot project within the Ayrshire & Arran Primary Care Trust to establish the necessary functionality for ETP, with vendors of GP and pharmacy systems engaged to ensure interoperability.<sup>(14)</sup> During the pilot, GPs practices successfully issued more than 1 million ETP prescriptions.<sup>(142)</sup> The scope of the ePharmacy programme was then broadened, first focussed on connecting all community pharmacists to the NHS email system, NHS Net.

# 2005

All community pharmacists were connected to the NHS email system, NHS Net.<sup>(14)</sup>

# 2008

Rollout of eAMS began, with 1.9 million prescriptions sent electronically in July.<sup>(14)</sup>

# 2009

In July, it was reported that Scotland had become the first country in the UK to deliver an electronic prescription service, with more than 90% of prescriptions submitted electronically.<sup>(24)</sup> The electronic Acute Medication Service was enabled in more than 99% of Scottish GP practices and pharmacies.

# 2010

The second element of Scotland's ePharmacy Programme, the Chronic Medication Service, was launched in 2010.<sup>(146)</sup> In this year, more than 90% of prescriptions in Scotland were issued electronically.

### 2014

Electronic prescribing was universal and linked to ePharmacy systems, with community pharmacists using the CMS system to manage repeat prescriptions.<sup>(143)</sup> In addition, the Emergency Care Summary (ECS) was added to Patient View, listing all the medicines that have been prescribed to the patient.<sup>(143,147,148)</sup> It is the best available current record of prescription medicines, reconciling data from the patient's GP, hospital stays and other sources.<sup>(149)</sup> Patients can opt in to allow GP prescribing to be shown in their ECS.<sup>(150)</sup>

### **Current Model**

The core infrastructure for ePrescribing in Scotland is shown in Figure 6.<sup>(142)</sup>



#### Figure 6. eAcute Medicines Service (Scotland)

As with the other UK systems, each Scottish GP practice system generates a paper prescription with a 2D barcode and sends an eScript to the ePharmacy Message Store. The community pharmacist scans the barcode to retrieve the eScript then dispenses the medication. Dispensing a prescription automatically sends an electronic claim to NHS National Services Scotland (NSS). The NSS include the Practitioner Services Division, the Information Services Division, the Payment Process (DCVP), the ePay rules engine and a service to scan and process messages.

# 3.3 Baltic States

# 3.3.1 Estonia

Estonia is considered to be one of the most digitally advanced nations in the EU, if not the world.<sup>(9,25)</sup> All prescriptions are managed electronically and the ePrescribing service is
considered to be one of the most successful and widely adopted of Estonia's eHealth services.<sup>(9)</sup>

## Scale

Estonia is a parliamentary democracy.<sup>(151)</sup> With a population of just over 1.3 million people, it is one of the smallest nations in the EU.<sup>(25)</sup>

## Governance

The Estonian Ministry of Social Affairs has responsibility for health policy and strategy. The Estonian health system uses a single public payer model, providing mandatory health insurance for almost all of the population. The Estonian Health Insurance Fund, which is the single public payer, manages the reimbursement of all public prescriptions. The fund originally developed and continues to manage the ePrescribing service.

The main stakeholder groups include:

- Pharmacist groups:
  - Estonian Pharmacies Association (Eesti Apteekide Uhendus, EAU)<sup>(152)</sup>
  - Estonian Pharmacies Union (Eesti Apteekrite Liit, EAU)<sup>(153)</sup>
- Physician groups:
  - Estonian Medical Association (Eesti Arstide Liit, EAL)<sup>(154)</sup>
  - Family Physicians Association of Estonia (Eesti Perearstide Selts, EPS)<sup>(155)</sup>
- Other stakeholder groups:
  - Estonian Health Insurance Fund (Eesti Haigekassa, EHIF)<sup>(156)</sup>
  - State Agency of Medicines (Ravimiamet, SAM)<sup>(157)</sup>
  - Health and Welfare Information Technology Centre (formerly Estonian E-Health Foundation - Eesti E-Tervise Sihtasutus)<sup>(158)</sup>
  - o eHealth software vendors
  - major hospitals.

## Strategy

Estonia began the digitization of government services shortly after it achieved independence from Russia in 1991. This digitization laid the foundations of the legislative framework for electronic services and built public trust in these services. The Estonian eHealth Foundation was established in 2005 to coordinate eGovernment services. However, the Estonian Health Insurance Fund funded and developed the ePrescribing system separately. The fund

provided financial incentives for physicians and hospitals to submit expenses electronically, which drove adoption.

Specific legislation also encouraged adoption. In 2002, all pharmacies were obliged by law to transmit prescription information for reimbursement electronically to the single public payer, the Estonian Health Insurance Fund. By 2005, all reimbursement claims and prescription data were submitted electronically. In 2007, legislation obliged all healthcare providers to send medical data to the Estonian National Health Information System (EHIS), for which the Ministry and the Estonian E-Health Foundation are now jointly responsible.

From 2010, all prescriptions had to be processed electronically, using the newly launched digital prescription service. When the digital prescription service was launched in 2010, all pharmacies were legally obliged to process prescriptions electronically through the Estonian Medical Prescription Centre (PRC).<sup>(2)</sup> The project's aim was to make ePrescribing of drugs possible in every doctor's office and to make the filling of e-prescriptions possible in every pharmacy.

## History

Key step in the development of ePrescribing in Estonia are outlined below.

#### 2003

Central government established X-Road, the secure digital data transmission network.<sup>(159)</sup> Initially, X-Road enabled the exchange of data between the Estonian Health Insurance Fund and some of its partners.<sup>(159)</sup>

## 2005 to 2008

More Estonian national e-Health infrastructure and services were developed using X-Road.<sup>(43)</sup> The Estonian Health Insurance Fund also developed the TORU data service system, which enabled GPs and other healthcare providers to submit claims and expenses electronically.<sup>(43)</sup> As the single public health payer in Estonia, the Estonian Health Insurance Fund reimbursed all eligible prescription expenses using a paper-based system.<sup>(43)</sup> The TORU service improved efficiency and reduced the costs associated with processing these claims manually.<sup>(43)</sup>

Next, the Estonian Health Insurance Fund developed the ePrescribing service to monitor consumption and to improve the transparency of the prescribing process. The fund worked with physician, pharmacy and other stakeholder groups to ensure that the prescription service was compatible with their systems, taking into account GP's practices. For example, GPs were used to unstructured dosage information and so, to encourage adoption, the dosage field was not structured in the prescription service dataset.

## 2010

The ePrescribing service became operational since 1 January 2010, when pharmacies were obliged by law to start processing electronic prescriptions through the Estonian Medical Prescription Centre (PRC). It allows data to be exchanged between patients, care providers, pharmacies and the EHIF. Known as e-Prescription, the system is a centralized and paperless system for issuing and handling medical prescriptions.<sup>(6)</sup>

#### 2011

By May 2011, 84% of prescriptions were electronic and more than 95% of pharmacies were ready to process the prescriptions.<sup>(2)</sup> Additionally, a survey showed that 91% of users were satisfied with the service.

#### 2013

By 2013, 96.9% of all prescriptions were fully digital and processed through the eprescription service.<sup>(43)</sup>

## 2017

The prescription service underwent a major update in 2017. In response to a request from physicians' associations, the drug interaction database, SFINX, was integrated to provide decision support. SFINX was first released in 2005 and had been integrated into the Swedish and Finnish decision support systems.<sup>(160)</sup> A pilot implementation held in North Estonian Medical Centre (NEMC) in early 2015 detected 164 unique pairs of drug interactions (DDIs) and was considered a success.<sup>(161)</sup> Integration with SFINX required a number of changes, for example, structure was added to the dosage information, which had previously been left unstructured to mirror GP processes and, therefore, encourage adoption.

## **Current model**

In the Estonian system, the GP forwards an electronic prescription for a patient to the national database.<sup>(6)</sup> The e-prescription is then available immediately in every pharmacy at the patient's request, when the patient presents their ID card. As the e-Prescription system draws on data from the national health insurance fund, any medical subsidies to which the patient is entitled also appear. The patient can also request a refill by e-mail, Skype, or phone, removing the need for a visit to the doctor.

To issue a prescription, the prescriber creates an entry in the patient's shared medication record. Patients can use this record, together with their electronic ID (eID), to obtain their medication in any pharmacy in the country. Patients can view an audit trail of data access and use. Patient consent is not required for data access, though patients can restrict access or opt out. In 2011, Estonia was one of the few countries in Europe that managed the entire ePrescription sequence electronically, from the electronic capture of the prescription in the GP's office through electronic transfer to dispensing in the pharmacy.<sup>(86)</sup> The ePrescription service used a pull model, where the physician sent the prescription to a central data repository using a HL7 standard message. The prescription could be retrieved from the repository by any pharmacy.

## **Technical standards**

Documentation shared by the Estonian Health Insurance Fund showed how the Estonian Medical Prescription Centre is integrated into the X-Road distributed architecture. This is illustrated in Figure 7.



## Figure 7. Estonian ePrescription Architecture

All communication is over X-Road, using SOAP web services. Examples of the web services include:

- medicines lists/medication sales permits services (State Agency of Medicines)
- health service providers service/licensed doctors service (Health Board)
- pharmacies and pharmacists service (State Agency of Medicines)
- personal authorization for buying medication (eHealth service or Population Registry under the Ministry of the Interior)
- patient information, insurance details (health insurance register service).

The original ePrescribing service used SOAP for both prescribing and dispensing, with HL7 also used in prescribing. Today, efforts are continuing to make the HL7 standard obsolete. In comparison with SOAP, HL7 messages are seen to be 5 to 10 times larger and to be more complicated in that they require more effort to extract information or to develop new services.

#### **Lessons learned**

While ultimately successful, the 'big bang' approach to national adoption initially caused capacity problems thanks to a relatively quick uptake.<sup>(9)</sup> Physicians were requested to continue using paper prescriptions over the summer months of 2010 to relieve these capacity problems.<sup>(43)</sup> From the second half of 2011, the TORU was closed down and all communications concerning prescriptions were routed through the PRC. From January 2012, all non-reimbursable prescriptions were also digitized. By 2013, 96.9% of all prescriptions were fully digital and processed through the e-prescription service.

The e-prescription service has had a considerable positive effect. By 2014, the e-prescription service was considered to be the most widespread e-health service in Estonia.<sup>(43)</sup> It is reported to have saved an average of 30 minutes per day and saw financial gains only two years after implementation.<sup>(44)</sup> User satisfaction is high among physicians, pharmacists and patients. Furthermore, the e-prescription service supported the development of other e-health services such as the national Electronic Health Record.

However, some obstacles impeded the implementation process. Healthcare organizations and pharmacies were reluctant to invest additional resources to enable the service. Central resources could have been allocated for upgrading local systems. Stakeholder engagement was also shown to be very important, and some physicians and pharmacists expressed negative views about the value of the service in the media. Moreover, the initial issues with capacity highlight the need for accurate capacity analysis.

# 3.4 Northern Europe

## 3.4.1 The Netherlands

All GPs in the Netherlands use an electronic medical record management system, which includes a module to create prescriptions electronically (Elektronisch Voorschrijf Systeem [EVS]).<sup>(26)</sup> Since 2014, prescribers are mandated to use an EVS to generate prescriptions.<sup>(26)</sup> However, while regional networks exist, there is still no national system for the electronic exchange of prescription information.<sup>(27)</sup> GPs send the electronic prescription to the patient's nominated pharmacy as an EDIFACT message, in most cases using a secure healthcare mail system.

## Scale

The Netherlands is a parliamentary democracy with a constitutional monarchy. The Netherlands is divided into 12 provinces and just over 400 municipalities.<sup>(162)</sup> Eurostat estimated the population of the Netherlands to be just under 17.1 million on 1 January 2017.<sup>(25)</sup>

## Governance

The Ministry of Health, Welfare and Sport has overall responsibility for setting nationwide health policy, though these responsibilities are increasingly shared with local authorities.<sup>(26)</sup> Operational delivery of services is largely delegated to a number of separate organizations, the majority of which are privately owned.<sup>(26)</sup> The municipalities are responsible for public health, social care and youth care.<sup>(26)</sup>

A mandatory universal health insurance scheme, covering 100% of the population, has been in place since 2006.<sup>(27)</sup> Insurance is operated by private health insurance funds (both for profit and not-for-profit) and accessed through contracts with providers.<sup>(27)</sup> The insurance package is fixed by law.<sup>(27)</sup> Health insurers set a nominal community-related insurance premium corresponding to the package but compete in a regulated environment.<sup>(27)</sup>

Each Dutch resident must register with a GP, who can refer patients to the hospitals, thereby acting as both a gatekeeper and guide to the system for the patient.<sup>(27)</sup> Exchange of this data occurs at regional level, with nearly 90% of GPs exchanging patient data electronically with public pharmacies, emergency GP services and hospitals.<sup>(27)</sup>

Stakeholder groups representing general practitioners include:

- The Dutch Association of General Practitioners (Landelijke Huisarten Vereeniging, LHV) supports and represents GPs at a national level.<sup>(14,106)</sup>
- The Dutch College of General Practitioners (Nederlandse Huisartsen Genootschap, NHG) provides scientific support for general practice.<sup>(14,106)</sup>

The main stakeholder group for pharmaceutical matters is:

 The Royal Dutch Pharmacists Association (Koninlijke Nederlandse Maatschappij ter bevordering der Pharmacie, KNMP).

The main stakeholder groups involved in setting technical and semantic standards are:

- The Nationaal ICT Instituut in de Zorg (Nictiz), which is the national expertise center that facilitates the development of ICT in healthcare.<sup>(14)</sup>
- The Association of Care Providers for Care Communication (Vereniging van Zorgaanbieders voor Zorgcommunicatie (VZVZ) is responsible for the exchange of medical data through the National Switching Point (Landelijk Schakelpunt, LSP) of the healthcare infrastructure, ensuring that the network functions properly, in technical and organizational terms.<sup>(163)</sup>

Other stakeholders include the Healthcare Information Council (Informatieberaadzorg.nl), an administrative cooperation between various stakeholders and the Ministry of Health, Welfare and Sports.<sup>(164)</sup> Founded in 2014, the council is working to establish a sustainable information system.<sup>(164)</sup> Part of this work includes defining standards to ensure the efficient exchange of data.<sup>(164)</sup>

## Strategy

In the 1990s, the Dutch College of General Practitioners understood the potential benefits of interoperability between GP practice management systems and devised the Dutch GP Information System specification (Huisarts Informatie Systeem).<sup>(106)</sup> The Ministry for Health, Welfare, and Sports introduced a policy to incentivize GPs' adoption of the specification, which included an ePrescription module that produced a paper script.<sup>(106)</sup> Any qualifying expenses were reimbursed to GPs when they implemented a certified GP Information System.<sup>(106)</sup>

On the pharmacy side, the Royal Dutch Pharmacists' Association had established a Medicines Database in 1980. In 1999, the database was renamed the Dutch Geneesmiddelen Standaard (G-Standaard) and its scope was expanded considerably. The G-Standaard provides more detail around medicines themselves such as brand names, active ingredients, and contra-indications. It also introduced pharmacodynamics information—for example, the typical time that the medicine remains at a certain concentration in the blood. And it provided up-to-date market information, including new medicines. The information was structured to meet international standards, such as those developed by the World Health Organization.

There are approximately 5 to 10 different community pharmacy system packages on the market, all of which use the G-Standaard. The G-Standaard is released monthly by Z-Index.<sup>(165)</sup>

Between 2008 and 2014, legislation to support the electronic transfer of medical data, including ePrescriptions, was also introduced.<sup>(166)</sup> In 2008, the Dutch Senate approved the "Use of the Citizen Service Number (Burgerservicenummer, BSN) in Healthcare" Act. The BSN is the unique identifier used for each Dutch citizen in public services. Up to 2008, only public institutions were permitted use the BSN.<sup>(166)</sup> The 2008 Act enabled private organizations—such as hospitals, GPs, pharmacists, and insurance companies—to use the BSN when providing healthcare services. From 2009, these organizations were required to use the BSN when communicating with each other, to support interoperability. They were also required to assign each new patient a BSN. However, they were permitted to continue to use identifiers from their legacy systems in internal communications, to accommodate patients who typically would not have BSNs—for example, non-residents and newborns.

The Electronic Health Record Act, supporting the national exchange of medical record data, was submitted in 2009 but rejected by the Senate in 2011.<sup>(166)</sup> In an effort to reduce the level of medication errors, a new law came into force in January 2012 mandating the use of an electronic prescription system.<sup>(6,167)</sup> Since 2014, prescribers may only prescribe medication using an EVS.<sup>(26)</sup>

The Dutch Personal Data Protection Act came into force in January 2016, following on from the earlier Personal Data Protection Act.<sup>(168)</sup> The act outlined the obligations around collection of personal data, for example, the collector's obligations to secure the data against

theft and to inform citizens of why their data was being collected and how it would be used.<sup>(168,169)</sup>

In October 2016, the Dutch Parliament passed a law that gave citizens the right of digital access to their health and care information in the systems of care-providing organizations. Secondly, the law grants patients the right to specify in detail which parts of their information may be shared with which care provider. The law will be formally enforced by 2019.

The Ministry for Health, Welfare and Sports published the Policy Agenda VWS 2018: Innovation.<sup>(170)</sup> It recognized that healthcare could no longer be delivered without secure exchange of data and healthcare ICT.<sup>(170)</sup> Its stated intention is for all Dutch citizens to access to their own medical data by 2020.<sup>(170)</sup>

As part of this strategy, the MedMij program has been launched.<sup>(171)</sup> The program is a collaboration between the Healthcare Information Council and a collective of parties aimed at making it possible for Dutch citizens to collect and use their health data within a personally chosen health environment, that is, within an app or website.<sup>(171)</sup> MedMij ensures that medical data from different sources can be exchanged safely, by defining requirements and rules such as those for privacy and authentication.<sup>(171,172)</sup> MedMij is being led by the Dutch Patients' Federation.

Other initiatives to support this policy of innovation in healthcare ICT include CareInnovation (zorginnovatie.nl), which is an open source platform and community dedicated to fostering innovation in healthcare.<sup>(173)</sup>

## History

Key steps in the development of ePrescribing in the Netherlands are outlined below.

## **Early foundations**

Dutch GPs have been active in the development and implementation of health information systems, with the first computer installed in a GP's office in 1978.<sup>(106)</sup> During the mid 1980s, GPs and IT professionals recognized the potential of health IT, setting up the Coordination Workgroup on Informatisiation and Automation (WCIA).<sup>(106)</sup> They worked with vendors to

developed the Dutch computer-based GP Information System model model (Huisarts Informatie Systeem [HIS]).<sup>(106)</sup> The model ensured commonality among the handful of software suppliers providing GP management systems and is still used today. ePrescription was considered to be an essential module of the GP Information System. The system operated by producing a printed paper script that the GP signed.<sup>(106)</sup>

## 1998 to 2003

In 1998, the Dutch College of General Practitioners developed a standalone Elektronisch Voorschrijf Systeem (EVS) electronic prescription application.<sup>(106)</sup> Originally distributed on CDs, the EVS was available from 1998 to 2003, but was later integrated into the GP Information System.<sup>(106)</sup> The EVS provided decision support based on the patient's diagnosis using the International Classification of Primary Care (ICPC), together with other criteria such as the family history and age.<sup>(106)</sup> The GP Information System model was extended to allow for the exchange of prescription data between GP and pharmacy using the EDIFACT messaging standard.<sup>(106)</sup>

## 2002

Two organizations were founded, each of which played an important role in the development and adoption of ePrescribing:<sup>(106)</sup>

- Ozis Foundation was established to develop open standards for the electronic exchange of data between healthcare providers.<sup>(106,174)</sup> The foundation developed regional clusters (OZIS rings), which facilitated electronic communication between regional GPs and pharmacies.<sup>(106,174)</sup> The last OZIS cluster was phased out in December 2015.<sup>(166)</sup>
- The Nationaal ICT Instituut in de Zorg (Nictiz) was established initially to create a framework for the exchange of patient information and for communication between GPs and other healthcare providers (in terms of national infrastructure, electronic messages, and safety).<sup>(106)</sup> Latterly, it coordinates the implementation of health IT projects and provided governance for eHealth projects.

As a short-term goal, Nictiz focused on exchanging medication records, which were considered of interest to health practitioners.<sup>(26)</sup> Thereafter, Nictiz developed a national healthcare information hub, the National Switching Point (Landelijk Schakel Punt [LSP]), as part of the AORTA project.<sup>(14)</sup> AORTA is the Dutch national healthcare infrastructure for the

exchange of healthcare data.<sup>(14)</sup> Using the LSP, GPs could see the patient's summary record, while both GPs and pharmacists could see the patient's medication record.<sup>(14)</sup>

AORTA was intended to be national, rather than local or regional, in scope and to use HL7v3, rather than EDIFACT, as a messaging standard. It was also intended to ensure that the national database was consistent. Both houses of the Dutch parliament debated the proposed use of the AORTA national infrastructure, covering concerns around patient privacy and the obligation of GPs and community pharmacists to connect. One key outcome of these discussions was that healthcare should be regulated by market forces, not by the government. Another was that, although opt-in was the norm under the data protection law, an opt-out was proposed to avoid placing an unacceptable burden of administration on GPs. This Electronic Health Record Act was finally rejected by the Senate in April 2011.

## 2012

These discussions led to the split of Nictiz into two separate organizations in 2012:

- The National Competence Centre for eHealth (Nationaal ICT Instituut in de Zorg, Nictiz) remained dedicated to the development of national standards for eHealth and to providing guidance and expertise.
- The Association of Care Providers for Care Communication (Vereniging van Zorgaanbieders voor Zorgcommunicatie, VZVZ) took over responsibility for the AORTA infrastructure and related implementation issues. Since care providers in the Netherlands are not public institutions, this meant the transition of the infrastructure from public to private ownership, as mandated by the Senate.

Membership of the Association of Care Providers for Care Communication was open to healthcare providers such as GPs, hospitals and pharmacists. The association was cofinanced by the health insurance companies.

The decision that the market, not the government, should manage healthcare data meant that healthcare providers had the right to use any infrastructure they chose. Membership of the Association of Care Providers for Care Communication was made voluntary, and several groups of healthcare providers set up their own regional initiatives, beside the OZIS clusters which were still in existence. These clusters were largely based on the secure, point-to-point transfer of EDIFACT-based messages. The EDIFACT-based message model was superseded

by newer models and the last OZIS cluster was decommissioned in 2015. However, a large number of EDIFACT messages are still sent using the secure mail system—for example, discharge letters and laboratory results. Beside the OZIS legacy, regional clusters based on Cross-enterprise Document Sharing (XDS) document exchange networks were created. XDS is a standard set by Integrating the Healthcare Enterprise (IHE).

Today, the XDS-based clusters are growing in number (approximately 25 in 2018) and in data load. Their main area of application is in the exchange of imaging for cardiology and radiology between hospitals. Secure email based on the EDIFACT messaging standard is still in use. And AORTA handles much data in a small number of use cases, including information exchange between GP practice management systems and community pharmacy management system.

While AORTA was originally intended to handle the electronic transfer of prescriptions, the medication overview is not linked to ePrescribing. GPs send electronic prescriptions, generated by the GP Information Systems specification, directly to the nominated community pharmacy as EDIFACT messages using the secure mail system — a 'push' model. Thus, there is still no national infrastructure for ePrescribing. The Netherlands also took part in the European Patients Smart Open Services (epSOS) project but did not create a pilot.

More than 50% of GPs offer the ability to request repeat prescriptions online.<sup>(175)</sup> However, while the percentage of healthcare users who were aware of this capability rose from 21% in 2013 to 33% in 2016, this service is not generally used.

#### **Lessons learned**

The high adoption rate of the GP Information Systems, with ePrescription module, is attributed to two factors.<sup>(106)</sup> First, the Coordination Workgroup on Informatisation and Automation worked with vendors during the development of the GP Information System model to identify minimum requirements and ensure the standard of the final system.<sup>(106)</sup> GPs could then obtain certification for compliance with this standard, which guaranteed the standard of the system for GPs and allowed the Workgroup to regulate GP practice management systems.<sup>(106)</sup> Second, the Dutch Association of General Practitioners and the Dutch College of General Practitioners worked with vendors to ensure that the EVS was compatible with the health information system while the now defunct District Associations of General Practitioners liaised with GPs to ensure EVS compatibility with their systems.<sup>(106)</sup>

Other factors that contributed to the adoption of ePrescribing in the Netherlands include:

- the early adoption of the EDIFACT messaging standard for regional OZIS clusters, with funding available to vendors to support implementation
- the ongoing maintenance of the national drug reference catalogue by Royal Dutch Pharmacists Association (KNMP),
- the existence of the national healthcare identifier, which uniquely identified all patients in the Netherlands, since 2008.

The EVS electronic prescription system is integrated into the GP information systems, in which all GPs in the Netherlands record medical data about their patients.<sup>(26)</sup> The system monitors unsafe situations and so has improved both the quality of prescriptions and the use of electronic medical records. It has also reduced expenditure on medications.

When debating the AORTA project in 2012, the Dutch government also highlighted the value of standardization and of providing high-quality health information. However, it appears that the decision that healthcare providers could connect to any infrastructure has resulted in the development of a number of regional infrastructures in parallel and that these infrastructures have yet to achieve full interoperability.

# **3.5 Cross-border ePrescribing Programmes**

This section looks at efforts by the European Union to create the infrastructure for crossborder ePrescribing.

## **European Patient Smart Open Services (epSOS)**

Running from 2008 to 2013, the European Patient Smart Open Services (epSOS) project was an EU-wider pilot project that developed and tested an eHealth framework and an ICT infrastructure for secure cross-border access to patient health information between different European healthcare systems, including ePrescribing.<sup>(28)</sup> The epSOS pilot was designed to test the legal, organizational, semantic and technical aspects of cross-border information exchange.<sup>(176)</sup> It was intended to demonstrate a measurable improvement in cross-border medical services.<sup>(28)</sup>

Participating countries were at different stages of ePrescription implementation, making it necessary to define both a minimum dataset and a maximum dataset for the transfer an ePrescription across EU border.<sup>(177)</sup> This resulted in the EU member states agreeing a number of semantic interoperability standards for patient summaries and for cross-border electronic transfer of prescriptions.<sup>(28)</sup> The dataset for cross-border electronic transfer of prescriptions is described in Appendix A — epSOS Prescription Dataset.

The project needed to take account of different local classification systems and languages. The prevalent use of HL7 Clinical Document Architecture (CDA) in participating countries led epSOS semantic services to use CDA 2.0 with the additional constraints of the HL7 continuity of care document (CCD) and IHE Patient Care Co-ordination (IHE PCC). It also needed to take account of other variations in legislative and governance. For example, cross border dispensing could cause issues around generic substitution, which is allowed in most, but not all, member states.<sup>(177)</sup> However, this issue was resolved by an agreement that generic substitution would follow the laws of the country of treatment, rather than the country of affiliation.<sup>(177)</sup>

The epSOS project relied on an internal mechanism of governance based on the guidelines from the project.<sup>(28)</sup> Each country in the project was represented by their National Contact Point (NCP).<sup>(28)</sup> The Framework Agreement (FWA) created NCPs as legal entities that were legally entitled to process patient data as part of the epSOS pilot and legally mandated by the national authority to act as an interface as an interface between the existing different national functions and infrastructures.<sup>(28)</sup>

The epSOS infrastructure architecture was based on a Circle of Trust (CoT), consisting of mutually trusted consuming and providing gateways (NCPs) beyond national or regional territories.<sup>(28)</sup> This trusted node infrastructure implemented the core epSOS security services and, thereby, ensured the confidentiality of medical data transmission and the authenticity of epSOS services.<sup>(28)</sup> Each participating member state was thus accountable for setting up the epSOS NCP and carrying out their pilot operations.<sup>(28)</sup>

As early as 2010, a consortium was engaged to develop a set of open source components that could be adopted by participating member states to build their implementation of the NCP.<sup>(178)</sup> The OpenNCP initiative has released two toolkits:

• a pre-configured NCP kit, which member states could use without customization

 an OpenNCP toolkit, which provide each member country with the open source components they need to build their local implementation of NCP.<sup>(28)</sup>

Each kit also includes unit testing, system integration testing and cross-border interoperability conformance tests, supporting adoption and integration of the epSOS infrastructure with each member state's national infrastructure.<sup>(28)</sup> The report emphasized the importance of continuing work on the development of the epSOS components and architecture.

## **Evaluation findings**

The project used a range of agreed activities to evaluate the perception and potential impact of epSOS services from the point of view of end users, both health professionals (physicians and pharmacists) and patients.<sup>(179)</sup> The overall conclusions were positive, with all end users feeling that the service would improve quality of care and access to services and both the interface and the information being seen as easy to use.<sup>(179)</sup> However, concerns were raised around integration with national health IT systems and in particular around patient identification, given the diverse range of identity systems in use.<sup>(179)</sup>

A JASEHN report on the implementation of epSOS ePrescription Guidelines found that member states are largely ready from an organizational and a technical viewpoint and that they have the requisite procedures to ensure that only registered health professionals will be involved in the ePrescription and eDispensation process.<sup>(180)</sup> However, it found that countries lacked legal preparedness, with half of EU countries have no law defining how to identify patients in other member states.<sup>(180)</sup>

## Recommendations

The recommendations report covered the legislative, organizational, semantic and technical sustainability of the epSOS pilot project<sup>(28)</sup>:

## Legislative sustainability

The report noted that proposed regulations for data protection and for electronic identification, though not health sector-specific, created conditions for harmonization in several legislative areas that are critical to the functioning of cross-border eHealth services.<sup>(28)</sup> However, it noted that the EU and national legislative frameworks needed to be

extended to cover data protection and confidentiality, a clear legal basis for patient consent, security of national systems, legal concerns around national health systems and liability for treatment abroad. Among other things, the report recommended creating a trusted environment between member states for the provision of cross-border services, with patient audit capability, and that conditions for legal and organization interoperability be created.

## **Organization sustainability**

The recommendations report included a formal review of performance measures, such as the basis for service-level agreements and updates to specifications from the project.<sup>(28)</sup>

## Semantic sustainability

The report discussed the development of semantic standards, including the data sets for ePrescription, eDispensation and the Patient Summary.<sup>(28)</sup> It discussed the considerations that went into their creation, such as non-ambiguity of clinical terms, and their application across the EU. Recommendations in this area included the development of formal tooling, engagement with standards development organizations and a use-case-based approach.<sup>(28)</sup>

## **Technical sustainability**

NCPs were identified as the technical elements ensuring interoperability across national borders, while Intergrating the Healthcare Enterprise (IHE) profiles governed the interoperability between NCPs. Each member state was also free to implement the most suitable National Connector solution as an interface between its NCP and national infrastructure.

The most important recommendation from the project was that a sustainable trusted environment be established between member states for the provision of cross border service. Another key recommendation was that each country or region be represented by its National Contact Point for eHealth (NCPeH), which might be different to the NCP foreseen under EU Directive 2011/24/EU. The National Contact Point for eHealth (NCPeH) would instead as a communication gateway and maintaining compliance to normative interfaces for structure, behaviour, and security policy.

When the epSOS project finished in 2014, work continued in two main streams:

- Connecting Europe Facility (CEF) eHealth Digital Service Infrastructure (eHDSI), which develops and implements digital services infrastructures for cross-border exchange of patient summaries and ePrescribing
- OpenNCP consortium, which is an open source community supporting member states' development of their implementation of NCP.

## **Connecting Europe Facility — Digital Service Infrastructure**

In 2014, the Connecting Europe Facility (CEF) began a six year project to develop and deploy the digital services required to support cross-border health data exchange, in particular, for ePrescribing and for the Patient Summary.<sup>(30)</sup> The eHealth Digital Service Infrastructure (eHDSI) comprises a range of Digital Service Infrastructures for eHealth, eProcurement, and other areas.<sup>(30)</sup> It also includes the development and implementation of building block Digital Service Infrastructures (DSIs), such as electronic identifier (eID) and electronic signature (eSignature) services enabling the recognition and validation of electronic identification and signatures across EU borders.<sup>(181)</sup>

The eHealth Digital Service Infrastructure (eHDSI) project also involved the set-up and deployment of National Contact Points for eHealth (NCPeH), each of which is responsible for eHealth Digital Service Infrastructure (eHDSI) in their respective country.<sup>(30)</sup> Collectively, the EU network and all such operations used to exchange real patient-related data are known as Cross Border eHealth Information Services (CBeHIS).<sup>(31)</sup> Cross Border eHealth Information Services (CBeHIS) are managed by the eHealth Network, a voluntary collaboration of the national authorities responsible for digital healthcare in all EU countries.<sup>(29)</sup> The eHealth Network was set up to speed up the deployment of eHealth and plays a key role in solving interoperability challenges between electronic health systems.<sup>(89)</sup>

Among the prerequisites for the set-up and deployment of National Contact Points for eHealth (NCPeH), the member state must establish a national or regional network for healthcare providers. When the EU member state wants to connect to the eHealth Digital Service Infrastructure (eHDSI) through their National Contact Point for eHealth (NCPeH), they are first required to submit to an audit.<sup>(30)</sup> The eHealth Network then reviews the audit report and determines if the member state is eligible to connect.<sup>(31)</sup>

In 2016, the OpenNCP governance model changed and the project was moved into the Directorate General for Health and Food Safety, with a goal to moving the pilot OpenNCP into the Connecting Europe Facility's eHealth Digital Service Infrastructure (eHDSI).<sup>(182)</sup> The epSOS ePrescribing capability is being rolled out as part of three waves of eHDSI deployments in Europe:

- Wave 1 February 2018
- Wave 2 February 2019
- Wave 3 February 2020

## Participation

The Irish ePrescribing programme is scheduled to implement the capability to provide the epSOS Patient Summary and ePrescriptions in Wave 3 ('Country A') but is not scheduled to have the capability to process this information from other EU countries ('Country B'). This is just one aspect of ePrescribing in the Irish context.

# Chapter 4 ePrescribing worldwide

This section summarizes changes to ePrescribing practices in three countries covered by the original review: the United States, Australia and New Zealand.

# 4.1 United States

In the US, there is a drive towards ePrescribing both in general and in an effort to reduce the abuse of controlled substances.

## Scale

The United States is a federal democracy consisting of 50 states. The US Statistics Bureau recorded the population at just under 309 million people in 2010 and estimates it to be 327 million in 2018.<sup>(183)</sup>

## Governance

The US system is primarily one of private insurance, with governmental insurance provided for certain citizens who do not have private insurance.<sup>(14,184)</sup> The public funded components include:

- Medicare, a federal programme that covers individuals aged 65 and over, as well as some disabled individuals
- Medicaid, a programme designed for the low-income and disabled
- Children's Health Insurance Program, which covers children whose families make too much money to qualify for Medicaid but make too little to purchase private health insurance
- Veterans Health Administration, a federally administered programme for military veterans.

Since the 1940s, most insurance was paid for by employers who offer healthcare benefits as a form of compensation to attract employees.<sup>(14)</sup> However, with excessive inflation of healthcare costs, many employers are being forced to reduce the healthcare related benefits.<sup>(14)</sup> In 2010, the Affordable Care Act, also known as Obamacare, was passed to reform federal healthcare by extending health coverage to those who otherwise could not afford it and requiring that healthcare plans meet certain minimum coverage standards.<sup>(185)</sup>

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) was the first and most significant piece of legislation regarding electronic processing of health information.<sup>(186)</sup> The Act included administrative simplification provisions that required the United States Department of Health and Human Services (HHS) to adopt national standards for electronic healthcare transactions and code sets, unique health identifiers and security.<sup>(186)</sup>

Between 2000 and 2003, the HHS published rules relating the HIPAA provisions:

- The Privacy Rule (2000, with modified version in 2002), set standards for the protection of individually identifiable health information.<sup>(186)</sup> Compliance was required by 2003.<sup>(186)</sup>
- The Security Rule (2003) set national standards for protecting the confidentiality, integrity, and availability of protected health information.<sup>(186)</sup> Compliance was required by 2005.<sup>(186)</sup>

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 required Medicare Part D to support an electronic prescription system, with a planned implementation date of April 2009.<sup>(14,32,33)</sup> The Act was prompted by the findings of the *To Err is Human, Building a Safer Healthcare System* report, with the expectation that ePrescribing would improve the quality and safety of medication use while lowering costs.<sup>(14,33,49)</sup> It also called for the adoption and testing of specific technical standards for the data exchange transactions needed.<sup>(33)</sup>

In 2004, the Certification Commission for Health Information Technology (CCHIT), an independent, non-profit organization, was established using federal and industry funding to provide certification of electronic health records (EHRs) and their networks.<sup>(33)</sup> The organization undertook education and outreach to promote adoption.<sup>(33)</sup> The Healthcare Information Technology Standards Panel (HITSP) was created in 2005 to address issues with interoperability by integrating standards.<sup>(33)</sup>

The Center for Improving Medication Management (CIMM) was established as a centre of excellence in 2007.<sup>(14)</sup> This collaborative forum defined best practices for:

- processing prescriptions electronically
- using electronic communication between patient, GP and pharmacist to improve patient compliance with medication orders.<sup>(14)</sup>

The centre educates clinicians and their staff on the best approaches to implementing ePrescribing technologies and integrating with the day-to-day workflow.<sup>(14)</sup>

To accelerate the adoption of ePrescribing, the National ePrescribing Safety Initiative (NEPSI), a coalition of US technology companies and healthcare organizations, provided free access to simple, safe and secure electronic prescribing for physicians.<sup>(187)</sup>

The Medicare Improvements for Patients and Providers Act (MIPPA) was passed in 2008 to encourage the use of ePrescribing for Medicare recipients.<sup>(32)</sup> By May, fifty two pieces of legislation had been introduced across nine states, for example, Minnesota enacted legislation that required physicians who have contracts with state employee health plan medical networks to use ePrescribing by 2011.<sup>(33)</sup>

Two mergers also helped to unify ePrescribing standards and software:

- SureScripts and RxHub merged to form a single, nationwide network for eprescriptions
- the health information software companies, Allscripts and Misys, merged.

In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act provided \$19 billion dollars to incentivize healthcare providers' meaningful use of EHR, that is, in a way that coordinated and improved patient care,according to the standards set by the Centers for Medicare and Medicaid Services (CMS).<sup>(32)</sup> HITECH considered ePrescribing as a key component of meaningful use.<sup>(32)</sup> Healthcare providers who became meaningful EHR users in 2010 or 2011 received almost double the amount given to those adopting in later.<sup>(14)</sup>

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 changed the way clinicians were rewarded for providing care and required the removal of Social Security Numbers from all Medicare cards by April 2019.<sup>(184,185)</sup>

Healthcare in the United States remains fragmented.<sup>(184)</sup> In 2015, about 67.2% of residents had private voluntary health insurance, while 37.1% were covered by public health programs such as Medicare, Medicaid and military programs.<sup>(184)</sup> About 9.1% of the population are uninsured.<sup>(184)</sup>

The US Department of Health and Human Services is the federal government's principal agency for health care services and oversees a number of organizations such as the Centers for Disease Control and Prevention.<sup>(184)</sup> The National Academy of Medicine advises on policy.<sup>(184)</sup>

## Strategy

In 2003, policymakers viewed ePrescribing as an information technology that could provide almost immediate benefits and could be implemented either within an EHR or alone.<sup>(32,33)</sup> To support the planned implementation by Medicare, ePrescribing standards were agreed in 2005 and piloted in 2006.<sup>(14,33)</sup> The Institute of Medicine published a pivotal report *Preventing Medication Errors*, which outlined opportunities for providers to improve medication safety. These opportunities including use of technologies such as ePrescribing and the computerized monitoring of adverse drug events as well as a cultural change, leading to the next level of safety.<sup>(14)</sup>

Government agencies and private insurance companies are leading a move from the specialist-focused system to a system centred on patient care.<sup>(184)</sup> This strategy is seen as a means of strengthening primary care and linking medical services more closely to community services.<sup>(184)</sup>

Over the course of 2008 and 2009, two Acts incentivized the use of both ePrescribing and the EHR:

- The MIPPA Act offered bonuses for qualified prescribers who sent prescriptions electronically using a certified system.<sup>(14,32,33)</sup> Reimbursed until 2013, a bonus of 2% was available in 2009 and 2010, falling by 0.5% annually until the end of 2013.<sup>(14,33)</sup> Additionally, prescribers not using ePrescribing by 2012 were to face penalties starting at 1% of their Medicare reimbursement rates.<sup>(14,33)</sup> To avoid these penalties, prescribers just needed to send 10 prescriptions electronically in the first six months of 2011 and 25 prescriptions during 2012.<sup>(14)</sup>
- The HITECH Act provided substantial financial incentives to encourage physicians and hospitals to adopt health IT — in particular, EHRs — that were capable of sending electronic prescriptions to pharmacy and 40% of eligible prescriptions must be sent electronically during a reporting period.<sup>(14)</sup>

Legislation for the ePrescribing of Schedule II through V controlled substances was passed in 2010.<sup>(188)</sup>

## A note on electronic prescription of controlled substances

The drive to combat fraud, error and the abuse of controlled substances started in 2008, when the State of Minnesota enacted legislation mandating that prescribers and pharmacists must use electronic prescriptions by 1 January 2011.<sup>(189)</sup> The law was intended to encourage adoption and included no fines or penalties for non-compliance. In 2013, 99% of Minnesota physicians were prescribing electronically, up from 70% in 2011.<sup>(190)</sup> 97% of community pharmacists were able to use electronic prescriptions, up from 92% in 2011.<sup>(190)</sup>

In 2013, the first part of New York's Internet System for Tracking Over Prescribing (I-STOP) law came into effect.<sup>(191)</sup> During this phase, an online database was developed, listing all controlled substances prescribed to a patient.<sup>(191,192)</sup> Prescribers were required to check the database before prescribing a controlled substance.<sup>(191)</sup>

By April 2014, more than 40% of physicians in all US states were ePrescribing using an EHR.<sup>(193)</sup> In 12 states, between 80 and 100 percent of physicians were ePrescribing.<sup>(193)</sup> In 31 states, between 60 and 80 percent were ePrescribing and, in the final seven states, between 40 and 60 percent were ePrescribing.<sup>(193)</sup>

By 2016, 90% pharmacies in the US could accept an electronic prescription while 70% of physicians were ePrescribing using an EHR.<sup>(193)</sup> In its 2016 national progress report, SureScripts stated that its Sentinel system analyzed more than 1.6 billion e-prescriptions each year.<sup>(193)</sup>

In that year, the second part of the New York (I-STOP) law came into force.<sup>(192,193)</sup> The I-STOP law mandated that all prescriptions be sent through authorized ePrescribing systems to pharmacies, with paper prescriptions permitted only in exceptional circumstances such as power outages or technology failures.<sup>(193)</sup> Moreover, for the first time in any state in the US, New York introduced penalties for non-compliance, such as fines, jail time, or loss or suspension of licence.<sup>(193)</sup>

Since 2015, ePrescribing of controlled substances has been legal in all states for controlled substances.<sup>(194)</sup> In 2017, Connecticut mandated the electronic prescribing of opioids and other controlled substances, which, it is hoped, will combating the epidemic of abuse.<sup>(195)</sup> California, Missouri and Vermont are considering similar legislations, with discussions are ongoing in Massachusetts, Texas and Ohio.<sup>(192)</sup>

While ePrescribing is not without its challenges, both staff and patients seem to be aware of the limitations—for example, patients will not be able to shop around for cheaper medication. Instead, they need to specify a pharmacy or pick one from a pre-populated list. Moreover, if the medication is too expensive or not available, the prescriber will need to cancel the prescription by phone and reissue it.

Researchers note that, in comparison with the European infrastructure, US ePrescribing infrastructure is decentralized and diffuse.<sup>(42)</sup> Core components of successful e-prescription adoption in EU countries include a centralized architecture, a national electronic prescription database and the use of a national patient ID. The US does not have a unit coordinator and leader to create and maintain a national electronic prescription database. The US has only a national prescription network and the US's only national prescription system also lacks a national patient ID, another feature of successful implementations.

## **Lessons learned**

A progress report from 2009 provides the best summary of the lessons learned from ePrescribing in the United State. The report noted a dramatic rise in ePrescriptions: from 13 million in 2006 to 100 million in 2008.<sup>(33)</sup> It cited pilot-testing and industry collaboration as one of the most valuable lessons learned, noting in particular the need for pilot-testing before standards were adopted.<sup>(33)</sup> Finally, the authors held that even small pilots had yielded valuable results, helped create needed metrics, and demonstrated return on investment.<sup>(33)</sup> ePrescribing industry collaboration on pilot-testing implementations and tweaking standards had also proven valuable.<sup>(33)</sup> Payment and policy levers were among the factors that had also contributed to this steep rise in use: the US Federal Government, US state governments and private insurers had all provided significant incentives for meaningful use, including ePrescribing.<sup>(33)</sup>

However, the report also noted that figure of 100 million ePrescriptions was a small fraction of the estimated 1.45 billion prescriptions and renewals annually eligible for routing.<sup>(33)</sup> It

also estimated that fewer than 1 in 10 physicians had adopted ePrescribing.<sup>(33)</sup> Adoption was slowed by the challenges in keeping physicians using electronic systems after they had been installed.<sup>(33)</sup> Disconnects between the pace of standards development and adoption, legislative requirements and implementations (particularly at state level), and evolving business needs also slowed adoption.<sup>(33)</sup> Some prescribers hesitated to install ePrescribing systems when ePrescribing systems were not standards-based and interoperable.<sup>(33)</sup>

The report recommended some next steps for encouraging adoption.<sup>(33)</sup> While incentive payments certainly helped, effective education, implementation, and training were also very important.<sup>(33)</sup> Collaboration to ensure that ePrescribing offerings were standards-based and interoperable would also reassure prescribers who were hesitating.<sup>(33)</sup> Providers would also benefit from a clear business case that outlined their expected returns, not just those for other stakeholders.<sup>(33)</sup> It recommended more efforts to reach disengaged stakeholders, such as those in rural areas, whose concerns and requirements were not well understood.<sup>(33)</sup> Finally, it noted the importance of addressing concerns about patients' privacy and data security, some of which had stalled some legislation needed to expand the use of healthcare IT.<sup>(33)</sup>

# 4.2 Australia

## Population

The Commonwealth of Australia is a constitutional monarchy, with a federal system of government.<sup>(196,197)</sup> In 2017, Australia's population was estimated to be over 24.6 million people.<sup>(36,37)</sup>

## Governance

Government in Australia is divided into three levels – a federal government, eight state/territory governments and 560 local government councils.<sup>(198)</sup> The Department of Health plays a dominant role in policy making, while the six state governments and two mainland territory governments are responsible for healthcare in their regions, for example, operating public hospitals.<sup>(198)</sup> Since 1992, the Coalition of Australian Governments (COAG) manages matters that need national coordination such as healthcare.<sup>(199)</sup> The Australian Health Ministers' Advisory Council (AHMAC) advises the COAG on health services, policy and programs.

The Australian healthcare system provides universal access to services through the Medicare programme, which is funded largely through general taxation.<sup>(197)</sup> Medicare covers public hospitals, medical services and pharmaceuticals.<sup>(197)</sup> Private patients benefit from subsidized insurance and Medicare subsidies for medical services, according to the Medical Benefits Schedule (MBS).<sup>(197)</sup> GPs play a gate keeping role, that is, specialist treatment is covered by public health insurance only with a referral from a GP.<sup>(197)</sup>

Main stakeholder groups include:

- the Australian Medical Association (AMA)
- the Royal Australian College of General Practitioners (RACGP)
- the Pharmaceutical Society of Australia (PSA)
- the Pharmacy Guide of Australia (PGA).

The Pharmaceutical Benefits Scheme (PBS) provides subsidized drugs at a set fee, which is lower for welfare recipients.<sup>(197)</sup> Established over 50 years ago, the scheme covers more than 600 drugs and covers more than 90% of all prescriptions written in Australia.<sup>(197)</sup> The Australian Pharmaceutical Benefits Scheme processed more than 208 million prescriptions in 2016 alone.<sup>(36,37)</sup> Given the volume of prescriptions processed, ePrescribing, and medication management in general, continue to be an important pillar of Australia's eHealth program.

## Strategy

From 2005 to 2016, the National E-Health Transition Authority Limited (NEHTA) was tasked with identifying and developing the necessary foundations for eHealth.<sup>(14)</sup> A collaborative enterprise by the Australian Commonwealth, State and Territory governments, NEHTA was established in 2005 with five strategic objectives:

- to deliver, operationalize and enhance essential foundations required to enable eHealth
- to coordinate the progression of priority eHealth initiatives
- to manage and deliver the key components of the Department of Health Australia Personally Controlled Electronic Health Record (PEHCR)
- to accelerate national adoption of eHealth
- to lead the further progression of eHealth in Australia.<sup>(14)</sup>

NEHTA led the development and implementation of standards, including those for ePrescribing.<sup>(14)</sup> NEHTA's work was supported by several subsequent strategies, assessments and agreements:

- the National eHealth Strategy (2008)
- the National eHealth Partnership Agreement (2009)
- a Memorandum of Understanding signed by all Australian governments (2012).<sup>(200)</sup>

The *National eHealth Strategy* listed two priority eHealth services — an eHealth portal for citizens and an ePrescription service.<sup>(201)</sup> Electronic Transfer of Prescriptions (ETP) was seen as the highest priority initiative within the wider Electronic Medications Management (eMM) programme, and it was believed that it would provide an early opportunity to connect a significant group of healthcare providers at national scale.<sup>(50)</sup>

Also in 2008, KPMG completed a consultancy report on electronic prescribing and dispensing on behalf of the Department of Health and Ageing that outlined key aspects of ePrescribing implementation.<sup>(34)</sup> The report outlined a number of components that were essential to the success of the program and recommended that any ePrescribing process be implemented in a staged and incremental fashion, as significant changes to multiple business processes simultaneously could trigger resistance from users.<sup>(34)</sup> These stages were:

**Stage one** enhanced existing paper-based processes with an equivalent electronic model, supporting the future development of a prescription exchange service (PES). The changes included:

- use of barcode identifiers on paper prescriptions
- use of terminology standards for medicines
- support for digital signatures.

The establishment of a prescription exchange service was seen as central to the success of the ePrescribing initiative.<sup>(34)</sup> Exclusive point-to-point systems were seen as a useful interim arrangement only.<sup>(34)</sup>

**Stage two** added support for electronic management of Medicare reimbursements and for the de-identified prescription data to be sent the National Medicines Policy Database to be used for statistical and research purposes.<sup>(34)</sup>

*Stage three* would see the integration of the ePrescription service with wider eHealth services, including support for individual electronic health records and quality use of medicines (QUM), which was considered a key benefit.<sup>(34)</sup> Decision support would be added, with prescribers and dispensers able to retrieve appropriate information from the prescriptions database.<sup>(34)</sup> Capabilities such as adding annotations to, or sending notifications about, prescriptions were also included, as was the ability to cancel prescriptions.<sup>(34)</sup>

The National eHealth Partnership Agreement of 2009 formalized the aspirations and financial contributions of all the Australian governments to eHealth development.<sup>(202)</sup> At that time, differing governance principles applied in the Australian states and territories. In 2010, NEHTA identified a set of six privacy principles that were common to all jurisdictions and specified the ePrescription service in line with these principles.<sup>(14)</sup> The Australian Government also commissioned two privacy impact assessments on the Personally Controlled Electronic Health Record (PEHCR). The first assessment, in 2011, resulted in recommendations in a range of supporting areas, including governance.<sup>(203)</sup>

The Memorandum of Understanding signed by all the Australian governments in 2012 commited to the development of an effective national eHealth capability and outlined the steps needed.<sup>(204)</sup> The 2012 Memorandum of Understanding included commitments to develop and deliver the core elements of a national infrastructure, to take an incremental and pragmatic approach to building the eHealth capability and to actively engage key stakeholders in the design and delivery of the eHealth solutions, including the ePrescribing service.<sup>(204)</sup> The parties agreed to fund the development of core eHealth services such as the development of specifications and standards, clinical terminology services, the Healthcare Identifiers Service, a national authentication service for healthcare providers, and, where appropriate, to use a National Product catalogue.<sup>(35,204)</sup>

In July 2016, NEHTA was rebranded as the Australian Digital Health Agency, while the PCEHR was renamed My Health Record.<sup>(205)</sup> In January 2017, the Australian Digital Health Agency announced the establishment of a new Medicines Safety Program. The group has four primary objectives, including reviewing all current and planned digital activities, prioritising activities and projects, and developing an evidence-based roadmap. In the short term, the steering group will work with stakeholders to 'enhance medicines management use and capability in the My Health Record system'.

Australia's *National Digital Health Strategy (2018-2022)* was published in April 2017.<sup>(206)</sup> In the area of electronic prescribing and medication management, key goals of the strategy are:

- by end of 2018, to provide all consumers and their healthcare providers with the ability to view their prescribed and dispensed medications in the My Health Record system
- by 2022, to provide digitally enabled paper-free options for all medication management in Australia.

## History

Key steps in the development of ePrescribing in Australia are outlined below.

## 2005

Following its establishment in 2005, NEHTA focused on implementing and delivering eHealth services for the most commonly exchanged health information, which include pathology reports, referrals, discharge summaries and medication management.<sup>(14)</sup>

## 2008 to 2013

Between 2008 and 2013, NEHTA led the development of foundational components for ePrescribing and other eHealth services that were outlined in the 2008 eHealth strategy.<sup>(200)</sup> These components included a national clinical terminology service, a national authentication service for healthcare providers, a national identifier service, messaging and documentation standards, and a secure access framework for eHealth.

The Electronic Transfer of Prescriptions version 1.1 (ETP 1.1) Concept of Operations document mentioned outlined the conceptual model for the ePrescribing service.<sup>(35)</sup> It used a staged approach to implementation, and defined the document access key (DAK) as the unique identifier for each prescription item.<sup>(35)</sup> It specified that, while paper prescriptions could contain more than one prescription item, each electronic prescription item merited a separate prescription with unique DAK barcode.<sup>(35)</sup>

The document described two levels of implementation, which NEHTA supported. A third level of ETP, where patients could choose whether to receive the prescription in paper or

electronically, was investigated but not implemented. NEHTA also recognized and supported point-to-point transfer of prescriptions electronically from prescriber directly to dispenser purely as a transition to transfer using a message broker/prescription exchange.

The following diagrams show the two levels of ePrescribing that were supported in ETP 1.1.

# ETP Level 2 – Message sent from GP to Pharmacy using message broker and repository



# Figure 8. ETP Level 2 — Message sent from GP to Pharmacy using message broker and repository (Australia)

- ePrescribing. The prescriber uses the electronic prescribing system (EPS) a component of the prescriber's clinical software package to generate an ePrescription, which is signed digitally by the prescriber, and to provide a printed notification with document access key (DAK) barcode to the patient.
- 2. **Electronic transfer of the prescription.** The prescription exchange service (PES) stores the electronic prescription.

3. **eDispensing.** The dispenser scans the DAK barcode using the electronic dispensing system (EDS), which identifies and retrieves the correct prescription. Optionally, the dispenser can send an acknowledgement.

As part of the rollout, two vendors developed prescription exchange services, which are used to transfer the prescription information asynchronously between prescribers and dispensers. The Pharmacy Guild of Australia developed and launched eRX's Script Exchange, the first prescription exchange service, in 2009.<sup>(207)</sup> MediSecure later developed their prescription exchange service (PES), which was endorsed by the Royal College of General Practitioners of Australia. Unfortunately, the two prescription exchange services could not interoperate, that is, eRX systems could not read printed prescriptions generated in MediSecure systems and vice versa.

## 2013

The providers of each announced that Medisecure and eRX's Script Exchange had finally achieved interoperability.<sup>(207)</sup> In practice, this also meant that eRX systems could read the barcode from prescriptions generated using MediSecure systems and vice versa. Interoperability between these two prescription exchange services meant that the national ePrescribing service could now take advantage of the national medication repository.<sup>(208)</sup>

## 2015

By this time, 95.7% of GPs in Australia had implemented eTP v1.1, using software provided by either eRX or MediSecure.<sup>(209)</sup> In July 2015, the PEHCR was rolled out.<sup>(210)</sup> While most Australian GPs already had their own electronic records system, the PEHCR placed all the patient's records in a nationally linked database, where healthcare providers can, with the patient's consent, access the patient's information and where patients can manage their own information, including medications.<sup>(210)</sup>

As part of the overall medication strategy, the Australian Department of Human Services also mandated that all pharmacies must move to online claiming by the end of June of 2015.<sup>(211,212)</sup> Since that time, the Department no longer accepts paper prescriptions as part of Medicare claims.

#### Lessons learned and future developments

NEHTA noted that the electronic transfer of prescription capability was built on a series of national infrastructure services:

- terminologies standards, including the Australian Medicines Terminology (AMT) and SNOMED CT
- secure messaging standards, such as HL 7 version 2.4
- standard identification service (Unique health identifier [UHI]), holding the identities of healthcare providers and patients
- National Authentication Service for Health (NASH), using the identities from the identification service to deliver capabilities such as digital signatures.<sup>(38)</sup>

In spite of the combined effort of the Commonwealth, the Pharmacy Guild, and the two prescription exchange operators, eRX and MediSecure, electronic prescribing remains a high cost for the Australian state. Under the Sixth Community Pharmacist Act (FCPA), pharmacists continue to be paid 15 cents for each electronic prescription dispensed to offset the 15 cents that eRX and MediSecure charge for each digital prescription processed.<sup>(213)</sup> However, eRX reported dispensing 753,000 electronic prescriptions at a cost of AU\$112,950 per day.

In 2014, eRX launched a free app for smartphone and tablet.<sup>(208)</sup> The eRX Express app enables patients to place an order for their prescription in the eRX-enabled pharmacy of their choice and then collect the prescription at a given date and time. The patient scans the prescription barcode with their smartphone then uses the printed prescription notification to collect the dispensed medications. Before relevant digital signature legislation was passed, the prescriber's signature on the printed prescription notification was required.

A 2016 academic paper proposed a more cost-effective solution to take advantage of digital signature legislation.<sup>(208)</sup> The patient's smartphone or tablet is used instead of the eRX prescription exchange service, receiving both prescription and bar-coded key from the GP's electronic prescribing system and transferring them to the selected pharmacy's electronic dispensing system. This proposed model cuts costs considerably; however, storing both prescription information and the access key on the patient's phone did introduce risk if the phone was lost. Cancelling the prescription would require the use of an additional text message or another method.

# 4.3 New Zealand

## Scale

The estimated resident population of New Zealand is just under 4.8 million.<sup>(214)</sup>

## Governance

The Ministry of Health has overall responsibility for health and disability services and provides advice to the Minister of Health and, in turn, the government of New Zealand on policy issues.<sup>(215)</sup> For administrative purposes, New Zealand is divided into 20 District Health Boards (DHBs) that either provide or fund health and disability services for the population in each of the DHBs. Primary healthcare, including GP services, are contracted by DHBs to primary healthcare organisations (PHOs), who either directly provide the services or indirectly through member providers.

The Health Information Strategy Advisory Committee (HISAC) was established in 2005, with the responsibility of implementation strategic health information program.<sup>(216)</sup> The National Health Board (NHB) was established in 2009 to improve coordination between the 20 district health boards (DHBs) and supervise expenditure of public health funding. The NHB, which is a ministerial committee working within the Ministry of Health, aims to consolidate national planning and funding of all IT, workforce planning and investment.

The National Health IT Board (NHITB), a subcommittee of the NHB, was founded in 2010 to provide strategic leadership and funding for information systems in the health and disability sector, replacing the HISAC.<sup>(14)</sup> It focused on IT investments that offer patient safety and value for money and on building relationships while progressing critical foundation investments to support an improved health information model. It also aimed to support future healthcare delivery models and set a direction for the appropriate and effective use of personal health information. In the same year, a subcommittee of the NHITB, the Health Information Standards Organization, was established to support and promote the development, understanding and use of fit-for-purpose health information standards.

The NHITB had overall responsibility for the national ePrescribing solution in New Zealand. Initially, the Privacy Act (1993) and Health Information Privacy Code (1994) formed the basis for information governance rules in the New Zealand health and social care sector. However, information governance arrangements were fragmented, leading the NHITB to

establish an expert advisory group (EAG) to address the issue. The EAG comprised the Primary Health Care IT Governance Group, the District Health Board CEO Information Group, National Programmes Group and the Ministry of Health Major IT Projects Group. To strengthen leadership and accountability for new health initiatives such as the ePrescribing solution, the NHITB developed a national governance model in consultation with the EAG. Following an extensive public consultation, the EAG also developed an information governance framework. The new framework provided governing standards and guidance to all e-health initiatives at a national level.

In August 2016, the New Zealand Ministry of Health abolished the National Health IT Board and replaced it with the New Zealand Digital Advisory Board.<sup>(217)</sup> Electronic prescriptions continue to form an important part of the board's digital health strategy.<sup>(218)</sup> The HISO published the *Health Information Governance Guidelines* in 2017. These guidelines outline the policies and procedures for health providers who collect and share personal health information.<sup>(219)</sup>

#### Strategy

As noted in the original international review, ePrescribing has been on the New Zealand Health IT agenda since 2005.<sup>(14)</sup> In that year, the Health Information Strategy for New Zealand (HIS-NZ) defined the key elements for a federated electronic health information model to support and improve health outcomes, at both individual and population level. The strategy proposed 12 action zones ranging from national network strategy, identifiers for individuals and organisations, national systems including laboratory systems, ePharmacy systems, chronic disease management systems and an action zone relating to national systems access. Some of the actions zones were seen as building blocks and provided benefit in their own right, while others were dependent on the existence of these building blocks. Action zone 4, ePharmacy, detailed a roadmap for the development of a national ePrescribing solution.

Action zone 4 in the original strategy outlined a roadmap for ePrescribing which included the eMedicines programme. The programme, in turn, covered the New Zealand ePrescription Service, inpatient ePrescribing, medicines reconciliation, a universal list of medications, a medicines formulary describing current use, and medication aspects of other projects such as eReferrals and discharges. ePrescribing was expected to deliver a wide range of benefits to patients, prescribers, and organizations.

As the authority responsible for implementing the HIS-NZ, the HISAC developed two ePrescribing standards:

- Electronic Pharmaceutical Business Process Standard
- Electronic Pharmaceutical Messaging Standard.

The NHITB initiated key projects including Health Identity, Shared Care Planning for Long Term Conditions and Community ePrescribing. In order to achieve this, the Board focused on prioritised areas including an eMedicines programme, National Solutions, Regional (DHB) Information Platforms and Integrated Care Initiatives.

The eMedicines Programme developed electronic systems to support the safe, effective and appropriate use of medicines. The programme includes the New Zealand ePrescription Service (NZePS), enabling GP to send prescriptions to community pharmacists electronically. National trials of the New Zealand ePrescription Service (NZePS) are underway. Other components of the programme include inpatient prescribing, medicines reconciliation, medicines formulary, universal list of medicines, and the medication aspects of other projects including eReferrals, eDischarges, shared care planning, and clinical data repositories (CDRs).
# History

At the time of the original review, the NZ ePrescription Service (NZePS) had begun a trial of a message-broker-based ePrescribing system.



# Figure 9. New Zealand ePrescription Service

In the trial, electronic prescribing mimicked the paper-script-based business practice and the paper prescription remained the legal document:

- ePrescribing. The prescriber generates a paper prescription, which the prescriber signs and that includes a **1D barcode** that uniquely identifies the prescription with a unique identifier.
- 2. **Electronic transfer of the prescription.** The electronic prescription is sent to the prescription exchange, where it is stored until it is downloaded and dispensed.
- 3. **eDispensing.** The dispenser scans the 1D barcode on the paper prescription, which identifies the prescription information in the prescription exchange, then downloads it to the dispensing system. The dispenser can optionally send an acknowledgement that the prescription items have been dispensed.

New Zealand ePrescription Service (NZePS) also provided the prescriber with the ability to add the reason for prescribing and other comments, which were sent with the prescription

and to request notification when a patient's medication has not been dispensed. The dispenser could also send dispensing comments back to the prescriber.

The transaction broker was able to forward the prescription to clinical data repositories (CDRs), but was not a CDR itself. GPs or pharmacists could not search the broker for a list of the patient's current medications nor did the broker store any information on a patient's medication history. The systems used in the trial were also participating in the trial use of the New Zealand Universal List of Medicine, another project being led by the National Health IT Board (NHITB). Finally, prescribers may not influence the patient's choice of pharmacy for any gain.

Community trials of the New Zealand ePrescription Service (NZePS) began in March 2011, following by national rollout from July 2012. Two practice management system suppliers were ready to upgrade their systems to link to the New Zealand ePrescription Service (NZePS). The Ministry for Health worked with other suppliers towards upgrading their systems. In December 2016, 47 GP practices reportedly used the New Zealand ePrescription Service (NZePS) to generate 61,000 ePrescriptions while pharmacies generated 10,000 ePrescriptions. In June 2017, this had risen significantly again, with 66 GP practices reportedly using the New Zealand ePrescription Service (NZePS) to generate 113,000 ePrescriptions while pharmacies used the service to processed 37,000 ePrescriptions.<sup>(39)</sup>

# **Chapter 5** Research and analysis

This chapter discusses research that has been carried out into the actual benefits delivered by national ePrescribing programmes and the factors that contributed to the success, or otherwise, of national ePrescribing programmes.<sup>(3,9,12,40,42,43,44,51,109)</sup> The research focussed primarily on European countries, and the findings reflect the experiences of the European leaders in ePrescribing.

# 5.1.1 Benefits realized by national ePrescribing programmes

This section describes some of the actual benefits attributed to the introduction of ePrescribing programmes.

NHS Digital estimated that, over the three years from 2013 to 2016, the 'transformative' electronic prescription service saved the NHS £130 million.<sup>(109)</sup> Prescribers saved £327 million, while dispensers saved nearly £60 million over the same period.<sup>(109)</sup> NHS Digital also reported significant time savings for prescribers, for dispensers, and for patients.<sup>(109)</sup>

# Health and social benefits

Health benefits from ePrescribing included reduced medication errors, with approximately half of the 17% of patient hospitalizations through error being considered avoidable.<sup>(9)</sup> The Estonian Health Information Fund estimated that 80,000 (6%) of patients would benefit from the error reduction aspect of ePrescribing, while prescription errors were reduced by 15% in Sweden.<sup>(9)</sup> ePrescribing can make time-critical medications more readily available, for example, Estonian data indicates that increased availability of emergency contraceptives was correlated with use of ePrescribing.<sup>(9)</sup> ePrescribing systems can also provide useful data on patients' adherence (or otherwise) to prescribed medications, which can prompt policy measures to encourage adherence.<sup>(9)</sup> In the United States, Surescripts reported that electronic prescribing drove a 10% increase in patient first-fill medication adherence, which reduces hospital readmissions and improves patient care.<sup>(220)</sup>

Research also looked at the social benefits of ePrescribing systems.<sup>(9)</sup> In 2016, the percentage of patients who were satisfied with the ePrescribing service was high in Estonia (92%) and Nordic countries such as Sweden (85%).<sup>(221,222)</sup> However, patient satisfaction is

often based on the improvement that patients experience, for example, before the introduction of ePrescribing, UK pharmacists often collected patients' prescriptions from the GP, so patients experienced no change in service.<sup>(9,15)</sup> Patient satisfaction may also be affected by the implementation, for example, in the UK, patients felt constrained by having to nominate a pharmacy, rather than being able to drop in as they wished.<sup>(9)</sup> ePrescribing may also reduce patients' involvement, for example, the patient may need a doctor or pharmacist to tell them where in the process their ePrescription is.<sup>(9)</sup> Finally, ePrescribing may provide financial savings for countries and improve social care for the elderly.<sup>(9)</sup>

# Time savings and efficiency gains

ePrescribing costs far less and takes less time than processing the same prescriptions manually, saving time and money.<sup>(40)</sup> Swedish physicians estimated that electronic prescribing saved them about 30 minutes daily.<sup>(9,14)</sup> Estonian physicians estimated that repeat electronic prescriptions took about 10–15 seconds, with new prescriptions taking about 30–60 seconds.<sup>(43)</sup> The manual processes had not been timed and so no comparison was possible, making these perceived rather than measured time savings.<sup>(43)</sup>UK physicians saw repeat prescriptions as one of the top advantages of ePrescriptions.<sup>(223)</sup> UK physicians' estimates of time saved differed, and while most GPs found it faster to generate prescriptions faster.<sup>(105)</sup>

ePrescribing also resulted in efficiency gains for dispensers, included better stock management and less paperwork at the end of the month.<sup>(221)</sup> In research from 2016, 55% of Swedish pharmacists felt that they saved time using electronic retrieval and dispensing.<sup>(221)</sup> However, UK pharmacists could wait up to 30 seconds for a prescription to be downloaded from the Spine.<sup>(221)</sup> Evidence is mixed on whether ePrescribing reduced callbacks between prescribers and dispensers: early UK studies showed a drop from 6% to 1%.<sup>(224)</sup> However, a review of more than 30,000 Swedish prescriptions showed that 2% of electronic prescriptions required a callback compared to 1.2% of paper prescriptions.<sup>(225)</sup>

# **Cost benefits**

While Estonia saw the reduction of a small incidence of fraud thanks to ePrescribing, the benefits it realized in direct economic costs were far greater.<sup>(9)</sup> Printing costs for paper prescriptions dropped from  $\in$ 63,668 in 2009 to around  $\in$ 1,000 in 2010.<sup>(9)</sup> This meant that the country's investment in the electronic prescribing system was almost completely offset

by the savings on the printing and secure storage of the forms.<sup>(9)</sup> However, in the UK, EPS R2 potentially increased paper usage because GP printed prescriptions for patients who request them while pharmacists often print them to check.<sup>(15)</sup>

Any economic gains need to be offset against the implementation costs.<sup>(9)</sup> In Estonia, direct total implementation costs were estimated at  $\in$ 500,000 by 2016.<sup>(43)</sup> That figure includes once-off system implementation costs and annual maintenance costs, but excludes large scale costs of project management, system integration and other operating expenditures.<sup>(9)</sup> But Swedish numbers showed that these costs need to be viewed over several years.<sup>(226)</sup> By 2008, the cumulative investment costs over the eight years since nationwide implementation were estimated at  $\in$ 155 million, while the estimated cumulative benefits were estimated to be  $\in$ 330 million.<sup>(226)</sup>

# **Transparency and fraud detection**

When researchers investigated whether ePrescribing improved transparency, they found that prescribers were more accountable for what they prescribed, in terms of adhering to clinical guidelines, while dispensers' practices around the medications they dispense and how quickly they dispense were more transparent.<sup>(9)</sup> The Estonian system displayed the active ingredient, rather than the brand name, to GPs, who must justify adding a brand name.<sup>(9)</sup> Prescriptions by active ingredient, rather than brand name, went from 50% to 90% of all prescriptions, which reduced patients' out of pocket costs by about 25%, though the Estonian Health Insurance Fund's pharmaceutical costs were not reduced overall.<sup>(9)</sup>

ePrescribing can also counteract fraud, creating audit trails that make it more difficult to obtain or redeem multiple prescriptions, with faster detection of abuse and fraud.<sup>(227)</sup> Fraud reduction was the main driver behind the introduction of ePrescribing in Northern Ireland, where losses had been estimated as being more than  $\pounds$ 7 million.<sup>(9,17)</sup> In Estonia, ePrescribing revealed small group of single doctors misusing their entitlements to obtain psychotropic drugs in collaboration with criminal groups.<sup>(9)</sup>

# 5.1.2 Factors found to influence ePrescribing adoption

This section looks at research findings on the factors that can support or hamper the successful adoption of national ePrescribing programmes in Europe.

# Influence of national health model

Research has found a correlation between the national health system within a country and the successful adoption, or otherwise, of ePrescribing.<sup>(3)</sup> First, the research categorized the health systems used in Europe using commonly agreed criteria:

- Social Insurance Service Model (SIS), or Bismarck model: healthcare is supplied by a combination of public and private providers, typically funded from an insurance system that employers and employees deduct from payroll.
- National Health Service Model (NHS), or Beveridge model: healthcare is largely provided by a single, state authority, which may also be able to set standards and incentivize (or enforce) compliance.
- Transition countries (TC): healthcare systems are in transition, as these are largely former Eastern Bloc countries that have recently achieved independence.<sup>(3)</sup>

Then the researchers reviewed ePrescribing adoption in EU countries and found that countries with a national health service (NHS) were most likely to have adopted ePrescribing.<sup>(3)</sup> Countries with a social insurance service model typically had a lower rate of adoption than NHS model countries, which may be a result of the decentralized nature of the governance structure.<sup>(3)</sup> Finally, transition countries were found to be the least likely to have adopted ePrescribing.<sup>(3)</sup>

However, Estonia was found to be a clear exception, being a transition country that is considered one of the most digitally advanced nations in the world. One factor in this success may be that, similar to an NHS system, Estonia has a single public payer. This payer, the Estonian Health Insurance Fund, not only developed the ePrescribing service independently of the other eHealth services — usually developed by another dedicated standards institution — but could incentivize use, which spurred adoption.

# Influence of governance

Successful countries were more likely to have a single national authority for ePrescribing, together with a clear and specific ePrescribing strategy.<sup>(40)</sup> Such an authority usually had some remit for governance of ePrescribing standards, for example, overseeing the development of national standards, engaging stakeholders, managing national messaging and broker services among other ePrescribing activities.<sup>(40)</sup> Thus, a crucial requirement is a

clear vision defined in the ePrescribing strategy, with the programme led by an authority with the ability to agree, and ensure compliance with, appropriate standards and other factors.

#### Influence of leadership and stakeholder engagement

Researchers noted countries with successful ePrescribing programmes combined visionary leadership with strong local engagement — effectively combining both 'bottom up' and 'top down' approaches.<sup>(9,12,40,106)</sup> An effective ePrescribing system took account of end-users' requirements, that is, the needs of GPs, community pharmacists and others, and ensured that stakeholders were committed to the programme. <sup>(9,12,40,106)</sup> Effective leaders also had agreed and shared a single vision, that is, a clear agreement on strategy, such as implementation approach and common standards. <sup>(9,12,40,106)</sup> Thus, an effective program had the respect of stakeholders and balanced the vision with local needs. <sup>(9,12,40,106)</sup>

Effective leadership also tended to the financial resources needed.<sup>(9)</sup> For example, the Danish programme leadership preferred to introduce the ePrescribing programme on a voluntary basis, and when stakeholders had experienced the benefits, make the system mandatory.<sup>(9)</sup> MedCom worked closely with key stakeholders, gaining consensus on the standards to be implemented. The leaders of the Swedish ePrescribing programme also gained and retained the cooperation of all stakeholders, which was considered a key factor in successful adoption.<sup>(9)</sup> The Estonian Health Insurance Fund took a more centralized, but nonetheless successful, approach by mandating use of the ePrescribing process.

#### Influence of process and system design

The ePrescribing system needs to be well-designed for the business process of stakeholders including GPs and community pharmacists.<sup>(9,12,106)</sup> Where the ePrescribing system improves this business process, and where stakeholders are aware of this improvement, stakeholders are much more likely to adopt the system.<sup>(9)</sup> In Denmark, GPs adopted the electronic medication record because it provided an integrated and complete list of medication, with contraindications and up-to-date prices, which was far faster than the paper based process.<sup>(9)</sup> In contrast, UK interviewees told researchers that the ePrescribing systems needed to be optimized, for example, owing to the number of alerts they generated.<sup>(9)</sup> These shortcomings were attributed, at least in part, to vendors having little incentive to support interoperability or to innovate.<sup>(9)</sup>

#### Influence of common standards

Research again indicated the importance of an interoperability framework for secure information exchange between prescribers and dispensers and a data model and minimum dataset, including reference catalogues.<sup>(9,40)</sup> For example, the Danish eHealth agency, MedCom, defined national standards and tested and approved systems, which avoided the establishment of isolated islands who could communicate only with local partners.<sup>(9)</sup> From the beginning, prescriptions could be sent to any pharmacy in the country.<sup>(9)</sup> This common framework can allow for a certain amount of customization to local needs.<sup>(9)</sup> In contrast, the Dutch Government decided in 2010 to remove itself from decisions around healthcare standards and implementations. In effect, any group of GPs or other stakeholders were allowed to adopt any common infrastructure and standards that they wished to adopt. As a result, while regional networks were set up and are well used, the Netherlands still does not have a national ePrescribing system.

An effective set of national standards is considered to include a unique patient identifier.<sup>(9)</sup> Experts from Denmark and Estonia, two of the most digitally advanced nations, emphasise the widespread use of this patient identifier in everyday life.<sup>(9)</sup> A suitable legal framework is also necessary to protect citizens' data.<sup>(9)</sup>

# **Influence of financial incentives**

Competitive forces were considered to be the main drivers for high levels of adoption among community pharmacists in Denmark, Estonia and the UK.<sup>(9)</sup> In these countries, community pharmacies compete for patients and, therefore, invested in ePrescribing capabilities so as not to be outpaced by rivals who could offer the same capabilities.<sup>(9)</sup> In Sweden, the government-owned pharmacy chain initiated the ePrescribing programme, before handing responsibility to the eHealth agency following deregulation.<sup>(9)</sup> From the prescriber side, financial returns for stakeholders also need to be well understood.<sup>(9)</sup> Furthemore, Estonian GPs could clearly see the benefits of an automated system in the context of their legal obligation to mark the correct reimbursement calculation on the prescription.<sup>(9)</sup>

### Influence of wider eHealth strategy

Several researchers noted that ePrescribing is usually part of a wider strategic program of eHealth services, which is indicative of a certain maturity in the digitization process.<sup>(9,42,44)</sup> An

ePrescription service is seen as part of a 'family' of eHealth services, without which it may be far less effective, for example, if health records are kept on paper, there is much more work involved in providing an ePrescription service.<sup>(9)</sup> Four countries surveyed in the research (Denmark, Estonia, Sweden and the United Kingdom) introduced electronic medical records and ePrescribing concurrently.<sup>(9)</sup> In contrast, piecemeal introduction of eHealth services, including ePrescribing, can have adverse consequences in terms of service interoperability and results in fewer benefits.<sup>(9)</sup>

Additionally, where stakeholders are already using other eHealth services, the adoption of ePrescribing processes is less disruptive and can take advantage of investments already made, for example, where GPs were already receiving laboratory test results and hospital discharge summaries electronically, they had already invested in the necessary software and understood the benefits of electronic exchange of clinical documents.<sup>(9)</sup> Countries with a successful ePrescribing programme also tended to have established a national infrastructure that spans eHealth services, which avoids the situation of developing similar services — such as for user identification and authentication — for each individual eHealth service.<sup>(9)</sup>

## Influence of trust and digital readiness

ePrescriptions may raise questions of privacy, which rest on public trust in the institutional handling of sensitive data.<sup>(9)</sup> Estonia was considered to have built trust by gradually introducing useful eHealth services, without any failures, and with effective penalties for small data breaches.<sup>(9)</sup> In Denmark and Sweden, decades of research and investment in ePrescribing have also built public trust gradually.<sup>(9)</sup> In Denmark, Estonia and Sweden, citizens are also used to using eServices to file taxes, to vote and to sign documents electronically.<sup>(9)</sup> In contrast, UK NHS data breaches are more commonly reported and willingness to disclose personal information for eServices is lower.<sup>(9)</sup>

#### Influence of the implementation approach

A coordinated rollout was also considered crucial to the success of an ePrescribing programme.<sup>(9)</sup> As a small country, Estonia used a 'big bang' implementation approach, with the ePrescribing system implemented simultaneously throughout the country.<sup>(9,43)</sup> However, shortcomings in the piloting process meant that only when the system was implemented was it discovered that it could not tolerate the load. GPs were instructed to use paper prescriptions for six months while the issues were resolved.<sup>(9,43)</sup> Thus, managing expectations is now considered to be vital — it is important that the benefits of ePrescribing

are not over stated and to indicate that there will always be some issues to resolve.<sup>(9)</sup> Effective piloting was also identified as crucial—some UK implementations, which involved multiple systems, experienced similar technical problems that were subsequently compared and resolved.<sup>(9)</sup>

The structured and highly successful Swedish implementation strategy started with a central pilot in Stockholm, followed by competition driven rollouts in each locality.<sup>(9)</sup> Each locality planned their own training and operational startup and conducted evaluation meetings for three to six months after operations began.<sup>(9)</sup>

For larger countries, such as the UK, a phased approach was necessary to cope with the size and resulting complexity.<sup>(9)</sup> Early successes also built momentum for later phases in the implementation cycle.<sup>(9)</sup> Stakeholder support was also built gradually, with research indicating that early engagement of programme champions and management of strong dissenters contributing to success.<sup>(9)</sup>

# Influence of the installed base

Researchers note that the installed base—that is, the technologies, systems, and business processes already in use—has been shown to have a huge impact on eHealth services, including an ePrescribing service, that a national programme seeks to implement.<sup>(12)</sup> The pre-existing built environment, the standards already adopted and the existing and planned services need to be considered when deciding the technical architecture, standards and other aspects of the final ePrescribing solution.<sup>(12)</sup> All of Europe's ePrescribing leaders have some work remaining, for example, some systems use databases with unstructured information that require coding and possibly translation into English before the data can be usefully integrated with the ePrescribing service and other eHealth services.

# **Chapter 6 Conclusion**

This section summarizes the factors that were correlated with successful ePrescribing programmes in their respective countries. It then looks at where these factors have been taken into account by the Irish ePrescribing program and suggests factors that should inform the strategy and activities of the Irish national ePrescribing service.

# 6.1 Review of factors that could influence Irish adoption

First, each successful national ePrescribing programme was likely to have a clearly ePrescribing strategy, with a single national authority responsible for realizing the vision.<sup>(40)</sup> Such an authority usually had some responsibility for governance of ePrescribing standards, for example, overseeing the development of national standards, engaging stakeholders, and managing national messaging and broker services.<sup>(40)</sup> The authority often has the remit to ensure compliance with appropriate ePrescribing standards.

Successful ePrescribing programmes also combined visionary leadership with strong local engagement.<sup>(9)</sup> Programme leaders agreed and communicated a clear vision for the ePrescribing service, but also worked to understand and balance this vision with stakeholders' needs. Well-designed ePrescribing services took account of the business and real-world processes that they automated, such as community pharmacists' dispensing practices, and usually allowed some lead time for all participants to become accustomed to the new service.

ePrescribing also tended to be part of a wider strategic program of eHealth services, which is indicative of a certain maturity in the digitization process.<sup>(9,42,44)</sup> Without these services, ePrescribing may be far less effective.<sup>(9)</sup> Where other eHealth services had already been introduced, the foundations of information governance and a legislative framework had often been laid and trust in digital services had already been established. Countries with successful ePrescribing programmes often enacted specific eHealth legislation to support the adoption of ePrescribing at national level.<sup>(40)</sup>

Successful ePrescribing programmes were also designed to work well with the installed base, that is, with existing infrastructure, repositories, systems and services, while taking

account of the planned services and developments in the national roadmap for healthcare IT. However, the ePrescribing service also needed to be able to cope with the pace of adoption, particularly if this was extremely high. A phased approach ensured that successful early pilots could build momentum for later phases. This also gave time for common issues to emerge, for legislative and information governance measures to mature, and for all participants to become accustomed to using the service.

Research also indicated the importance of an interoperability framework for secure information exchange with other services, such as an electronic medical record (EMR) system. A system to uniquely identify citizens was also a crucial component, with the system required to uniquely identify healthcare professionals such as GPs and pharmacists.<sup>(40)</sup>

# 6.2 Review of Irish ePrescribing programme

This section discusses the progress that the Irish ePrescribing programme has made towards the adoption of national ePrescribing.

The vision for the Irish ePrescribing program is set out in the Department of Health's eHealth strategy. The goal of ePrescribing strategy in Ireland is to reduce errors, thereby reducing the associated costs, and speeding up patient access to medication.<sup>(41)</sup> The eHealth Ireland organization is responsible for realizing this vision and, in June 2015, announced the National ePrescribing Programme, which included ePrescribing in primary care and the National Medicinal Product Catalogue among its projects.

The National ePrescribing Programme also published its plan for a phased, standards-based implementation. The programme's phased approach included the development of the initial building blocks (phase 1), leading to an 'ePrescription' phase (phase 2), followed by the roll out of ePrescribing in primary care (phase 3). The adoption of a phased, pilot-based approach is in line with recommendations and best practices.

As part of phase 1, eHealth Ireland worked with a number of organizations to develop a relevant interoperability framework based on national and international standards. The Health Information and Quality Authority of Ireland (HIQA), whose statutory remit includes

developing national technical standards for health information, has defined and agreed the related standards for messaging and datasets, including:

- *ePrescription dataset and clinical document architecture standard* (March 2015)
- Data model for an electronic medicinal product reference catalogue a National Standard (March 2015)
- National Standard for a Dispensing Note including a Clinical Document Architecture specification (January 2017).

In November 2016, the Irish Department of Health acquired a national licence for SNOMED when it became the 29<sup>th</sup> member of SNOMED International. Moreover, national health identifier legislation has been passed, permitting the creation and use of the Individual Health Identifier. As discussed, all successful national ePrescribing programmes used a national patient health identifier, which now has the legislative basis for use in Ireland.

Two ePrescribing pilot projects have also been undertaken. The first pilot, which transferred prescription information directly from GP to pharmacy, indicated that using a transaction broker was preferred. In the second pilot project, GPs sent the prescription information to the cloud and generated the legal paper script that included a barcode. Pharmacists then scanned the barcode, ensuring the correct prescription information was downloaded.

The model mirrors stakeholders' current business processes and gives stakeholders time to become accustomed to and provide feedback on their user experience. It also gives time for the legislative and information governance framework to mature. Work continues to understand the necessary legislative and governance measures that are still required, including whether specific health information legislation is needed.

# 6.3 Further considerations for successful adoption

Given the progress to date, and the lessons learned from other national ePrescribing programmes worldwide, the following considerations could support the successful adoption of the ePrescribing service.

# 6.3.1 Strong ongoing engagement with key stakeholders

Successful ePrescribing programmes typically balance local and national needs, continually sharing a clear national vision that also meets important local requirements. This approach

can also mirror the clear, coordinated approach characteristic of the national health insurance model that is correlated with successful ePrescribing programmes. It can also mitigate any challenges that Ireland's social insurance health model could pose.

eHealth Ireland can continue to articulate its clear vision for ePrescribing as part of an electronic medical record system (EMR). The programme can continue to engage GPs, community pharmacists, vendors and other stakeholders fully in designing and testing the service, building their commitment to the programme and ensuring that local needs are met. Stakeholders were found to be more engaged when they understand and experience clear benefits from a new ePrescribing service. It has also proven useful to engage with strong objectors early in the lifecycle in order to understand and address their concerns. Consideration also needs to be given to the financial and other impacts on stakeholders.

# 6.3.2 Continuing phased implementation approach

The ePharmacy programme has already undertaken two pilot projects, in line with international best practice and experience. Undertaking further pilot projects could offer further benefits, for example, for stakeholders to contribute more to the design or for more rigorous testing of the system. Stakeholders should be involved in the design and development of the ePrescribing service as well as in engagement and training activities. In the early phase, successful programmes identified several 'champions', who have helped to raise awareness and to educate those stakeholders that they represent.

# 6.3.3 Continuing integration with the wider eHealth strategy

ePrescribing programmes typically realized the full benefits when integrated other eHealth services, especially with an electronic medical record (EMR). Introducing an electronic health record, a longitudinal record often derived from EMRs, is a core goal of the Irish national eHealth strategy. When the specifications and requirements for these, and other, core components are defined, the ePrescribing service will need to ensure interoperability, for example, initially, with the National Medicinal Product Catalogue and, later, the planned electronic health record (EHR) system.

Integration with the installed base may also require additional effort, such as coding. Finally, the national ePrescribing service may also want, as the programme matures, to be cognisant

of the requirements for Ireland's participation in Wave 3 of the Connecting for Europe Framework project in 2020 and beyond.

# **Appendix A** — epSOS ePrescription Dataset

This appendix lists the dataset developed by the European Patient Smart Open Services (epSOS) project.

Originally expected to run for one year, the pilot ran from April 2012 to June 2014 and included 25 countries. Participating countries that were at different stages of ePrescription implementation, making it necessary to define both a minimum dataset and a maximum dataset for the transfer an ePrescription across EU border. To identify this common minimum dataset, all use cases possible in the large scale pilot were identified then five possible use cases were defined:

Use Case	Home Country	Prescribing Country	Dispensing Country	Comment
0	A	А	А	Regular situation. No special epSOS action upfront.
1	А	А	В	Medication already prescribed in Country A.
2	А	В	В	Medication newly prescribed in Country B.
3	А	В	А	Medication prescribed in country B and dispensed in home country.
4	А	В	С	Two foreign countries involved.

To take part in the pilot, each country needed to be able to satisfy the requirements to allow use case 1, the most common scenario, where a patient from country A has a prescription issued in country A and the prescription is dispensed in country B.

The pre-conditions for use case 1 were:

- The patient has a valid prescription, issued electronically in their home country A
- The pharmacy in country B has a mechanism to validate the identity of the patient and to handle patient consent against country A.

This assumes that both prescriber and dispenser are authorized in their respective countries.

The prescriber in Country A must be able to make the requested 'available' prescriptions accessible, which implies that country A can calculate the 'available' prescriptions, that is, it

has the necessary information or parameters to select the prescriptions that can be dispensed at that moment.

Country A must provide, maintain, and support a logical country node (NCP) supporting communication of the information identified in this section with country B and vice versa. A chain of trust must also exist between system actors in this process.

# **Common dataset**

Questionnaires were distributed to participant countries to ascertain their requirements regarding the electronic transfer of prescription. These requirements were analyzed and a common minimum and maximum dataset were agreed. The maximum dataset includes patient identification data, prescriber identity data, ePrescription data, dispenser identity data and dispensed medicine data. The minimum dataset containing this information from one country can then be put into a format defined by epSOS Semantic Services and transferred to the other country.<sup>(65)</sup>

This table lists the dataset developed by the European Patient Smart Open Services (epSOS) project:

# Identification of the patient

Surname [ISO TS 22220] Given name [ISO TS 22220] Date of birth [ISO TS 22220] Personal identifier

Gender

# Authentication of the prescription

Prescription ID

Issue date

# Identification of the prescribing health professional

Surname

Given name

Professional qualifications

Details of direct contact

Work address

(Digital or electronic) signature

Health care provider identifier (HCPI)

# Identification of the prescribed product

Name of the item [+ identifier as described in ISO IS 11615] Name of the item [+ identifier as described in ISO IS 11616] Strength of the item [Article 1 of Directive 2001/83/EC]

# **Prescription information**

Pharmaceutical dose form

Quantity

Dose regimen

Duration of treatment (start and/or stop time)

Directions for use

Pharmaceutical preparation description

# **Optional elements of prescription**

# Identification of the patient

Address details

Native language (could be taken from the ISO language table [ISO 639.2 or ISO 639-3)]

# **Patient characteristics**

Body weight

Body height

Drug allergies and drug sensitivities

Patient conditions

# **Prescription information**

Prescription expiry date

Repeat/refills

Minimum dispensing interval

Reason for prescription

Substitution handling

# eDispensation

# Identification of the dispenser

Name of dispenser

ISO 3166 country code of the dispenser

Address of the dispenser

Personal identification number of the patient, together with the ISO 3166 country code

Identification number of the prescription

Items dispensed



### Figure 10. EpSOS Interoperability Process

## epSOS Architecture

The epSOS architecture is based on Integrating the Healthcare Enterprise (IHE) profiles and the service oriented paradigm. The basic building blocks required for interoperability across country borders are listed here:

# National Interface and National Connector

The National Interface connects the epSOS Common Components and the National Connector. The National Connector is not part of the epSOS Common Components. National Connector Interfaces exposed to the national infrastructure are country-specific. The National Connector is responsible for accessing the national infrastructure and fulfilling the national requirements.

# Portal and Portal Adapter

The Portal is a Graphical User Interface used by the health professional when providing epSOS Services, including ePrescribing to patients. Two different Portals are part of the Common Components and each country can decide which one they would like to use. If a country develops a portal solution of its own, then they are obliged to use the Portal Adapter, which is a web service.

# Core Elements

The 'Core Elements' are the Common Components which were defined within the epSOS project and belong to the business layer in the NCP architecture. They consist of the Workflow Manager, the Security Manager, the Transformation Manager, the Terminology Service Access Manager, the Audit Trail Writer, the Audit Repository and the Routing Manager.

# EpSOS Interface

The epSOS interface is also a part of the Common Components defined in epSOS and belongs to the epSOS communication layer in the national contact point architecture. It consists of the Inbound Protocol Terminator (when acting as the patient's home country) and the Outbound Protocol Terminator (when acting as the patient's visiting country).

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