

"A Medicines and Drugs Reference Catalogue for e-Prescribing in Ireland"

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A dissertation submitted to the University of Dublin,
in partial fulfilment of the requirements for the degree of
Master of Science in Health Informatics

2011

Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work and has not been submitted as an exercise for a degree at this or any other university.

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Abstract

Title: A Medicines and Drugs Reference Catalogue for e-Prescribing in Ireland

Author: Brendan Kernan

E-Prescribing is part of the interoperable e-Health strategy. Many countries have implemented e-Prescribing and have identified as a requirement shareable data on medicines and drugs. These data are shared using reference catalogues. If Ireland is to embark on an e-Prescribing programme a reference catalogue must be implemented. This dissertation answers the “why” and the “how” questions on implementing a medicines and drugs reference catalogue.

A State of the Art literature review explores the catalysts for e-Prescribing and then examines the trends in reference catalogues with the emphasis on medicines and drugs. It examines how terminologies are playing an increasingly important role. Then the Irish context is examined to determine the current status and readiness for a reference catalogue.

The research methodology employed is qualitative multi case study analysis. The data is structured to allow comparisons across each country in addition drawing conclusions about each country individually. How academic rigour can be applied to case study is developed as a tool to aid the analysis.

The author explores the development and implementation of a medicine and drugs reference catalogues in four countries the United States, the United Kingdom, Australia and New Zealand. Their experiences are discussed and developed to produce findings which might be relevant for Ireland.

The findings are then rationalised and recommendations are made for consideration in an Irish context. The recommendations focus on areas such as clinical terminologies, data models, organisation and publishing the reference catalogue. The significant recommendations are the adoption of a standard data model, an early decision on SNOMED and the establishment of a trusted government agency to manage and publish the medicines and drugs catalogue.

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Abbreviations

ACOM	Australian Catalogue of Medicines
ADE	Adverse Drug Event
AMP	Actual Medicinal Product
AMPP	Actual Medicinal Product Pack
AMT	Australian Medicines Terminology
ARTG	Australian Register of Therapeutic Goods
ATC	Anatomical Therapeutic Classification
BNF	British National Formulary
CDS	Clinical Decision Support
CDT	Common Technical Document
CEN	European Committee for Standardisation (<i>trans: Comité Européen de Normalisation</i>)
CPOE	Computerised Physician Order Entry
CTPP	Containerised Trade Product Pack
EHR	Electronic Health Record
EPS	Electronic Prescription Service
EU	European Union
FDA	Federal Drugs Agency
GP	General Practitioner
GPIT	General Practice Information Technology
GPMS	General Practice Management System
GTIN	Global Trade Item Number
HL7	Health Level Seven
HISO	Health Information Standards Organisation
HSE	Health Services Executive
ICD	International Classifications of Diseases

ICGP	Irish College of General Practitioners
ICT	Information and Communications Technology
INN	International Non-Proprietary Name
IMB	Irish Medicines Board
INF	Irish National Formulary
IOM	Institute of Medicine
IPHA	Irish Pharmaceutical Healthcare Association
IHTSDO	International Health Terminology Standards Development Organisation
IOM	Institute of Medicine
IPU	Irish Pharmacy Union
ISO	International Organisation for Standards
IT	Information Technology
MA	Market Authorisation
MINS	Monthly Index of Medical Specialities
MP	Medicinal Product
MPP	Medicinal Product Pack
MPUU	Medicinal Product Unit of Use
NCHS	National Centre for Health Statistics
NCTIS	National Clinical Terminology and Information Service
NCVHS	National Centre for Vital and Health Statistics
NHS	National Health Service
NEHTA	National e-Health Transition Authority
NZULM	New Zealand Universal List of Medicines
NZMT	New Zealand Medicines Terminology
OECD	Organisation for Economic Co-operation and Development
OTC	Over the Counter
PBS	Pharmaceutical Benefits Scheme

PCEHR	Personally Controller Electronic Health Record
PCRS	Primary Care Reimbursement Services
RA	Regulatory Authority
SCDC	Semantic Clinical Drug Component
SNDO	Standard Nomenclature of Diseases and Operations
SNOMED CT	Systematised Nomenclature of Medicine Clinical Terminology
SMM	Safe Medication Management
SNF	Semantic Normal Form
SPHA	Society of Hospital Pharmacists of Australia Coding Scheme
SmPC	Summary of Product Characteristics
TGA	Therapeutic Goods Association
TP	Trade Product
TPP	Trade Product Pack
TTY	Term Type
UK	United Kingdom
UK dm+d	UK Dictionary of Drugs and Devices
UKCPRS	United Kingdom Clinical Products Reference Sources
US	United States
USNLM	US National Library of Medicines
VMP	Virtual Medicinal Product
VMPP	Virtual Medicinal Product Pack
VTM	Virtual Therapeutic Moiety
WHO	World Health Organisation

1 Introduction

1.1 Introduction

Information is the key to success. Benjamin Disraeli (*Politician 1804- 1881*) asserted:

...as a rule the most successful man in life is the man who has the best information (Disraeli, circa 1880).

Disraeli's rule is still relevant today. In healthcare, the clinician with the best information will deliver the best healthcare to the patient.

Peter Hinssen, a leading Information Technology analyst, defines information in more expressive terms:

Information is about content, collaboration, intelligence and knowledge. Information is the cornerstone of our organisations. Defining an information strategy for the New Normal is crucial. In the New Normal, information centres on people. It's about how we work, share, publish and find information in the future (Hinssen, 2010 p. 121).

Healthcare information is about people, namely the clinician and the patient. At the point of care the clinician uses the information available to make an informed choice about the patient's treatment. Healthcare information is about content, collaboration, intelligence, knowledge and the impact it has on the health and wellness of the individual patient. This information needs to be accurate, reliable and safe.

This dissertation applies Hinssen's definition of Information and Disraeli's rule in the specific context of e-Prescribing. Specifically, it examines the requirements for a medicines and drugs reference catalogue to support e-Prescribing. Finally, it recommends how a medicines and drugs reference catalogue should be implemented in Ireland.

1.2 E-Prescribing Overview

Man has been prescribing, dispensing and administering medicines to cure all types of illnesses since ancient times. However, despite many years of accumulated knowledge there is still the capacity to do harm to the patient when treating their illnesses with various medications (Kohn et al., 2000 p 26-48, Chap 2).

The Organisation for Economic Co-operation and Development (OECD) has reported that Information and Communications Technology (ICT) when applied to Healthcare can deliver benefits in terms of patient safety (Organisation for Economic Co-Operation and Development, 2010 p. 12). Electronic prescribing or e-Prescribing is one area where ICT can deliver benefits. E-Prescribing facilitates the clinician to make informed choices when selecting the patient's medication(s). The Institute of Medicine (IOM) citing Bates et al. asserts that e-Prescribing improves patient safety by reducing medication errors while at the same time reducing costs (2001 p. 153). Goundrey-Smith agrees, stating that e-Prescribing has 'benefits in terms of risk management and risk reduction, and also financial cost' (2008 p. 6).

E-Prescribing alerts the clinician to potential dangers to the patient based on the medications prescribed. It achieves this by using a number of applications and reference databases that work together to guide the clinician's choice of medication. A medicines and drug reference catalogue is one of the reference databases required. Goundrey-Smith states that e-Prescribing depends on the 'availability of high quality data' about the medicines and drugs that will be prescribed, dispensed, administered and then recorded in the Electronic Health Record (EHR) (2008 p. 93).

The EHR is a record where all health related events over a patient's lifetime, including all medications prescribed by a doctor, dispensed by a pharmacist, and then taken by or administered to the patient. E-Prescribing is considered as an enabler for the EHR because it facilitates the easy capture of a patient's medication history. Once stored electronically the data can be shared between different healthcare applications over a patient's lifetime. However, the

medication data needs to be formatted in a way suited for storing in databases over a long period of time.

1.3 Rationale for the Dissertation

There are multiple sources of information on medicines and drugs. However, not all are suitable for e-Prescribing. In particular, when the information is shared between applications and when the EHR is the objective. The data models, the data sets and data formats are not standardised. This lack of standards is not unique to Ireland other countries have encountered the same problem. They have taken steps and explored how this data can be shared or made interoperable using a medicines and drugs reference catalogue and have started to implement solutions.

In recent research, O'Grady explored the lack of a medications record in Ireland and concluded that Ireland needed a consistent drug file or catalogue (O'Grady, 2010 p. 44 & 58). O'Grady recommends that a national drug file should be implemented for the purposes of a patient medications record. However, the research does not discuss the drugs file itself. This study expands on O'Grady's research and examines the options available for a drug file in Ireland.

1.3.1 A Medicines and Drug Reference Catalogue for E-Prescribing

A medicines and drugs reference catalogue is a drugs file containing data structured and formatted in a specified way. The medicines data relates to how the patient is prescribed and administered the drug. The drug data relates to the active ingredient(s) that causes the therapeutic effect. In the catalogue, these data are detailed using a standard data model. In e-Prescribing, the catalogue supports applications such as the patient's medication record, clinical decision support and the electronic transmission of the patient's prescription to a pharmacy. In the pharmacy, the catalogue supports dispensing and at the bedside it supports administering medication to the

patient. The data in the catalogue is a common language or terminology to support the different applications.

This study looks at the issues and decisions that may have to be taken and makes recommendations on implementing a solution.

1.4 Research Question

The author believes that a medicines and drug reference catalogue is a core requirement in Health Informatics and in particular e-Prescribing. This study explores developments in other countries and will attempt to answer the following question.

Using the knowledge and experience of other countries worldwide, why and how might Ireland develop and implement a medicines and drugs reference catalogue to support e-Prescribing?

1.5 Aims and Objectives

The aim of the research is to determine the critical issues when implementing the catalogue and to make recommendations on how they should be addressed. The specific objectives below will facilitate exploring these issues.

- Why should a medicines and drugs reference catalogue be implemented? An examination of the role a catalogue plays in e-Prescribing and health records.
- What are the drivers and experiences of other countries? What are the challenges they faced?
- What technology is required? What are the latest trends in catalogue implementations and what is the future direction of that technology?

- What organisational framework is needed to support a catalogue? How should a medicines and drug catalogue be managed and delivered to the user community?
- Using the experiences in other countries identify the key issues for Ireland.

1.6 Motivation

The motivation for this research is the fact that Ireland has yet to decide how to implement a medicines and drugs reference catalogue. As O’Grady highlighted, there is a void, which if it is not addressed will continue to act as a barrier to the development of even a basic interoperable medication record (2010 p. 58).

1.7 Guide to the Dissertation

Chapter 1: Introduction

The author introduces the topic of e-Prescribing and the importance of accurate and reliable information about medicines and drugs. A Medicines and Drugs Reference Catalogue is proposed as a tool by which this information can be provided in Ireland. The research question and the research objectives are introduced to explore how this might be achieved.

Chapter 2: State of the Art

This chapter examines the topics of e-Prescribing using a medicines and drugs catalogues in literature to determine the reasons why e-Prescribing is so critical, what is the current State of the Art and where Ireland is positioned now. Each perspective is individually researched and conclusions are made based on the findings.

Chapter 3: Research Methodology

The author explains the rationale for selecting case studies as the research methodology. The author also explains how academic rigour was applied.

Chapter 4: Case Studies Analysis and Interviews

The author individually explores the why, and how, each country developed a medicines and drugs reference catalogues. The analysis is performed using common headings and a conclusion is made about each case.

Chapter 5: Findings and Analysis

This chapter evaluates all the cases together. Qualitative analysis techniques using keywords, themes and phases are used to perform a cross-case analysis.

Chapter 6: Recommendations

The findings in chapter 5 will be used to develop a rational and recommendations for Ireland. Areas of further research, if applicable, will be identified. The limitations in this research are also documented.

2 State of The Art Review

2.1 Introduction

A State of the Art literature review was undertaken to deepen the author's knowledge and understanding of the research topic.

The review was categorised as illustrated in Figure 2-1. These categories were selected to focus the review, constrain the research topics and to reject superfluous information.

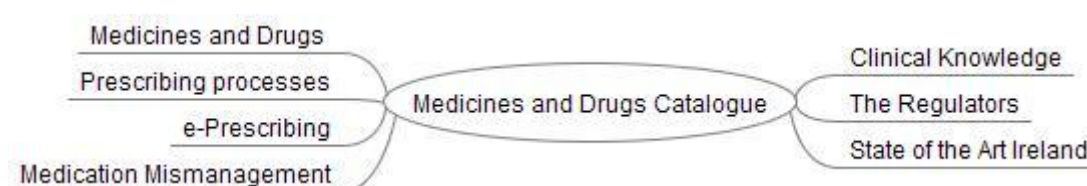


Figure 2-1 Mindmap of State of the Art

A sample of the sources accessed were peer reviewed journal articles, past theses, reference handbooks, national and international reports and reports prepared by government and non-government agencies. Online access was used to search research databases such as Sci-Verse, PubMed, ISI Web of Knowledge and Google Scholar. Websites were accessed where documents relating to e-Prescribing and specifically to medicines and drugs catalogues where available. Finally, the websites of various organisations providing catalogue services were accessed.

The author examined the catalysts that are driving the need for e-Prescribing. Of particular attention is the use of medication. This is reported on in section 2.2.

In section 2.3 the author reviews the information on medicines and drugs used by clinicians and available today in Ireland.

In section 2.4 international and national reports on medication mismanagement are examined for the causes of medication mismanagement and strategies to prevent adverse drug events (ADEs) are investigated.

In section 2.5 the author assesses the overall data architecture used in e-Prescribing and the role that a medications and drugs reference catalogue plays.

Preliminary research had identified that clinical terminologies are playing an increasingly important role in Health Informatics. E-Prescribing and the medicine and drugs catalogue are not immune to this development. This relationship is explored in section 2.6.

In most countries a regulating authority is responsible for medicines and drugs. They are the main source of information on medicines and drugs. The role regulating authorities is studied in section 2.7.

Finally, the State of the Art in Ireland is examined in section 2.8.

2.2 Medicines and Drugs - A Growth Industry

2.2.1 Use of Prescription Items

The use of medicines and drugs is on the increase. In the United States (US), the National Centre for Health Statistics (NCHS) reported in October 2010 that:

Over the last 10 years, the percentage of Americans who took at least one prescription drug in the past month increased from 44% to 48%. The use of two or more drugs increased from 25% to 31%. The use of five or more drugs increased from 6% to 11% (Gu Q et al., 2010 p. 1).

In the United Kingdom (UK), the National Health Service (NHS) (2011) reported that prescribing by General Practitioners (GP) shows a year on year

increase. From April 2006 to March 2007, the total number of prescribed items was 752 million. In the same period, for 2009 to 2010, the total number of items prescribed increased to 886 million. This represents a 5.9% annual increase.

In Ireland, the Primary Care Reimbursement Services (PCRS) (2007 p. 15) reported that the number of prescription items increased from 40.5 million to 44.3 million in the year 2006. At the same time, the average number of prescribed items per script also increased from 2.91 to 3. The Health Service Executive (HSE) (2010 p. 31) has budgeted for 63 million prescription items on 20 million claims. The trend in Ireland mirrors the increasing trend in other countries.

2.2.2 Conclusion

These reports illustrate that the number of prescriptions and the number of items per prescription are both increasing, not only in Ireland but also across the global economies. The trends are upwards and will continue to rise into the future.

2.3 Current Information Resources

2.3.1 Published References

Today, in Ireland, when clinicians prescribe medications they can use a number of different references. A samples of these references are:

- Monthly Index of Medical Specialities (MIMS)
- The Irish National Formulary
- Online Services

The handbooks contain information provided by the Summary of Product Characteristics (SmPC). The SmPC is published by the Irish Medicines Board (IMB) at the same time the medicine is authorised for use. Extracts from two handbooks are shown in Figure 2-1 MIMS (MIMS Ireland, 2003) and in Figure 2-3 The Irish Formulary (The Irish Formulary, 2010).

Alternatively, the Irish Pharmaceutical Healthcare Association (IPHA) publishes the information online at www.medicines.ie (2011). The index in Figure 2-4 illustrates the nature of the content that may be searched and viewed for Abilify tablets, orodispersible, oral solution.

Although a detailed discussion on the merits of one source over another source is beyond the scope of this study, it is noted that these handbooks are published by different organisations for different purposes. They are updated periodically and the rate of update varies. There is no guarantee that information is consistent or authoritative.

The website www.medicines.ie contains the most data and is more readable. Both handbooks use condensed text and coding to communicate the information. They all contain details about the medication including descriptions, form, route, dosage levels, special precautions, contraindications, drug interactions and adverse reactions.

However, there are differences between them. Medicines.ie does not display the reimbursement data, whereas the two handbooks do. The Anatomical Therapeutic Classification (ATC) is detailed in the Irish Formulary, but is not in MINS or on the www.medicines.ie. There is a lack of consistency between the sources.

The most significant disadvantage with these sources is that they cannot be integrated directly into an IT application and as a result they are not automated as part of the prescribing process. Using these references relies heavily on the clinician cross-checking and interpreting the information and then taking action. It is a manual activity calling for judgement which has a potential for error.

Notes on using MIMS and key to symbols

- [CD]** indicates a product is controlled under the Misuse of Drugs Act.
- [OTC]** over the counter.
- [1]** indicates a preparation which may be dispensed **once only** unless specific instructions are issued to the contrary.
- [6]** indicates a preparation which in the absence of specific instructions to the contrary may be dispensed for **six months only**, and at such intervals over the six month period following its issue as the dispenser considers appropriate, having regard to dosage rate.

Pharmacological class

ent-ctd = enteric coated
film-ctd = film coated
sug-ctd = sugar coated
rcv = rubber capped vial
Cal/Pk = calendar pack

Dosage

Active Ingredient

[SPORT] indicates sport classification.

[GMS] indicates GMS reimbursable.

[HT] indicates High Tech Scheme.

[Hospital] implies that the drug is for consultant use only or that therapy should be initiated under consultant's supervision.

Prices: The trade price is given for all products and does not include the pharmacist dispensing fees. They are quoted to enable the prescriber to compare the cost of proprietary preparations and do not have any relation to the retail cost of the drug, nor of its cost if obtained on a private prescription.

COZAAR-COMP M.S.D.

[6] **[SPORT]** **[GMS]**

Angiotensin II antagonist/Thiazide

Losartan (potassium) 50mg, hydrochlorothiazide 12.5mg. Yellow oval film-ctd tab. marked 717. 28, €21.56.

[INDICATION] Hypertension; not usually appropriate for initial therapy.

[ADULT] Initially 1 daily, increasing to max. 2 daily if necessary.

[CHILD] Not recommended.

Contra Hepatic impairment, severe renal impairment, anuria. Pregnancy, lactation.

SP-Warning Renal impairment, renal artery stenosis, haemodynamically significant obstructive valvular disease, cardiomyopathy. SLE, gout. Monitor serum electrolytes.

Drug-Int K⁺ sparing diuretics, K⁺ suppl. or salts, barbiturates, narcotics, alcohol, antidiabetic agents, cholestyramine, colestipol, corticosteroids, adrenaline, tubocurarine, lithium, NSAIDs (indomethacin), rifampicin, fluconazole.

Ad-Reaction Dizziness, orthostatic effects, rash, angioedema, headache, GI upset, diarrhoea, chest infections.

Contra

Contraindications. Conditions where the product should not be given. Hypersensitivity to a drug (**and/or excipients**) or its class is assumed to be a contraindication in all entries.

SP-Warning

Special precautions. Conditions where special attention is required, or tests are to be performed.

Drug-Int

Drug interactions. Drugs which may affect, or be affected by the product if prescribed together.

Ad-Reaction

Adverse drug reactions. Most frequently reported side effects, with those that are serious but less common.

This monograph is a guide to prescribing information. It is not a substitute for the Summary of Product Characteristics (SmPC).

Figure 2-2 Sample Extract from MIMS

Raloxifene

ATC Code: SERMs (G03XC01).

Sport: Prohibited. **Driving:** Unlikely to impair.

Dose: Adult, Elderly: Oral with or without food. 1 tab daily.

Renal Impairment: Mild/moderate, caution. Severe, contraindicated.

Hepatic Impairment: Including cholestasis, contraindicated.

CI: Active (or history of) VTE (including DVT, pulmonary embolism, retinal vein thrombosis), unexplained uterine bleeding. Signs or symptoms of endometrial cancer (inadequate data).

Interactions: Effect of Other Drugs on Raloxifene: Co-Admin Not Recommended: Systemic oestrogens. *Reduced Absorption:* Colestyramine, other anion exchange resins.

Effect of Raloxifene on Other Drugs: Warfarin, other coumarin derivatives: *Monitor prothrombin time.*

SP: Increased VTE risk (illness, prolonged immobilisation, discontinue immediately; restart only when full mobility resumed). Uterine bleeding (investigate, especially endometrial atrophy, benign endometrial polyps). Metabolism primarily in liver (monitor serum bilirubin, gamma-glutamyl transferase, alkaline phosphatase, ALT, AST). Increased triglycerides (especially with history of oral oestrogen-induced hypertriglyceridaemia); monitor. Only for use for osteoporosis treatment and prevention after breast cancer treatment, including adjuvant therapy, completed. Not effective for reducing vasodilatation (hot flushes) or other menopausal symptoms associated with oestrogen deficiency.

Pregnancy, Lactation: Pregnancy, contraindicated. Lactation, not recommended.

ADR: Vascular (vasodilatation; VTE including DVT, pulmonary embolism, retinal vein thrombosis, superficial vein thrombophlebitis), musculoskeletal (leg cramps), general (flu-like syndrome, peripheral oedema).

Notes: See Class Effects 11.6.2 Other Drugs Affecting Bone Metabolism.

• Evista 60mg (Daiichi Sankyo)

RxB. PCRS. Price, 28, €27.94. 84, €83.83.

F/C tablet, raloxifene HCl. Elliptical white. Marked 4165. Lactose.

Figure 2-3 Sample Extract from the Irish Formulary

ispersible tablets...	
Summary of Pro	
SPC	Abilify tablets, orodispersible tablets, oral solution

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8. MARKETING AUTHORISATION NUMBER(S)
9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
10. DATE OF REVISION OF THE TEXT

Figure 2-4 Table of Contents - Medicines On Line

2.4 Medication Mismanagement

In recent years, reports on medication mismanagement and in particular ADEs have been published. With medication usage on the increase, the complex nature of the medicine data and the access to that data, there are increasing concerns about medication mismanagement.

The Institute of Medicine (IOM) report "*To Err is Human*" stated that 'Healthcare was not as safe as it should be' (eds Kohn et al., 2000 p.26). Exploring the reasons for this, the report used data from literature and concluded that patients can suffer an ADE as a result of medication mismanagement rather than as an outcome of the patient's condition. The IOM report cites Leape et al. (Kohn et al., 2000 p. 35) who concluded that 10% of all adverse events were related to ADEs. Kohn et al. summarised further findings of a study conducted by Lesar et al. on the preventable errors, see Table 2-1.

Preventable factors associated with errors	%
Drug Therapy Knowledge	30%
Knowledge of Patient Factors that affect Drug Therapy	29.2%
Calculations, decimal points, or unit and rate expression factors	17.7%
Nomenclature – incorrect drug name, dosage form or abbreviations	13.4%

Table 2-1 Preventable Factors associated with ADEs (Kohn et al., 2000 p. 37)

Kohn et al. surmise that errors in prescribing are often preventable. They cite many more reports on inappropriate preventable prescribing and the outcomes of that prescribing (2000 p. 38-39).

In the UK, the Audit Commission (2001 p. 19) in seminal report "*A Spoonful of Sugar*" indicated that '10.8 per cent of patients on medical wards experienced' an ADE. Of these, '46 per cent were judged to be preventable' and '12 per cent of adverse drug events were related to medication use'.

In Ireland, the Commission on Patient Safety and Quality Assurance (2008 p.147-182) acknowledges the extent of ADEs in Irish healthcare. Their analysis points to the milieu which can give rise to ADEs and the need for mandatory ADE drug reporting. The Commission refers to other national and international reports and expresses concerns about medication reconciliation:

...having a complete and accurate list of each patient's current medications from all sources at all points of contact and verifying and reconciling the medications to reduce error (p. 182).

The extent of medication error in Ireland can be estimated using reports prepared by the Clinical Indemnity Scheme. This is a scheme to insure the Irish State against losses arising from clinical error including ADE. In the period, 1st January, 2004 to the 31st December 2010, there were 35,510 reported ADEs (Kirke et al., 2011). These are analysed in detail in Table 2-2 (Clinical Indemnity Scheme, 2007, 2008, 2009, 2010).

Incident Type	2007	2008	2009	2010
Total number of incidents	N=5436	n=6,785	N=8251	N=6,882
Incorrect Dosage	1153	1569	1410	1245
Missed medication	844	1006	1394	1037
Medication incorrect/not reconciled			1032	-
Incorrect Medication	696	818	663	737
Incorrect Directions/Labelling	226	562	361	273
Incorrect Rate	226	241	250	-
Incorrect Frequency	152	178	229	-
Adv/Allergic Reaction to Known allergen	97	113	216	-
Incorrect Patient	198	176	183	-
Incorrect Time	129	136	151	-
Non Compliance with policy			141	-

Signature missing	71	143	134	-
Inappropriate self-medication	153	171	129	-
Duplicate Therapy		5	127	-
Incorrect Route	89	113	120	-
Incorrect Storage	80	1	107	-
Adverse/Allergic reaction to unknown allergen	71	88	100	-
Others				2999

Table 2-2 Summary of Incidents (Ireland)

From 2007 to 2010, the cause of each event is categorised and the number of events is reported by category. The yearly total of all events “N” heads each column. In 2010, 3000 incidents categorised as “others”, which would question the data collection and analysis process. When the above report is compared with the report in section 2.2.1 on the usage of medications, it can be deduced that there is a relationship between increasing usage and ADEs.

2.4.1 The Factors affecting Prescribing

The research in this section looked at the human side of prescribing. The presumption is that clinicians make a diagnosis and then prescribe the appropriate medication. However, diverse factors can influence the decision process of the clinician when selecting a medication. Factors such as the patient’s age, administration routes and dosage possibilities, the patient’s own allergies, the choices from different drug manufacturers, and how they might interact with other drugs and medicines influence the outcome. Unless appropriate care is taken, the interaction between patient attributes, other drugs and substances the patient is using and how it is administered can lead to ADEs. Buetow et al. aptly describe prescribing as a ‘science and art’ of getting the balance right between conflicting human factors (1997 p. 264).

2.4.2 Strategies to Improve Medication Safety

Medication mismanagement is a patient safety issue. This has prompted countries such as the US, UK, Australia and New Zealand to react and investigate how the problem should be remedied.

In the US, the IOM identified a number of strategies to prevent ADEs (Kohn et al., 2000 p. 183 -185). These strategies were crosschecked by the IOM with recommendations made by other health institutions. The IOM identified Computerised Physician Order Entry (CPOE) and recommended its implementation (P. 191-192). CPOE is a term used to describe medication orders or e-Prescribing but also includes orders for other clinical services such as pathology and radiology tests (Goundrey-Smith, 2008 p. 4).

However, the IOM (2001 p. 153) pointed to other strategies such as Clinical Decision Support (CDS). CDS when implemented with e-Prescribing, aids the clinician select the medication and when linked to the patient's record and medication history checks for potential ADE's. The CDS checks the dosage levels, allergens, patient's condition and previous drug history. If the clinician makes an error an alert is displayed. These benefits can only be realised when there is a link to a 'comprehensive patient specific clinical information with a medication knowledge database'.

In the UK, the Audit Commission also supports e-Prescribing and CDS other studies and stated that:

..electronic prescribing reduces medicine errors significantly by providing timely, legible information. One study concluded that improved information systems could contribute to the prevention of 78 per cent of transcription errors leading to adverse medicine events. Computerised systems containing rules to prevent incorrect or inappropriate prescribing have also reduced the incidence of errors and increased the appropriateness of medicine (2001 p. 25).

In Ireland, the Commission on Patient Safety and Quality Assurance cited an EU report on ICT in Healthcare (European Commission 2007) which recommended a switch from paper based records to electronic patient records

and to use ICT as a tool to improve patient safety. The Commission specifically recommends patient ICT for patient prescribing:

The effective use of quality based information systems, modern communications technology and effective use of health information has the potential to make a major contribution to improve patient safety ...reducing errors in drug prescribing by flagging allergies and contradictions and in the dispensing and administration of medications (2008 p 186-187).

2.4.3 Conclusion

In summary, reducing ADEs will improve patient safety. Medication management using e-Prescribing is a recommended solution that can bring about this improvement. However, the IOM makes the important point that the real benefit will only be achieved when e-Prescribing is part of an overall integrated solution which includes the patient's clinical data and information about medicines and drugs. These in turn will enable CDS. Having a medicines and drugs reference catalogue to facilitate CDS and recording patient data is an absolute necessity.

2.5 E-Prescribing

2.5.1 E-Prescribing overview

Goundrey-Smith states that a common definition for the term e-Prescribing does not exist (2008 p. 3). There are differences between the US and the UK. In the US, CPOE has a broader meaning. However, this author agrees with Goundrey-Smith's definition, which is also the NHS definition:

.....the utilisation of electronic systems to facilitate and enhance the communication of a prescription or medicine order, aiding the choice, administration and supply of a medicine through knowledge and decision support and providing a robust audit trail for the entire medicines use process (National Health Service, 2007).

Knowledge and decision support are the key words in above definition. For e-Prescribing to be fully effective, different types of knowledge are required from different databases. Goundrey-Smith illustrates the architecture for an e-Prescribing system in Figure 2-5

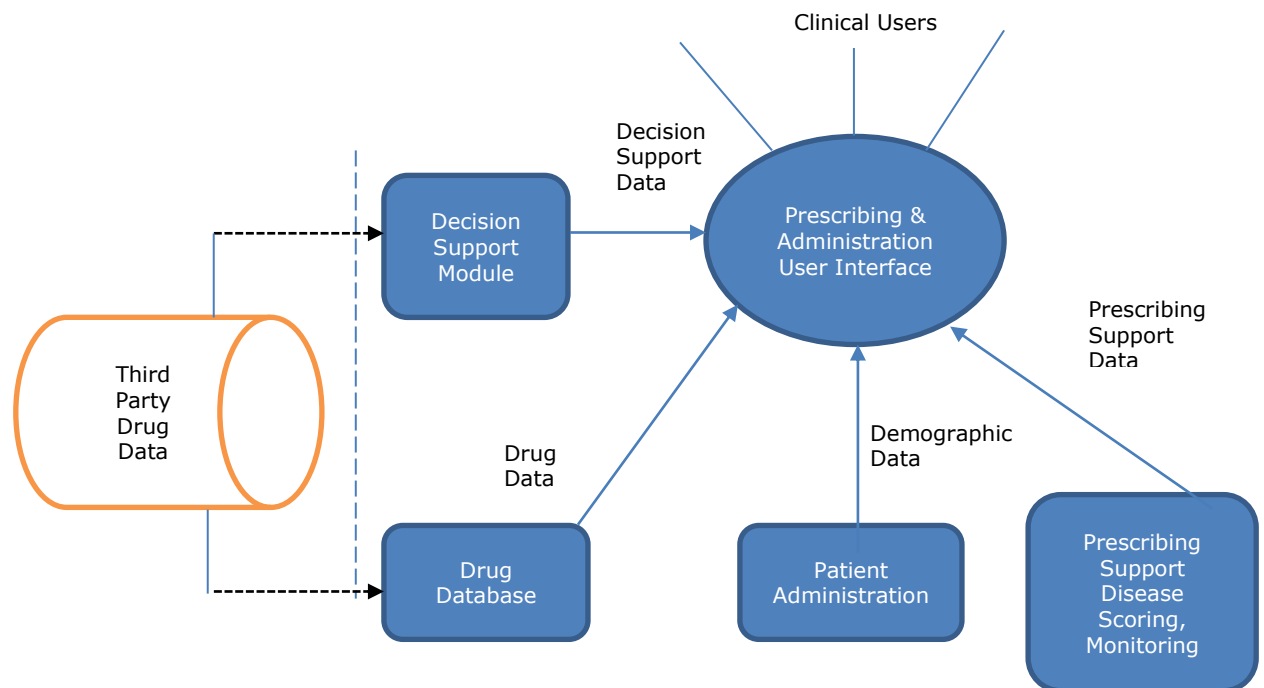


Figure 2-5 e-Prescribing Data Architecture (Goundrey-Smith, 2008 p. 78)

The patient's personal demographic and medication data is the first database. A disease database is needed for reporting purposes. Decision support rules support the alerts to warn the clinician, e.g., for contraindications, drug interactions, overdosing or potential allergic reactions by the patient are written to another database. The final database is the medicines and drugs data with contains the basic medicines and drug dataset the ingredient, the form, the strength and the route of administration.

Goundrey-Smith discusses the future of e-Prescribing in an interconnected environment (Goundrey-Smith, 2008 p. 135-137). He argues that e-Prescribing systems do not operate in isolation; they are part of a connected network of different applications. In a hospital, the e-Prescribing system may be connected to the hospital pharmacy, the patient administration system and

possibly, to a medical device that automatically administers the medication to the patient. Likewise, in primary care, e-Prescribing is part of a General Practice Management Software (GPMS) which will contain applications such as the patient's record. It may in turn be linked to a network to allow the transmission of prescriptions and patient data to the pharmacy. How information is exchanged between these applications, either within a hospital or remotely in primary care, will impact the design of the data models used by these applications.

2.5.2 Drug Information and Drug Databases

As shown above, e-Prescribing requires data about medicines and drugs. Information about medicines and drugs is complex. As discussed in section 2.3.1 clinicians have traditionally used handbooks for the information. Software solution providers, commercial organisations and other professional organisations seized the opportunity to develop proprietary drug databases. They all essentially contain the same information as the published handbooks. Goundrey-Smith lists a number of the significant databases, but describes them as referential and unsuitable for e-Prescribing (2008 p. 83-84). Goundrey-Smith argues that they are designed to be searched and viewed manually. The data format is free text and unstructured. The data are not coded in a manner that enables the open exchange of information with other applications. As a result they are a barrier to interoperability between applications. Prescription data cannot be exchanged seamlessly between the prescribing system in the surgery and another solution provider's dispensing system in the pharmacy without some form of intervention.

2.5.3 Conclusion

The analysis above highlights that a medicines and drugs catalogue must satisfy a number of requirements. It must be suitable for processing information within applications, but at the same time support the exchange of information between applications. This raises the following questions. What is the data model for a medicines and drugs data? With a number of solution

providers offering a drug file the next question is who should supply the drug file or the medicines and drugs data?

These questions will be explored in the case studies to determine the answers in other countries and to point to a possible solution for Ireland.

2.6 Clinical Knowledge Representation

Initial investigations by the author revealed that clinical knowledge representation is being transformed by terminology standards and this includes medicines and drug data. The Systemised Nomenclature for Medicine for Clinical Terms (SNOMED CT) is maintained by the International Health Terminology Standards Development Organisation (IHTSDO) and has been adopted by a number of countries (US, UK, Australia, and New Zealand). It is probably the most significant clinical terminology used today. IHTSDO has added the necessary structures to support medicines and drugs. The next section provides a background to clinical terminologies and how medicines and drugs are integrated as part of that clinical terminology data model.

2.6.1 Clinical Terminology Solutions

Clinical knowledge representation dates back to the 16th century. Chute states that classifications for health began with The London Bills of Mortality which classified 60 different causes of death (Chute, 1998). Since then many other forms of knowledge representation have come, gone and are now forgotten, while others have persisted.

The literature review reveals debates about the use of terminologies. Issues debated included the legacies of older solutions and multiple implementations of different terminologies. Spackman et al. (1997 p. 641-642) appealed for a single reference terminology that hospitals could use for all clinical applications. Chute argued about the unhelpful nature of competing terminologies:

...what we see and do for patients in a modern electronic medium is compromised for lack of a formal, fully specifiable description (1998 p. 68).

The question was raised about what applications should the terminologies support? Chute argues that the main functions of a terminology are for reimbursement, clinical information, patient health records and analysis purposes. He highlights the need 'for common and consistent systems for describing patient findings, diagnoses and interventions' (Chute, 1998 p. 71-72).

The above discussion highlights the desire that a terminology solution should be holistic and satisfy many clinical requirements. One of these requirements is a terminology for medicines and drugs to support the patient's medication record and e-Prescribing.

2.6.2 Drug Data and Medical Vocabularies

Lau and Lam further the case for Drug Information Databases to be treated similarly as clinical terminologies (Lau and Lam, 1999 p 97-101) arguing that there is a large audience for drug information. Applications such as longitudinal patient records, CDS, clinical trials, market analysis and cost control are dependent on a common language for medicine and drug data. Reviewing the then commercially available drug databases using Cimino's Desiderata which set out rules for terminology databases (see Appendix 1 for more detail on the Desiderata), they conclude that the existing databases complied with the Desiderata but they were primarily focused on pharmacy systems and not on e-Prescribing. They left the question open on whether or not medicines and drug databases would evolve into a terminology to support e-Prescribing.

2.6.3 SNOMED CT and Medicines

SNOMED CT has its origins in the US. The Standard Nomenclature of Diseases and Operations (SNDO) was developed by the New York Academy of Medicine.

In a reminisce paper, Chute states that SNOMED introduced a multi-axial structure which allowed codes in one axis, e.g. anatomy to reference another axis e.g. pathophysiology (2000 p. 299). In 1979 SNOMED was launched. Van Bemmelen et al. defines a nomenclature (terminology) as:

..a system that assigns codes to medical concepts and allows for the combination of these concepts (Bemmel et al., 1997 p. 585-586).

SNOMED enabled a clinical language to be constructed using phrases or concepts to describe a medical event or situation. It created a common language to represent clinical knowledge.

SNOMED CT has evolved and now includes many different clinical related axes or hierarchies. In respect of medicines and drugs, two important axes have been added. They are referred to in the SNOMED CT User Guide as the Substance and the Pharmaceutical/biologic Product hierarchies (IHTSDO, 2010 p. 60-63).

The substance hierarchy is used to record the chemical constituents of the drug. This data is related to adverse reactions, toxicity and poisoning data and it is used in prescribing. The Substance axis is used by the Pharmaceutical/Biologic hierarchy which is multi-layered for different use cases, specifically the use cases are 'e-Prescribing, CDS and formulary management' (p. 60). How the two hierarchies are combined in data model is shown in Figure 2-6 and Table 2-3 below. Figure 2-6 illustrates the hierarchical relationships between the concepts using the "Is A" directional relationship. Table 2-3 shows the data is detailed for a product, "Activase 10mg powder and solvent for injection solution vial (US Drug Extension)". Both the figure and the table illustrate the relationship between the global representation and the local representation of the data. (IHTSDO, 2010 p. 61-63). The figure also illustrates how a local representation of a medicines product is catered for in the hierarchy.

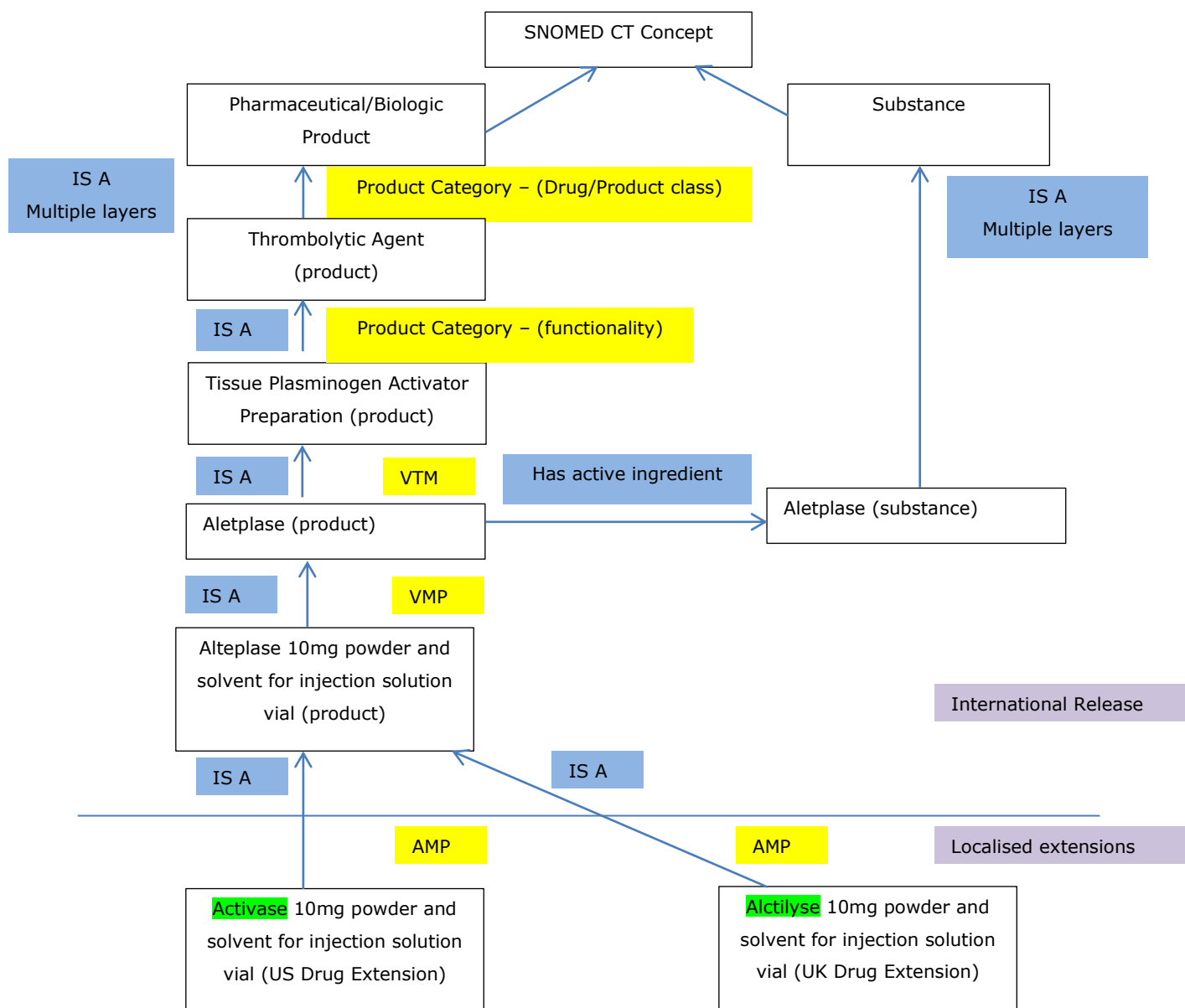


Figure 2-6 SNOMED Substance/Pharmaceutical/Biologic Data Model (p. 63)

Hierarchy	Name	Code	Level	Example
Pharmaceutical Biologic	Product Category-Drug/Product Class		Global Release	Thrombolytic agent (used to breakdown blood clots)
Pharmaceutical Biologic	Product Category-Functionality		Global Release	Tissue plasminogen Activator(breaks down the plasminogen to fibrinogen and fibrin)
Pharmaceutical Biologic Substance	Virtual Therapeutic Moiety	VTM	Global Release	Alteplase (is a recombinant substance produced by genetic engineering)
Pharmaceutical Biologic	Virtual Therapeutic Product	VMP	Global Release	Alteplase 10mg powder and solvent for injection solution vial (product name, strength, dose, form)
Pharmaceutical Biologic	Actual Medicinal Product	AMP	Local Release or extensions	Local description Activase10mg powder and solvent for injection solution vial

Table 2-3 Example using SNOMED Hierarchies for Medicines and Drugs

2.6.4 Other International Classification Systems

The author researched a number of other international classification schemes to determine if there was any direct relationship with a medicines and drugs reference catalogue.

Each pharmaceutical substance or active ingredient requires a unique name that is identifiable and does not infringe on trademarks. This name identifies the substance to the clinician. In 1953, WHO developed a naming convention called the International Non-Proprietary Name (INN) or generic name to identify substances. This was to avoid confusion and infringement on trademark names. The permitted names have to be 'distinctive in spelling, sound and should not be liable to confusion with other names' (Kopp-Kubel,

1995 p. 276). The names are constructed according to a set of guidelines laid down by an expert committee. A semantic structure is used based on abbreviations, stems, chemical names and groupings (Kopp-Kubel, 1995 p. 275-279). The use of the INN is now widespread. However, some of the substances may still retain their older name forms. It was noted that sometimes there are problems with how drugs are named when there is more than one substance involved and this can give rise to confusion (Goundrey-Smith, 2008 p. 87). This arises because the drug does not have an agreed approved name based on the combination.

The Anatomical Therapeutic Classification (ATC) was investigated and there are some references to indicate that there may be a link between ATC and SNOMED CT in the future (National E-Health Transition Authority, 2009a p. 2). However, this was not explored further in this study.

The third major coding system is the International Classifications of Diseases (ICD). There are two versions in use, ICD-9 and ICD-10. Goundrey-Smith analyses the usefulness of ICD-10 in terms of e-Prescribing. ICD-10 is used for 'coding diseases and diagnosis and would be a point of reference for decision support, where contraindications/precautions and drug-disease checks are performed' (Goundrey-Smith, 2008 p. 79). There may, in the future, be closer links between SNOMED CT and ICD when ICD-11 is released (Shorbaji, 2010). However, this was not explored further in this study.

2.6.5 Conclusion

SNOMED CT has gained significant momentum as a holistic international standard for clinical terminology. It is also the only terminology with a global presence that includes medicines and drugs. SNOMED CT includes the basic concepts for substances and Pharmaceutical/Biologic products. However, adopting SNOMED CT requires localisation if full integration between the local medicines and drugs reference catalogue and the other SNOMED CT hierarchies is required. This implies that the local medicines and drugs reference catalogue will need to be structured according to the SNOMED CT standards and rules.

2.7 The Role of Regulatory Agencies

2.7.1 Introduction

Governments establish Regulatory Authorities (RA) to manage the approval of medicines and drugs. In Ireland the RA is the Irish Medicines Board (IMB). They approve the use of medicines by issuing a Market Authorisation (MA) and they may attach particular local conditions to their use.

2.7.2 Market Authorisation

MA is to ensure the 'quality, safety and efficacy' of medicines (Irish Medicines Board, 2010). When a company makes an application seeking registration for a new product a document called the Summary of Product Characteristics (SmPC) template is required with the application (Irish Medicines Board, 2011). The template is submitted along with a folder of other documents called the Common Technical Documentation (CTD). The template is published as the final SmPC by the RA along with the MA number. The final/approved SmPC contains all the data necessary for the handbooks and web-sites as well as the specific requirements for the market see Section 2.3.1. Goundrey-Smith states that the SmPC is the definitive source of information (Goundrey-Smith, 2008 p. 84). Although, it is designed specifically for use by the RA, it contains a wealth of unstructured information, i.e., free text and not coded, for clinicians and for database providers.

A link between the SmPC and the terminologies described in Section 2.6.3 is made using the pharmacopoeial designation of the active ingredient and the ingredient in the local product.

2.7.3 Conclusion

The RAs have an important role as information providers. The RA is the authoritative source of data and the MA number is a key identifier for the medicine and drug product. Databases are available where the SmPC information can be accessed.

The medicines and drug terminologies are not directly relevant for the regulatory process nor are they a requirement for MA. However, the data supplied by the RA must be linked to the medicines and drugs reference catalogue. These linkages are based on data model described in section 2.6.3.

2.8 State of the Art – Ireland Initiatives in E-Prescribing

2.8.1 Introduction

There are a number of initiatives in Ireland which are relative to e-Prescribing and a medicines and drugs reference catalogue.

O'Grady highlighted that the Irish Pharmacy Union (IPU) have a drug file (O'Grady, 2010 p. 58). The author interviewed IPU representatives to assess the current status of the file.

The General Practice IT (GPIT) group of the Irish College of General Practitioners (ICGP) have an on-going development programme to 'promote computerisation in general practice' using GPMS which contains an e-Prescribing application (Irish College of General Practitioners, 2011).

The HSE established a Medication Safety Programme in 2010 (2011). Some of its objectives relate to a medicines and drug reference catalogue. These include standards for prescription forms and administration records, medication reconciliation, and medication management including electronic prescribing. The programme is an initiative under the Patient Safety First programme (2010).

2.8.2 Irish Pharmaceutical Union

The IPU drug file has been in use for over 20 years. It is maintained by the IPU and is distributed monthly to pharmacies, GPs, hospitals, solution providers, prisons, army and wholesalers. A subset is issued to GPs with the 'front of shop' items sold in pharmacies removed. Its core design is for pharmacy use but additional capability has been added for other purposes.

The IPU file contains information for both licensed and unlicensed medicines. There are 15,000 pharmaceutical products listed, 8,000 of which are part of the PCRS scheme. More than 2,000 products listed are unlicensed. The IPU uses the SmPC as the information source for the file. If the products are unlicensed, other sources such as the European Medicines Agency (2011), the British National Formulary (BNF) (2011) or Martindale (Martindale, 2011) are used.

Reimbursement information data is sourced from the PCRS. The IPU drug file will need to be updated in the near future to cater for planned changes to the reimbursement scheme.

The file also contains information on other products that are sold over the counter (OTC) in the pharmacy. Therefore it is not only used for medicines and drugs.

A core functionality of the IPU file is to enable pharmacists to reorder medicines and drugs from the wholesalers. The pharmacy application gathers the data about the items dispensed by the pharmacist. The data is used to prepare a replenishment order and once approved transmits the order electronically to the selected wholesaler. The IPU drug file has some limited functionality to support CDS. It provides some specific alerts, which can be looked up by the clinician. The IPU referred the author to other databases such as First DataBank (First DataBank, 2011) and Infomed (Infomed, 2011) which have more advanced CDS capabilities. The IPU stated that their file is not integrated by either application.

The ATC classification is available in the file, as is the INN naming for the medicine and drug.

It is the IPU's opinion that there are significant differences between the medicines available in the UK and Ireland. This is largely due to the different regulatory practices between the two countries. When asked if they thought that a medicines and drugs file from the UK could be adapted for Ireland they stated that the volume of work required would be very large. It is their view

that a file was already available in the IPU and that it might be used as the basis for a catalogue.

The IPU provided the file format for review. The file can potentially contain all of the following data price information, identifiers for bar codes and internal coding, GMS code (PCRS), internal classification for sorting purposes, trade name, poison classification, pack contents, names of suppliers and manufacturers, authorisation number, generic drug name, ingredients, warning codes for labels, dental filter, counselling codes, strength and form, ingredients, and point of sale data. It was stated that not all the data fields are populated for each record.

2.8.3 Development of GP Practice Management IT Systems

In Ireland, as part of the development of a health informatics infrastructure, a working group, the GPIT Group under the auspices of the ICGP, has published a Certification Protocol for GPMS (National GPIT Group, 2011). This protocol has evolved over ten years with releases in 1999, 2003 and 2008. A new release is planned in 2011/2012. It is expected that all GPMS applications sold in Ireland will conform and be certified to this protocol.

The GPMS certification protocol lists e-Prescribing including, dispensing (when connected to the pharmacy system) and administering medicines (where administration takes place within the GP's practice, e.g., immunisations) and CDS (p. 34-36). A drugs database is required to support these requirements. As a result the solution provider is required to have the licenses for the drug database to be used in the application. The intent is to allow the solution providers have the option to use a third party drugs database if they are not developing their own. This database will need to be updated at least quarterly.

The GPMS must be able to record the medications and immunisations, dose and route for each patient and report an allergic reaction. The GPMS, for each prescribing event, should be able to generate a prescription to enable correct dispensing and administering to the patient. Finally, the GPMS should be able to transmit an electronic prescription to the pharmacy.

2.8.4 Medication Safety Programme

E-Prescribing has been highlighted as one of the patient safety objectives. No progress has been reported on e-Prescribing.

2.8.5 Conclusion

The IPU has successfully managed to support a large part of the healthcare community in Ireland with the monthly issue of their drug file. By inference, a large number of the solution providers and IT departments have already built applications based on the contents of the file. The file is the most complete list of medicines and drugs in Ireland by virtue of the fact that it includes both licensed and unlicensed medicines. However, the file is not a pure medicines and drugs file as it contains additional OTC products. It reflects the requirements of a retail pharmacy business. However, it does include regulatory, reimbursement and supply chain.

There are plans to upgrade the IPU drug file for the new reference pricing scheme but there are no plans to build any more clinical related functionality, e.g., SNOMED or CDS.

The functionality requested by GPIT for the GPMS is impressive. However, there are a number of potential problems that should be addressed in relation to the drug databases. If each of the accredited GPMS solutions and the pharmacy solutions use different drug databases, there are potential interoperability issues. It will not be possible to exchange medicines and drug data directly between the GPMS, the pharmacy and the medication record. It will be necessary to have a mediation process to transpose one drug data file used by the GP to another used by the Pharmacist. Likewise to create a summary of care record which stores the patients medication history, each of the solutions need to represent drug data in a consistent way so that the information can follow the patient. The GPMS requires the capability to import and use a reference catalogue for medicines and drugs. It is partly for these

reasons that other countries developed medicines and drug reference catalogues.

3 Research Methodology

3.1 Introduction

This chapter explores the research methodology options and explains the rationale for the choice of a case study qualitative methodology to answer the research question:

Using the knowledge and experience of other countries worldwide, why and how might Ireland develop and implement a medicines and drugs reference catalogue to support e-Prescribing?

The selected methodology is described and a test is developed from literature to ensure that the methodology employed satisfies academic rigour.

3.2 Qualitative versus Quantitative

The choice of quantitative versus qualitative was driven by the possibility of answering the question using statistics and the lack of sufficient samples to satisfy the statistical rigour. In addition the scope of the research poses a challenge on the range of statistics that would need to be reported. Therefore qualitative techniques were investigated.

The author's research on the qualitative versus quantitative argument was brought to a conclusion by Onwuegbuzie and Leech (Onwuegbuzie and Leech, 2005 p.270-272). They argued that the debate has been divisive between the "Qs". There are merits and overlaps in the processes and instruments used for each type of methodology. They concluded that the aim should be pragmatic research rather than a mutually exclusive debate. Bansal and Corle state that pragmatic research is 'the coming of age for qualitative research' (2011 p.233-237). The author agrees with the pragmatic approach. Qualitative analysis is appropriate methodology to use to answer this research question.

3.3 Qualitative Analysis – Case Study

A variety of qualitative techniques were researched. Case study was selected as the most appropriate methodology to apply (Brender and Carlander, 2006). Potentially other methods might have been selected such as Interpretative Research. Further research was then undertaken to understand the case study methodology and how a case study methodology could satisfy academic rigour.

Reviewing case study literature, the most cited author was Robert Yin. Yin has been referenced by many scholars in a multitude of journals and has published various editions of the seminal book *Case Study Research* (Yin, 2009). Yin's work was the main reference for the protocols used in this study.

3.4 Definition of a Case Study

Yin's definition of a case study is broken into two statements (2009):

A case study is an empirical enquiry that

- investigates a contemporary phenomenon in depth and within its real life context, especially when
- the boundaries between the phenomenon and context are not clearly evident (p. 18).

This is supplemented by:

The case study inquiry

- copes with the technically distinctive situation in there will be many more variables of interest than data points and as one result
- relies on multiple sources of evidence, with data needing to converge in a triangulating fashion, and as another result
- benefits from prior development of theoretical propositions to guide data collection and analysis (p. 18).

The author believes that the topic is contemporary and is real life. There are no boundaries, but there are a large number of variables with multiple sources of evidence.

Yin argues that the case study methodology is the preferred methodology for the how and why questions (2009 p.2) and sets out the methodology described in this Chapter. Eisenhardt (1989 p.534) based on the previous editions of Yin's work, states that:

....he has defined case study research as a research strategy, developed a topology, of case study designs, and described replication logic which is essential to multiple case analysis.

And importantly from the point of view of academic rigour:

...stresses bringing the concerns of validity and reliability in experimental research design to the design of case study research.

Yin's case study model was developed in the field of social sciences and most examples used refer to government agencies, schools and other social contexts. However, Benbasat et al. argued that case study methodology is also relevant for Information Systems research (1987 p.370). Their reasoning is that case studies are an examination of a natural setting and secondly, the researcher can answer questions such as "how" and "why". Finally, this research methodology can be used in areas where there is little previous research. These reasons were subsequently expanded sixteen years later by Dubé and Paré (2003 p. 597). Dubé and Paré in their paper explored twenty two criteria under the headings Research Design, Data Collection and Data Analysis. The author considered these when designing this research but favoured the pragmatic approach. Dubé and Paré are critical of the way the methodology was applied and the lack of rigour in a selection of information systems based case studies (2003 p. 620-626). This author took measures to prevent such an assessment of this study.

3.5 Limitations of Case Studies

For every argument in favour of case study methodology, there are arguments against. Darke et al. summarised the weaknesses of case study research as 'difficulties in generalizing results' and the 'subjectivity of data collection and analysis' (1998 p. 287). As Yin acknowledges the limitations of case study methods, he states the lack of rigour is the greatest concern (2009). The following section sets out how this author addressed the lack of rigour for this study.

3.6 Remedies to the Limitations

Gibbert et al. published a summary framework for rigour in case study (2008 p. 1467). It was adopted by Yin (2009 p. 41) and Eisenhardt (2008 p.1466). The author selected Yin's approach.

	Construct Validity	Internal Validity	External Validity	Reliability
	Suggested Remedies			
(Yin, 2009)	Use multiple sources of evidence. Establish a chain of evidence. Have key informants review the draft.	Pattern matching. Explanation building. Address rival explanations. Use logic models.	Use replication logic in multiple case studies. Use theory in single case studies.	Use a case study protocol. Develop a case study database.

Table 3-1 Framework Case Study methodological rigour

Yin's approach is illustrated in Table 3-1. There are four points of validation and each point of validation has a selection of remedies that may be applied.

The author explains in the next section how these remedies were applied to this particular study.

3.7 The Yin Tests

The author set out to apply a methodology that would address each of the validation points using one or more of the remedies. Based on this the author proposes that the remedies selected are sufficient to support a claim that a rigorous case studies had been documented.

Construct Validity – this focuses on how well the issues relating to the research question have been examined.

Based on the suggested remedies the author decided that multiple case studies, each case study being a unit of analysis, were appropriate. The units of analysis were the US, the UK (England and Wales), Australia and New Zealand.

The chain of evidence is constructed using multiple sources of data for each unit of analysis; accessing literature and documentation such as specifications and reports, performing interviews (Australia, UK and New Zealand) and where possible, accessing the actual data contained in the medicines and drugs catalogues. All documents accessed are cited in the References List. For each unit of analysis, the author explains why the catalogue was developed, the selection of the data model and how the medicines and drugs reference catalogue is managed and published.

Internal Validity – The focus here is to see how each of the case studies is converging in order to draw conclusions. Do the events in each case study have a pattern or are there variables causing contrasting differences arising in the case studies?

Each case study is reported individually under the same headings using the available sources of data. Using the headings as a guide, a cross case analysis is performed using theme and pattern matching.

External Validity – focuses on whether or not the phenomena are applicable in more than one setting and if it can be generalised. Is there replication across each unit of analysis? As this was a multiple case study, theory was not applied.

As noted, four case studies were used in the research and the author checked for replication across all the case studies. This helps analytical generalisation using the empirical data.

The units of analyses were selected based on the literature review which identified those countries that were most active in developing their medicines and drugs reference catalogues.

Reliability – focuses on removing the potential for random error. Was the process systematic in answering the research question?

3.8 Case Study Protocol

As recommend in Yin's framework, a case study protocol was devised and a case study database created. The case study protocol was framed at the very early stages and presented to fellow students. The first step was to build a mind map and then to assimilate as much data as possible and build the database.

The second step was to document the State of the Art in a chronological order with a view to understanding the evolution of the topic, the technology and how the technology was applied in each unit of analysis. Ultimately the author's aim was to understand the milieu in each unit of analysis. Using replication logic generalisations could be drawn for the conclusions.

The third step was to use the information to develop a questionnaire to aid a semi-structured interview process with experts from three of the units of analysis, the UK, Australia and New Zealand. Semi-structured interviews were used to allow for the possibility of changing direction should the responses

require more exploration. The purpose of the interviews was to triangulate the data derived from the case study database.

The fourth step was to prepare for the interviews. A questionnaire was prepared based on the State of the Art. After review, the questionnaire was revised for circulation to the interviewees. The questions were kept at a high level with hints to the detail needed. In keeping with the ethical requirements of Trinity College, and the respect that should be accorded to the interviewees, the Introductory Papers, Questionnaire, Information Paper and Informed Consent form were sent to the interviewees in advance of the interviews (Yin, 2009 p. 73,74). A copy of the interview documentation is attached in Appendix 2.

The fifth step was the interview process. The interviews were recorded, one was conducted face to face and the second was conducted using conference call facilities. The records were transcribed for analysis after the interviews.

3.9 Conclusions

The author would contend that case study methodology constructed for this study would satisfy an academic rigour based on the validity checks detailed above. A systematic approach was adopted and the analysis techniques were based on recommended structures researched from literature.

The next Chapter reports on each unit of analysis using the methodology and protocols discussed above.

4 Case Studies

4.1 Introduction

In this Chapter, four case studies are analysed using the case study methodology outlined in Chapter 3. Four English speaking countries were selected, the US, the UK, Australia and New Zealand as the units of analysis. These countries each had advanced the development and implementation of a medicines and drugs reference catalogue, but not all were at the same level of implementation.

The analysis explores the different factors that affected the selection, development and delivery of a catalogue. Each case study is analysed under the following subheadings. These subheadings were used to guide the research and to facilitate cross case analysis.

- Background and Context
- Clinical Terminology Development and Adoption
- Medicines and Drugs Catalogue Implementation
- Organisation and Management
- Interview (where possible)
- Conclusions

In the first section, Background and Context, the current status and the catalysts for a medicines and drugs catalogue are discussed.

The Clinical Terminology section explores the adoption clinical terminologies as they impact the local medicine and drugs reference catalogue.

The section Medicines and Drugs Reference Catalogue discusses the catalogue itself with a particular emphasis on the data model used.

Under the heading Organisation and Management, the responsibility for the catalogue is outlined as well as how the catalogue is published to the users.

Experts from each country (except the US) were interviewed and the data from the interviews were triangulated with the evidence gathered by research to provide insight on the developments in each country.

Each case study is also analysed independently and the conclusions are recorded at the end of each case study. The cross case analysis is presented as findings in Chapter 5 with form the basis of the recommendations in Chapter 6.

4.2 Case Study 1 - The United States

4.2.1 Background and Context

A key driver for a medicines and drugs catalogue in the US was the Medicare Prescription Drug, Improvement and Modernisation Act (MMA) of 2003, which introduced substantial changes to prescription drug coverage starting in 2006. Bell and Freidman had referred to the previously reported benefits that e-Prescribing had delivered in hospital care which saw a reduction of 86% in medical errors and an 88% compliance (up from 14%) with the national formulary (Bell and Friedman, 2005 p. 1159). The Act sought to replicate these benefits by accelerating e-Prescribing implementation in ambulatory care. A central requirement to achieving this implementation was the greater use of standards to create better interoperability between IT applications such as e-Prescribing and dispensing. It was also proposed that with some advanced functionality, e-Prescribing would be seen as the first steps to the widespread adoption of an EHR (Bell and Friedman, 2005 p. 1159-1160). Bell and Freidman reported that the National Centre for Vital and Health Statistics (NCVHS) performed an inventory of the available standards to support e-Prescribing under the Act. One standard required was to enable the exchange data about clinical drugs, their 'codes (identifiers), dosage and patient instructions' (Exhibit 1 p. 1161). They noted that RxNorm, launched in 2004, was a potential solution to address the requirements of the Act.

RxNorm was launched in November 2004 as a standard terminology for medicines and drugs in the US. In April 2011, Nelson et al. published a review of RxNorm and its progress since 2005. They reported that there are 11 local terminologies using it as the reference catalogue with more 61,000 non-obsolete medicines and drug entries as of January 2011. User adoption as a result had increased significantly. The US Health Information Technical Standards Panel recommended RxNorm for recording Medication Brand Name, Medication Clinical Drug Name and Allergy/Adverse Event Product (Nelson et al., 2011 p 441-442).

Nelson et al. highlight that RxNorm has been associated with a variety of medication related projects. RxNav, RxTerms, MyMedicationList and MyRxPAD

are at different stages of development and implementation. RxNav is a browser application that allows a user lookup a medication on the Internet. This has been supplemented by an application that allows the user to download data about the medications. RxNav supports 27,000 medications and drugs. MyMedicationList helps patients create and maintain their personal medication records. RxTerms has been developed specifically for prescription writing. It transposes the names and concepts into meaningful terms that can be printed on the prescription. MyRxPad is a prototype application that interfaces with the MyMedicationList application. The prescriber can record the medications and export it to the MyMedicationList application using a standard Continuity of Care document format (2011 p. 447). They reported that e-Prescribing Subset of RxNorm to support e-Prescribing applications, including CDS, is still work in progress. RxNorm is used as a platform to develop applications but it will not be a full knowledge database with formulary and pricing information (2011 p. 447).

4.2.2 US Clinical Terminology

In the US, there are many different and diverse healthcare applications supported by many different classifications and terminologies. The U.S. National Library of Medicine (USNLM) developed a Metathesaurus and included these terminologies, but has not selected a single terminology for national use. The USNLM provides a pointer to the different concepts which can be used to specify a meaning for some healthcare concept (US National Library of Medicines, 2006).

4.2.3 US RxNorm

RxNorm was developed to address the diversity of information about medicines and drugs stored in the ULM. It is terminology based using concepts for drug identification and a relationship model between concepts. (Liu et al., 2005 p. 17). The building blocks for the terminology are described by Nelson et al. as Semantic Normal Forms (SNF). For example, a clinical drug has both an ingredient and strength. Each are represented as separate SNFs. When combined together they create a concept called the Semantic Clinical Drug

Component (SCDC). SCDC is what is called a term type (TTY). By using a set of SNFs many different types of concepts and TTYs can be built (Nelson et al., 2002 p. 557-561). The TTYs for RxNorm are listed in Table 4-1. The RxNorm data model then uses a set of relationships to link the concepts (TTY) into a relationship model illustrated in Figure 4-1 below

- constitutes/consists_of
- contains/contained_in
- dose_form_of/has_dose_form
- form_of/has_form
- ingredient_of/has_ingredient
- isa/inverse_isa
- precise_ingredient_of/has_precise_ingredient
- tradename_of/has_tradename

TTY	Concept Name	Definition	Example
IN	Ingredient	A compound or moiety that gives the drug its distinctive clinical properties. The preferred name is usually the USAN name.	Fluoxetine,
PIN	Precise Ingredient	A specified form of the ingredients that may or may not be clinically active. The most precise ingredients are salt and isomer forms	Fluoxetine Hydrochloride
MIN	Multiple Ingredients	Two or more ingredients created from SCDF.	Fluoxetine/Olanzapine
DF	Dose Form	Based on a defined list.	Topical Solution, Oral Tablet
SCDC	Semantic Clinical Drug Component	Ingredient plus strength—see section on Rules and Conventions, below, for units of measurement and for rules pertaining to the calculation of strengths	Fluoxetine 4 MG/ML
SCDF	Semantic Clinical Drug Form	Ingredient plus dose form.	Fluoxetine Oral Solution
SCD	Semantic Clinical Drug	Ingredient plus strength and dose form.	Fluoxetine 4 MG/ML Oral Solution
BN	Brand Name	A proprietary name for a family of products containing a specific active ingredient.	Prozac
SBDC	Semantic Branded Drug Component	Branded ingredient plus strength.	Fluoxetine 4 MG/ML [Prozac]
SBDF	Semantic Branded Drug Form	Branded ingredient plus dose form.	Fluoxetine Oral Solution [Prozac]
SBD	Semantic Branded Drug	Ingredient, strength and dose form plus brand name.	Fluoxetine 4 MG/ML Oral Solution [Prozac]
SY	Synonym of another TTY	Given for clarity	Prozac 4MG/ML Oral solution
BPCCK	Brand Name Pack	Branded Drug Delivery Device	12 (Ethinyl Estradiol 0.035 MG / Norethindrone 0.5 MG Oral Tablet) / 9 (Ethinyl Estradiol 0.035 MG / Norethindrone 1 MG Oral Tablet) / 7 (Inert Ingredients 1 MG Oral Tablet)} Pack [Leena 28 Day]
GPCK	Generic Pack	Generic Drug Delivery Device	11 (varenicline 0.5 MG Oral Tablet)/42 (varenicline 1 MG Oral Tablet) Pack

Where TTY is the Term Type Identifier

BPCCK and GPCK were added to address multi-individually prescribed components

Table 4-1 RxNorm Term Types (Liu et al., 2005 p 18-19)

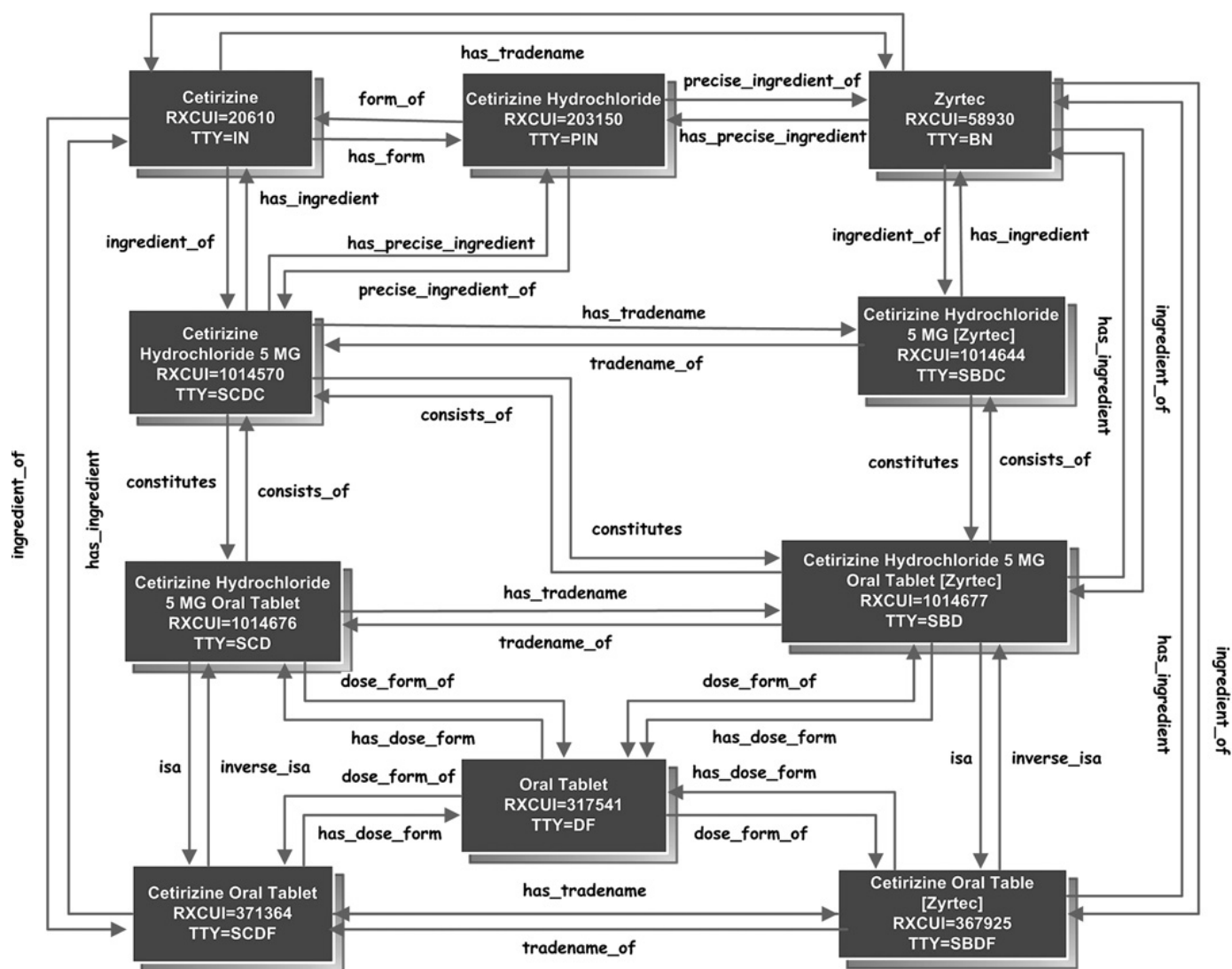


Figure 4-1 RxNorm Data and Relationship Model (Liu et al., 2005 p. 18)

The first step to build the terminology was to use the Veterans Administration National Drug File (VANDF) to upload the data and to test the model (Nelson et al., 2002 p. 557). Since then RxNorm has included many more drug files needed in the US. In 2011, the source drug files providing drug data are listed in Table 4-2. As more standalone drug files are added the coverage of RxNorm increases and also the mapping between the different terminologies.

Source Name Abbreviation	Source Name
GS	Gold Standard Alchemy
MDDDB	Medi-Span Master Drug Data Base
MMSL	Multum MediSource Lexicon
MMX	Micromedex RED BOOK
MSH	Medical Subject Headings (MeSH)
MTHFDA	FDA National Drug Code Directory
MTHSPL	FDA Structured Product Labels
NDDF	First DataBank
NDDF Plus	Source Vocabulary
NDFRT	Veterans Health Administration National Drug File - Reference Terminology
SNOMEDCT	SNOMED Clinical Terms (drug information)
VANDF	Veterans Health Administration National Drug File

Table 4-2 Source Drug File for RxNorm (US National Library of Medicine, 2011)

As each new medicine and drug is added to the database, unique concept identifiers RXCUI are assigned to the concepts. The details are manually edited by terminologists, verified and are then registered in the database. Despite implementing quality assurance processes, there is still much scope for error. Bodenreider and Peters used a graph based approach to audit a selection of drugs in RxNorm (Bodenreider and Peters, 2009). Whilst the paper was written to prove their auditing methodology, it did highlight the need for vigilance as a number of quality issues were identified such as missing nodes, missing links and extraneous links.

RxNorm is described by Fung et al. as a Consolidated Health Informatics solution (2008 p. 227). Applications based on RxNorm, such as RxTerms, can deliver immediate benefits such as unambiguous prescriptions (Nelson et al., 2011 p 445). Fung et al. tested both RxNorm and RxTerms and compared prescription writing speed using the two solutions. They reported that it was much more efficient to use RxTerms due to the decrease in the number of keystrokes required to limit the list of displayed items. The test covered 99% of all branded and generic medicines. They highlighted some database structural issues relating to packs containing ingredients of different strengths ,e.g., oral contraceptives (Fung et al., 2008 p 230-231).

However, as Nelson et al. point out this is a limited use of RxNorm; the healthcare community is waiting for the more fully functional e-Prescribing subset.

4.2.4 Organization and Management

RxNorm is one of the Terminologies maintained by the US National Library of Medicines.

Both RxNorm and RxTerms can be downloaded directly from the US Library of Medicines Website. RxNorm is completely updated monthly and there are weekly incremental updates.

4.2.5 Conclusion

The US case study identifies some pertinent findings. E-Prescribing has been identified as a government priority and legislation to support the development of e-Prescribing had been enacted. However, a medicines and drugs reference catalogue to support a fully functioning e-Prescribing application has yet to be provided.

There are several possible explanations for this result. One explanation is the complexity of the data model. It has many levels and the fact that an e-Prescribing subset is now required suggests that there were difficulties with the requirements for e-Prescribing either in creating the file or with the solution provider software capability. Another possible explanation is the advanced CDS rules. Solution providers may already provide solutions that were adequate, fit for purpose and are not willing to update their applications. Finally, the findings suggest this, attention was focused on integrating other proprietary drug terminologies to build a complete drugs file for the US.

What has been delivered is a catalogue that supports writing prescriptions. This may be explained by the culturally diverse nature of the population in the US. Other applications are in development such as the personal medications application. These are potentially part of an overall solution, but they are not the complete solution. They are creating different ways of storing and transferring

information between the clinician and the patient. These are incremental steps forward in the direction of the summary care record and medication reconciliation.

The findings show that there is the level of complexity of the US data model and as a result the need for subsets to support specific applications. It is important to focus on the intended outcomes as there is a danger of over-engineering the solution. The second contribution is that there is a value in having a complete drug file when starting to develop a medicines and drugs catalogue.

The findings also show that the US application falls short of delivering a fully functional e-Prescribing solution that includes clinical decision support.

4.3 Case Study 2 – United Kingdom

4.3.1 Background and Context

The National Health Service (NHS) was established to provide care to all UK citizens irrespective of their ability to pay. The NHS is responsible for both primary care and secondary care (National Health Service, 2008). It is also responsible for all developments in healthcare including ICT.

The Directory of Medicines and Drugs (dm+d) is the medicine and drugs reference catalogue developed and used by the NHS. It lists over 99.9% of all medicines and appliances used in primary care (Pharmaceutical Services Negotiating Committee, 2011) and is a core enabler for the NHS's Electronic Prescription Service (EPS) which is being implemented in phases (National Health Service, 2011). The dm+d file provides the identifiers and descriptions for the medicines in the electronic prescription messages.

4.3.2 UK Clinical Terminology

A GP, James Read developed a terminology commonly called Read Codes and this was selected by the NHS as their first Clinical Terminology. In 1999, it was decided to merge SNOMED RT with Read CT V3. An alliance was formed between the NHS and the College of American Pathologists to ensure that this happened (Stearns et al., 2001 p. 662,663). Bringing these two terminologies together contributed to the further development of SNOMED as an International Standard and provided the basis for further developments of SNOMED (Wang et al., 2002 p. 849). The NHS decided that SNOMED CT should become the Clinical Terminology standard for the UK. On 17th August 2011 the NHS announced that SNOMED CT was now a Foundation Standard and at the same time it was announced that the Read Code V2 and Read CT V3 are to be retired (UK Terminology Centre, 2011).

4.3.3 UK Directory of Medicines and Drugs

Work on the UK medicines and drugs reference catalogue (dm+d), started in 1998 after an information strategy highlighted that a standard way to describe medicines did not exist (Burns, 1998 p.49). The report recommended that a project under the UK Clinical Products Reference Sources (UKCPRS) should be established to develop a solution. Work started in 1999 with the objective that UKCPRS deliver a 'standard electronic vocabulary (terminology) and identifiers for clinical products (medicines, appliances and personal medical devices)'. The deliverable was to support the exchange of data between prescribing and dispensing systems, and to provide knowledge for clinical decision support. The first release of a primary care directory was in 2000 (National Health Service, 2010 p. 9).

Progress on dm+d adoption was initially slow due to differences between the stakeholders. The "A Spoonful of Sugar" report which highlighted cost and safety issues in the NHS, added impetus (Audit Commission UK, 2001 p. 60). The report refocused efforts to deliver e-Prescribing solutions and recommended standardised coding for medicines.

Using storyboards, a data model was developed to describe the data requirements for medicines (National Health Service, 2010 p. 11). The data model is made up of five subsections or concepts. These concepts are called Virtual Therapeutic Moiety (VTM), Virtual Medicinal Product (VMP), Actual Medicinal Product (AMP), Virtual Medicinal Product Pack (VMPP) and Actual Medicinal Product Pack (AMPP). The concepts, their definitions and examples are summarised in Table 4-3 (National Health Service, 2010 p. 16,17). The relationships between the concepts are shown in Figure 4-2. Associated with each concept is data set which suits particular needs and users (National Health Service, 2010 p. 18).

Concepts	Definition	Example
Virtual Therapeutic Moiety (VTM)	'A Virtual Therapeutic Moiety (VTM) is the abstract representation of the substance(s), formulated as a medicinal product, intended by an authorising health care professional for use in the treatment of the patient.'	Atenolol
Virtual Medicinal Product (VMP)	'A Virtual Medicinal Product (VMP) is an abstract concept representing the properties of one or more clinically equivalent Actual Medicinal Products, where clinical is defined as relating to the course of a disease.'	Atenolol 100 mg tablets
Actual Medicinal Product (AMP)	'An Actual Medicinal Product (AMP) is a single dose unit of a finished dose form (unless the product is presented as a continuous dosage form), attributable to an identified supplier that contains a specified amount of an ingredient substance.'	Atenolol 100 mg tablets (Alpharma)
Actual Medicinal Product Pack (AMPP)	'An Actual Medicinal Product Pack (AMPP) is the packaged product that is supplied for direct patient use or from which AMPs are supplied for direct patient use. It may contain multiple components each of which may or may not be an AMPP in their own right.'	Atenolol 100 mg tablets (Alpharma) x 28 tablet
Virtual Medicinal Product Pack (VMPP)	'A Virtual Medicinal Product Pack (VMPP) is an abstract concept representing the properties of one or more quantitatively equivalent AMPPs.'	Atenolol 100 mg tablets x 28 tablet

Table 4-3 Concepts in dm+d

The definition and examples Table 4-3 were extracted from the UK Data Model (National Health Service, 2010 p. 16,17)

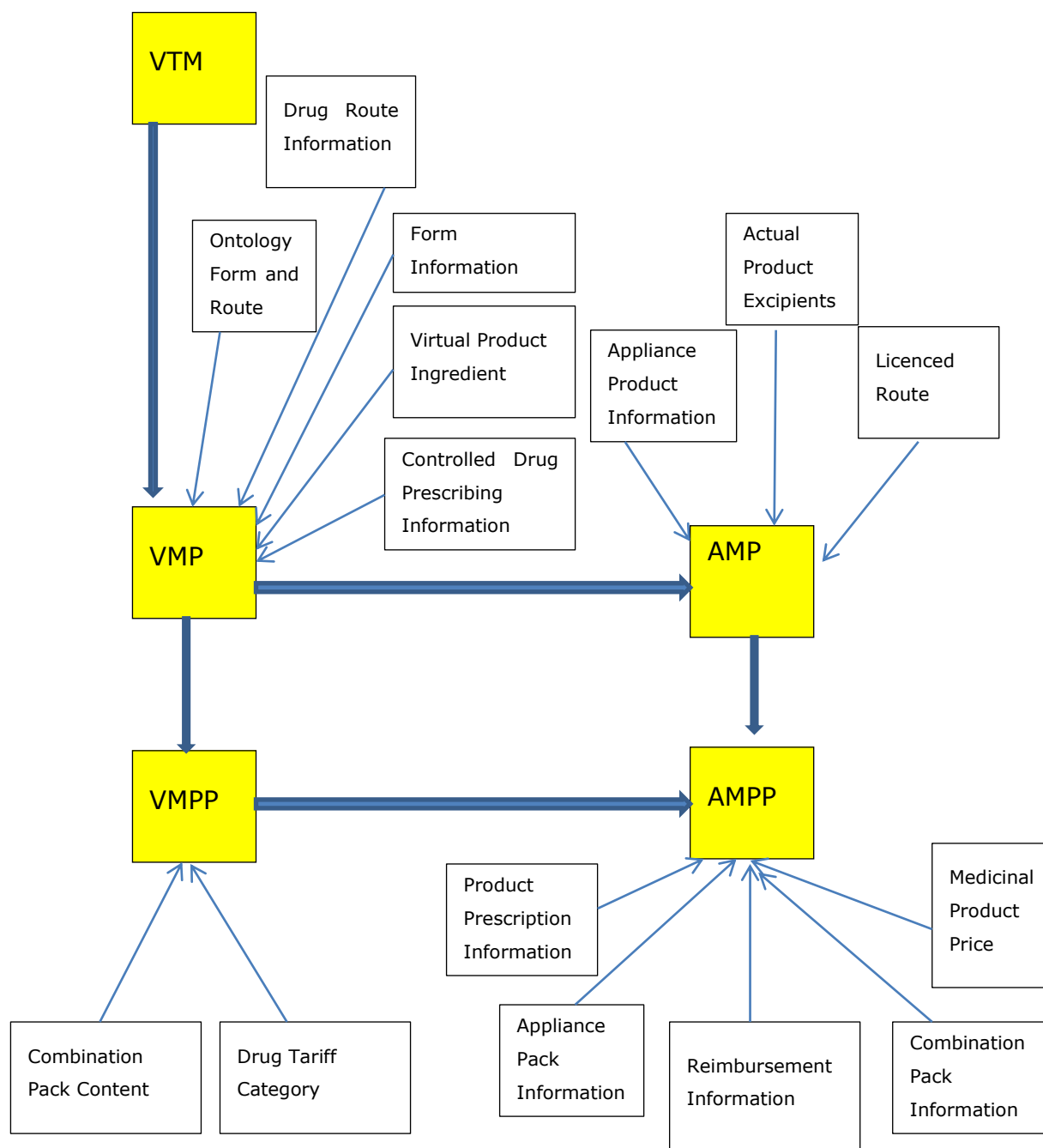


Figure 4-2 dm+d Data Model and Associated data (National Health Service, 2010 p. 18)

As there were many stakeholders/users, each with different dataset requirements, it was agreed that a catalogue containing everybody's data requirements was not possible. Conversely, a minimum data set would be of little benefit to any user. A compromise was to adopt a common basic data set that addressed everybody's needs. Additional data would be provided by other means. The dataset selected was based on the following data categories see Table 4-4.

Data Category	Data Set
Identification	Product Identification Medicinal Product names Pack Information Medicinal Product Suppliers Supplier Identity
Clinical	Ingredient or Substances Route of Administration Strength Units of Weight, Volume and Strength Form Excipients (additives)
Regulatory	Legal Status
Reimbursement	Reimbursement Data Price

Table 4-4 Data Requirements for dm+d

The dm+d does not include mapping to other coding and identification schemes such as Global Standard 1 (GS1) for supply chain purposes. However, bonus files are published which contain the link between the data model and GS1. However, recent communication from the NHS Business Services Authority indicated the intention to include the GS1 Global Trade Item Number (GTIN) in the dm+d file (Jepson, 2011).

When in 2009, the NHS decided to adopt SNOMED CT solution providers requested that the dm+d should be included in the SNOMED CT structure. This was because the dm+d and SNOMED data formats were not compatible and made it difficult to integrate both solutions in the same application (Goulding, 2009 p. 5,6). A second version of the dm+d was developed using the SNOMED CT architecture of concept identifiers, fully specified names, preferred names, relationships and other SNOMED CT requirements. SNOMED CT identifiers were assigned to the concepts in the dm+d model. Where SNOMED CT concepts and identifiers were not available, new UK concepts and identifiers were developed and assigned. This new dm+d was called the SNOMED CT UK Drug extension. The UK now supports two medicines and drugs reference catalogues. The UK SNOMED CT UK Drug extension has some data differences compared to the dm+d. For example, it excludes reimbursement data.

4.3.4 Organisation and Management

The responsibility for the maintenance and development of the UK directory has changed a number of times since 1999. The NHS recognised that terminology standards needed to be managed in a controlled way. The UK Terminology Centre was established, with the responsibility for developing, coordinating, maintaining and distributing all the NHS terminologies; Read Codes, SNOMED CT and dm+d. The UKCPRS were subsumed into the UK Terminology Centre and the Centre reports to the NHS Connecting for Health department, which is part of the Department of Health Informatics Directorate. The centre also partners with NHS Business Service Authority.

The UK Terminology Centre distributes the dm+d and SNOMED CT UK DRUG extension files. Users can register to receive a notification when new releases are available. They can logon to the ftp server and download the files. The dm+d files are published weekly and the SNOMED CT UK Drug extension files every 4 weeks. The author registered as a user and was able to access both sets of files. In the dm+d download there are seven XML files with associated style sheets. In the SNOMED CT UK Drug extension there are over 80 files in a delimited format. The files must be uploaded in a specific order to maintain referential integrity.

Additional files, called bonus files, are available that link to other data such as the BNF, the ATC and the GTIN.

The dm+d can be directly accessed via the Internet.

4.3.5 Interview with UK expert

A telephone interview was conducted with an expert from the UK on the 2nd June 2011. A paraphrased report of the interview is documented in Appendix 3. The interviewee highlighted the origins of UK project was cost management but it was subsumed into a larger project to address patient safety and the e-Health agenda. The dm+d was developed by a committee and implemented as a mediate standard.

The introduction of SNOMED CT complicated the dm+d adoption because there were now two dm+d catalogues to maintain. The interviewee was unequivocal about the limitations of SNOMED and the fact that it is not perfect. Also concern was expressed about the relationship between the responsible agency and the users.

The dm+d is only being used as a mediate standard by the solution providers. They prefer to maintain their drug databases mainly to support CDS. They used the dm+d to support the EPS.

4.3.6 Conclusions

The evidence from the UK highlights a number of relevant points. Firstly, because of the adoption of SNOMED CT, the UK now maintains two versions of the dm+d as a result of not deciding on SNOMED CT earlier. However, it should be noted that it is possible to implement a medicines and drugs reference catalogue without a terminology. However, this case exemplifies the fact that there are consequences should a terminology be adopted in the future, particularly on the solution providers.

Secondly, the dm+d is used in the EPS project as a reference for electronically writing the medication data of an prescription and transmitting the data to the pharmacy. The solution providers still use the legacy drug files to CDS. The application of the dm+d for e-Prescribing is therefore limited. The value proposition for solution providers to use the dm+d as the main drug file is not evident.

Thirdly, engagement with stakeholders is the key to success. The catalogue does not sit in isolation but within a user community. The main stakeholders are the NHS, clinicians including terminologists, the reimbursement agency, regulators and the solution providers. However, the stakeholder community is growing to include the supply chain side with a particular emphasis on dispensing and administering drugs.

Fourthly, the fact that the UK decided on a central agency to manage all terminologies including the dm+d files. This agency reports to two NHS departments IT and business services. There are potential synergies in this. Also, the management of mission critical standards cannot be subcontracted to a third party as there are possible issues of independence, trusted source and risk management that must be considered.

One of the less obvious justifications for a medicines and drugs catalogue is the cost savings from not having to implement local catalogues. The dm+d can be used as a base file which can be imported into a local database without keying in all the entries manually. This saves time and expense, and prevents potential accuracy and quality issues.

The minimal set of data used in the dm+d means that other data must be maintained in other databases. A super database maintaining all of the data in one location does not exist. The dm+d dataset is sufficient to support commonly needed functionalities. However, if other data is required it must be accessed for the other source databases.

In summary, the dm+d is more than just a terminology reference database for medicines and drugs. It links with the reimbursement data (removed in the SNOMED Versions), regulatory data and supply chain. It is a common index database to many other databases. However, at the present time it is underutilised in the UK because full e-Prescribing functionality with CDS is not enabled and as a result not integrated by the solution providers.

4.4 Case Study 3 - Australia

4.4.1 Background and Context

The National E-Health Transition Authority (NEHTA), a non-profit organisation, was established in 2005 by the Australian Federal Government to 'develop better ways of electronically collecting and securely exchanging health information' (National E-Health Transition Authority, 2011a). NEHTA's objectives included improving efficiencies by standardising information on medical products, reforming the procurement process and implementing standardised clinical data formats and terminologies. Due to the diverse and disparate development of healthcare across all the states in Australia there were many proprietary solutions. A standards approach was deemed to be the best option to address and develop interoperable e-Health (National E-Health Transition Authority, 2009b p. 1-2).

Australia took a holistic approach in relation to medicines and drugs. NEHTA focused on the following areas, all of which underpin the country's e-Health strategy:

- Clinical terminology determines the architecture of the medicine and drugs reference catalogue.
- E-Medication management focusing on the application areas and including prescribing, dispensing and the medication record.
- E-procurement which addresses the supply of the medicines and drugs, but also includes clinical related data on medicines.

In 2011, these projects are at various stages of development and implementation. The terminologies have been selected and the Australian Medicines Terminology (AMT) has been established (National E-Health Transition Authority, 2010a). Specifications for e-Medication have been released for pilot testing (National E-Health Transition Authority, 2010b). E-Procurement has launched the National Product Catalogue (NPC) for medicines (National E-Health Transition Authority, 2011b). Another important development has been the decision to develop the Personally Controlled Electronic Healthcare Record (PCEHR) using a national health identifier (Australian Government, 2011).

4.4.2 Australian Clinical Terminologies

The National Clinical Terminology and Information Service (NCTIS) was established by NETHA to develop and maintain terminology standards. The objective of NCTIS is to provide solutions that enable interoperability between healthcare applications. In 2006 NEHTA had recommended to the Australian Health Ministries Advisory Council that SNOMED CT should be the preferred terminology for Australia. The responsibility for its management was assigned to the NCTIS. SNOMED CT AU was developed by the NCTIS to suit the Australia requirements. (National E-Health Transition Authority, 2011c).

4.4.3 Australian Medicines Terminology

Prior to this Australia had numerous dissimilar drug knowledge databases in use by state agencies, federal authorities, healthcare providers and solution providers. The Therapeutic Goods Administration (TGA), Australian Register of Therapeutic Goods (ARTG), Pharmaceutical Benefits Scheme (PBS) and many other local, hospital and solution provider files all had different databases for other purposes. NEHTA set out to establish a standard to be used for medicines. This was to ensure consistency and enable interoperability. This development resulted in the development of the Australian Medicines Terminology (AMT) (National E-Health Transition Authority, 2009a p. 1-2).

The scope of the AMT covers the branded and generic drugs registered and listed with the TGA. It was developed to support prescribing, records, medication review, dispensing, administering and exchanging information. As the key role of the AMT is to link between other databases – PBS, ATC, Society of Hospital Pharmacists of Australia Coding Scheme (SHPA), TGA, ARTG and others, the AMT is a mediate standard (National E-Health Transition Authority, 2009a p. 1-2).

CDS and supply chain information is excluded from the AMT. CDS functionality is embedded in the solution provider applications and the intention is not to replace this. Supply Chain data is supplied by the NPC and which links to the AMT (National E-Health Transition Authority, 2009a p. 2). However, the NPC also provides data for the AMT.

The AMT data model was developed using HL7, the UK dm+d, the Australian Catalogue of Medicines (ACOM) and SNOMED CT. The AMT Model was then mapped to SNOMED CT. Where SNOMED CT did not meet the Australian needs, new concepts were defined, identified, documented and added to a redefined SNOMED CT-AU (National E-Health Transition Authority, 2009a). The data model is illustrated in Figure 4-3 and the concept definitions are detailed in Table 4-5 below.

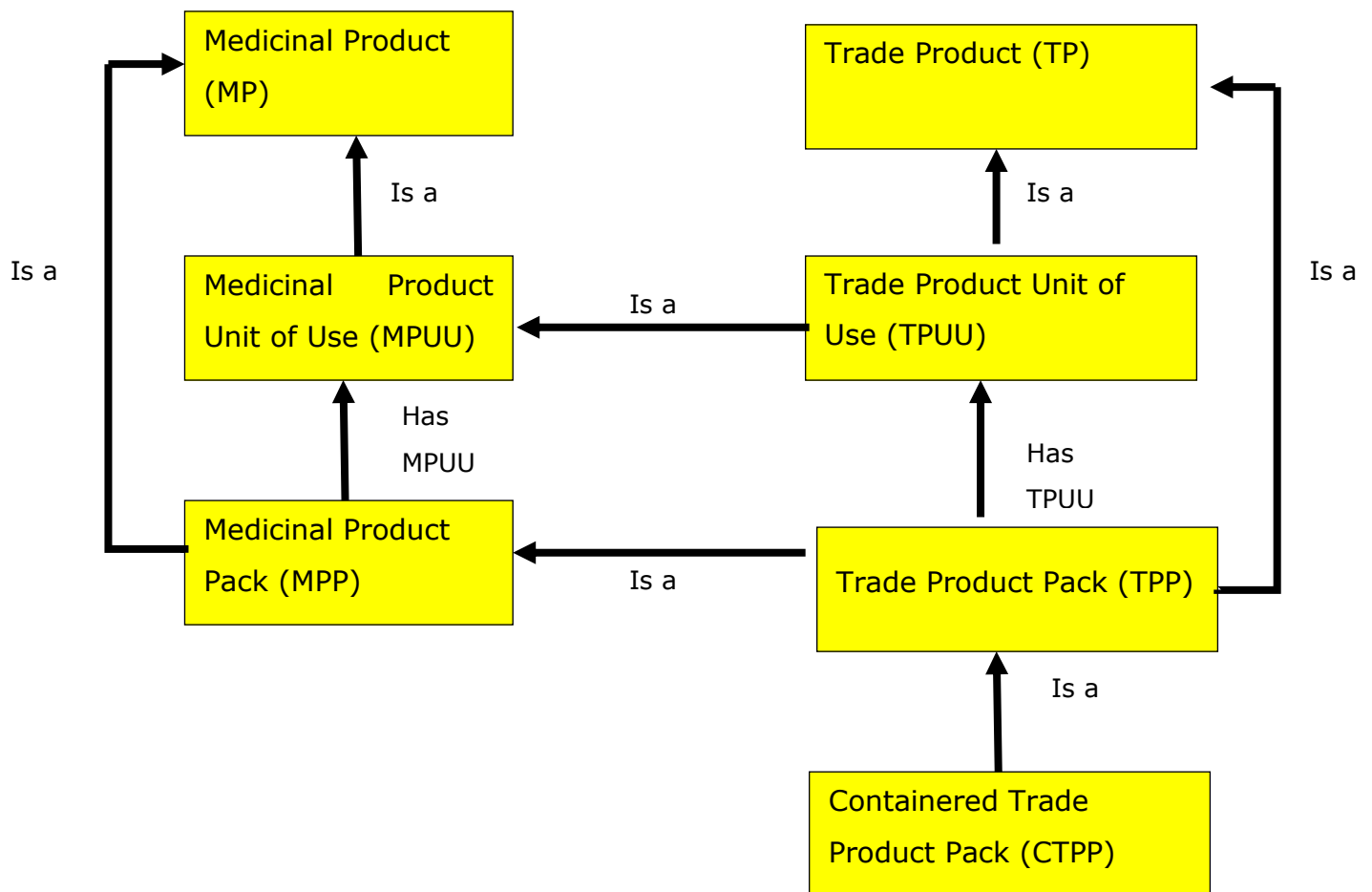


Figure 4-3 AMT Data Model (National E-Health Transition Authority, 2009ap. 21)

The following concepts, definitions and samples in Table 4-5 are extracted from AMT Editorial Rules (National E-Health Transition Authority, 2009a). Page references are provided in brackets ().

Concept	Definition	Example
Medicinal Product MP (p.24)	'A Medicinal Product is the abstract representation of the active ingredient(s) or substance(s) (devoid of strength and form), which when formulated as a medicinal product, is intended for use in treating or preventing disease in human beings.'	Amoxycillin
Medicinal Product Unit of Use MPUU (p.29)	'A Medicinal Product Unit of Use (MPUU) is an abstract concept representing the properties of one or more equivalent Trade Product Units of Use.'	amoxycillin 500 mg capsule
Medicinal Product Pack MPP (P.40)	'A Medicinal Product Pack (MPP) is an abstract concept representing the properties of one or more quantitatively and clinically equivalent Trade Product Packs (TPP).'	amoxycillin 500 mg capsule, 20 capsules
Trade Product TP (P. 50)	'The Trade Product represents the product brand name or the grouping of products into a "family", for either single component products that contain the same base of an active ingredient or components of multi-component products which contain the same combination of bases of the active Ingredients'.	Amoxil
Trade Product Unit of Use TPUU(P. 53)	'A Trade Product Unit of Use TPUU is a single dose unit of a finished dose form.'	Amoxil (amoxycillin (as trihydrate) 500 mg) capsule:hard, 1 capsule
Trade Product Pack TPP (P.66)	'A Trade Product Pack is the packaged product that is supplied for direct patient use.'	Amoxil (amoxycillin (as trihydrate) 500 mg) capsule: hard, 20 capsules
Container TPP (CTTP) (P. 77)	'The Containered Trade Product Pack (CTPP) is the packaged product that is supplied for direct patient use and includes details of the container type.'	Amoxil (amoxycillin (as trihydrate) 500 mg) capsule:hard, 20 capsules, blister pack

Table 4-5 Summary: Concepts in the AMT

Editorial rules defined the data set associated with each of the concepts listed in Table 4-5. The data for some of the attributes is supplied from other databases such as the NPC. The NPC was implemented to support e-Procurement and to provide identifiers for automatic data capture when dispensing and administering a medication (National E-Health Transition Authority, 2008). The NPC has replaced ACOM as the source for other data. The data in this catalogue is maintained by the manufacturer and includes information such as the TGA risk classification and PBS notification as well as information such as route and form.

4.4.4 Organisation and Management

The NCTIS is responsible for developing, maintaining and providing access to the catalogue. NCTIS is part of NEHTA and therefore is a governmental body. The catalogue is provided free of charge to the users.

The AMT is published monthly using a SNOMED structure. The author was not given authority to access the AMT files due to license restrictions.

The NCTIS has also indicated a version migration policy. Two versions of the AMT can co-exist (National E-Health Transition Authority, 2010a). The purpose of this is to support a transitional migration rather than a simultaneous updated.

4.4.5 Interview

A face to face interview was conducted with an expert from Australia on the 26th May 2011. A paraphrased report of the interview is documented in Appendix 5. The interviewee highlighted the scale of the Australian project which is continent wide; the organisational structure was established under a legislative programme, the infrastructure was based on standards specifically the adoption of SNOMED CT and the establishment of a terminology centre and the importance of the AMT was stressed.

The AMT is part of a grand interoperability plan with projects such as e-Prescribing and the PCEHR dependent on it. The Australians worked closely with other likeminded countries to develop their knowledge and expertise and not repeat their mistakes. The AMT was not developed in an instance; it took a number of years to reach its launch date.

The AMT implementation strategy needs the support of the solution providers. The approach by NEHTA is that solution provider must have compliance with NETHA's standard and solution providers must offer interoperable solutions to their customers. Therefore, they have to use the AMT for that purpose.

4.4.6 Conclusion

The overall objectives of patient safety, efficiencies, cost savings, and interoperability are the key drivers in Australia. In the same way that the US had issues on a grand scale, so too had Australia with many states, local government and others having different approaches to healthcare. Clearly, the Australian approach is to cover the entire continent where there are many pre-existing proprietary solutions. In this context the use of legislation to enable change is an important driver and is relevant for the Australian Federal structures. In addition, standards (national and international) were used to develop a common infrastructure. Australia sees benefits in using international standards and NEHTA's role and strategy is as a standards implementing organisation.

NEHTA developed SNOMED CT AU followed by the AMT. The AMT was based on dm+d for the data model and SNOMED CT AU for the terminology. The AMT extends the dm+d model further as it contains many more Australian devised concepts.

The AMT is a core or foundation requirement. If all the other health projects, the PCEHR, e-Prescribing, e-Pharmacy, e-Discharge and e-Referral are to meet their objectives the AMT must be used as each application depends on it. The AMT is a mediate standard must be used by solution providers participating in the projects. Other pre-existing terminologies are not replaced by the AMT.

The AMT is provided free of charge, but there is a mandated for the solution providers to use the AMT. The NPC is complementary to the AMT as a national solution as it is populated with additional relevant medicine and drug information.

Many of the projects are at an early stage of piloting and testing and the results of these activities will not be known for a number of years.

4.5 Case Study 4 - New Zealand

4.5.1 Background and Context

The New Zealand Health Information Standards Organisation (HISO) prepared a report in 2009 that recommended New Zealand should implement or develop a medicines and drugs terminology as part of an e-Pharmacy project (2009 p. 2). E-Pharmacy was the 4th action zone of 12 action zones for health information identified by the HISO (p. 4). In July 2011, the New Zealand Universal List of Medicines (NZULM), which includes the New Zealand Medicines and Drugs Terminology (NZMT) was launched as part of the Safe Medication Management Programme (SMM). The SMM is a programme focused on patient safety and its objectives are to:

...reduce the number of medication errors and adverse drug events in New Zealand, reduce the number of patients who are permanently disabled or die as a result of adverse drug events and to reduce the costs associated with remedial treatment of patient injury caused by adverse drug events (Safe Medication Management, 2009) .

The HISO Report summarised the prescribing issues. It identified that there were many sources of information about medicines which in effect caused confusion and problems. Issues such as unclear descriptions, unreliable matching of codes, lack of information about brand and generic names, and no information about the unit dose level were identified. The report states that these issues were barriers to CDS, accurate medication records, interoperability, governance and the ability to plan healthcare policy (p. 6). It recommended that New Zealand should develop a medicines and drugs terminology.

4.5.2 NZ Clinical Terminology

When IHTSDO was founded in 2007, New Zealand was already a Charter Member, but it was not until 2010 that they finally adopted SNOMED CT as its clinical terminology standard (Health Information Standards Organisation, 2010).

4.5.3 New Zealand Medicines Terminology

The HISO report analysed the pros and cons of the various options for a medicines and drugs catalogue (p. 12-22). After reviewing the other options, i.e., RxNorm and dm+d, the report recommended that New Zealand should adopt and adapt the Australian AMT data model, establish an organisation to develop the terminology, develop editorial software and use the AMT editorial rules, but localised them to suit New Zealand's particular needs. They decided to retain the existing pharmacy codes to support the previous medication history and legacy. Finally, local identifiers should be used until there was full integration with SNOMED CT. Then the local identifiers will be substituted with the approved SNOMED CT identifier.

New Zealand decided to use the Australian AMT data model see Figure 4-4 below and Table 4-5 Summary: Concepts in the AMT on page 62.

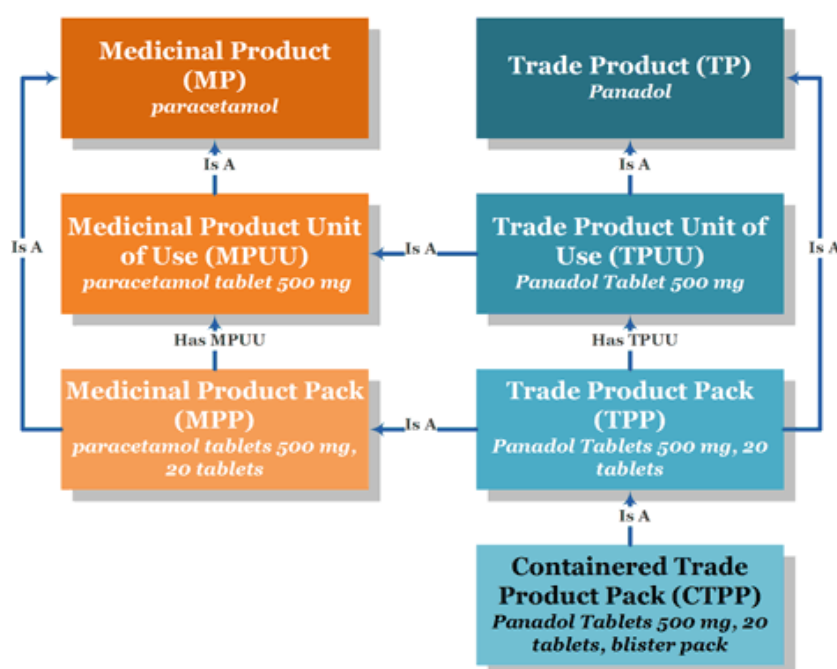


Figure 4-4 NZMT Data Model (New Zealand Universal List of Medicines, 2010a)

The New Zealand Medicines Terminology (NZMT) became part of a larger project which was to develop the New Zealand Universal List of Medicines (NZULM). The NZULM is a relational model linking three other databases. The other databases were operated by the regulator Medsafe, the reimbursement agency PMARMAC and the Pharmacy Guild's product catalogue. These databases were included into

the project and NZULM was the reference database to link them. Key data from each database was included in the NZULM. The structure is represented in Figure 4-5. The NZMT terminology, in addition to being a medicine and drug clinical terminology, is also a reference database to link to other databases. The data in Pharmac and Medsafe are maintained independently by their respective organisations. The logical model is shown in Figure 4-6. It is also planned to link the New Zealand NPC and replace the Pharmacy Guild database. The PHARMAC (ps_package) contains the reimbursement data and Medsafe (ms_package) contains the regulatory status.

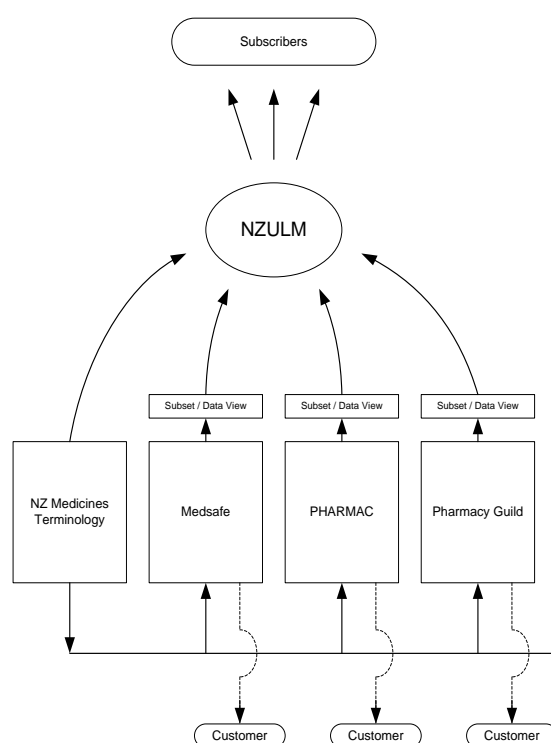


Figure 4-5 NZULM Service Concept (New Zealand Universal List of Medicines, 2011a p. 5)

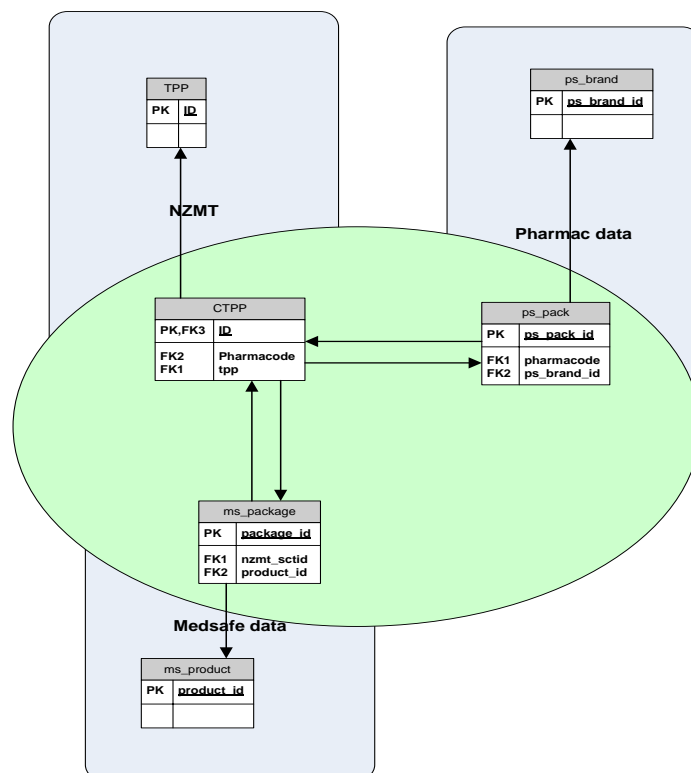


Figure 4-6 NZULM Logical Model (New Zealand Universal List of Medicines, 2011a p. 6)

MP	Medicinal Product Generic substance. Eg: Paracetamol. May refer to a complex product containing multiple substances. Eg: Paracetamol + Codeine.
MPUU	Medicinal Product Unit of Use Generic substance formulation including dose size and dose form. Eg: Paracetamol 50mg Tablet.
MPP	Medicinal Product Pack Generic substance pack size. Generally treated as an Abstract concept. Eg: Paracetamol 50mg Tablet, pack of 20.
TP	Trade Product A branded product. Eg: Panadol Eg: Panadol Night and Day (complex pack)
TPUU	Trade Product Unit of Use A branded product formulation including dose size and dose form. Eg: Panadol 50mg Tablet
TPP	Trade Product Pack A branded product formulation with pack size. Eg: Panadol 50mg Tablet, pack of 20
CTPP	Contained Trade Product Pack A branded product formulation with specified pack size and container. Eg: Panadol 50mg Tablet, pack of 20, Blister Pack

Table 4-6 New Zealand Concepts (New Zealand Universal List of Medicines, 2011a p. 17)

The NZUML does not directly support CDS. The New Zealand Medicines Formulary will provide the CDS data, e.g., indications, contraindications, interactions and prescriber information (New Zealand Universal List of Medicines, 2010a). The NZUML as described above is incomplete and only represents the current status. Following a series of questions to the NZUML representatives the planned structure was provided. This includes formulary, product catalogue and clinical reference information see Figure 4-7.

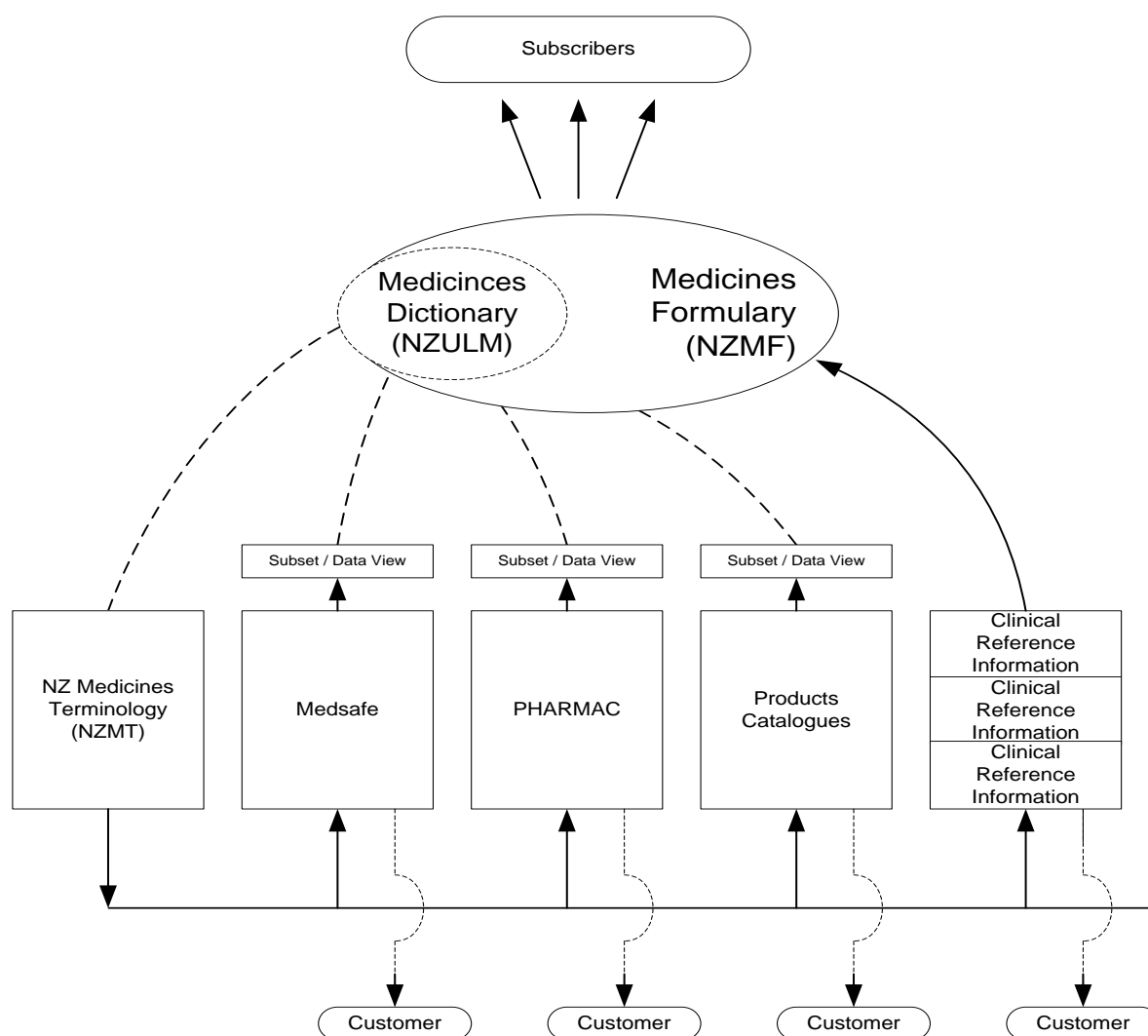


Figure 4-7 NZUML Planned Structure (Hunter, 2011)

At the present time, New Zealand does not have a NPC. However, the website clearly indicates the intention of integrating a NPC as part of the solution. The

catalogue link will be based on the GS1 GTIN as shown in Figure 4-8. It is understood that the Ministry of Health is in the near future to release a statement on the requirements for all pharmaceutical products to have a GTIN.

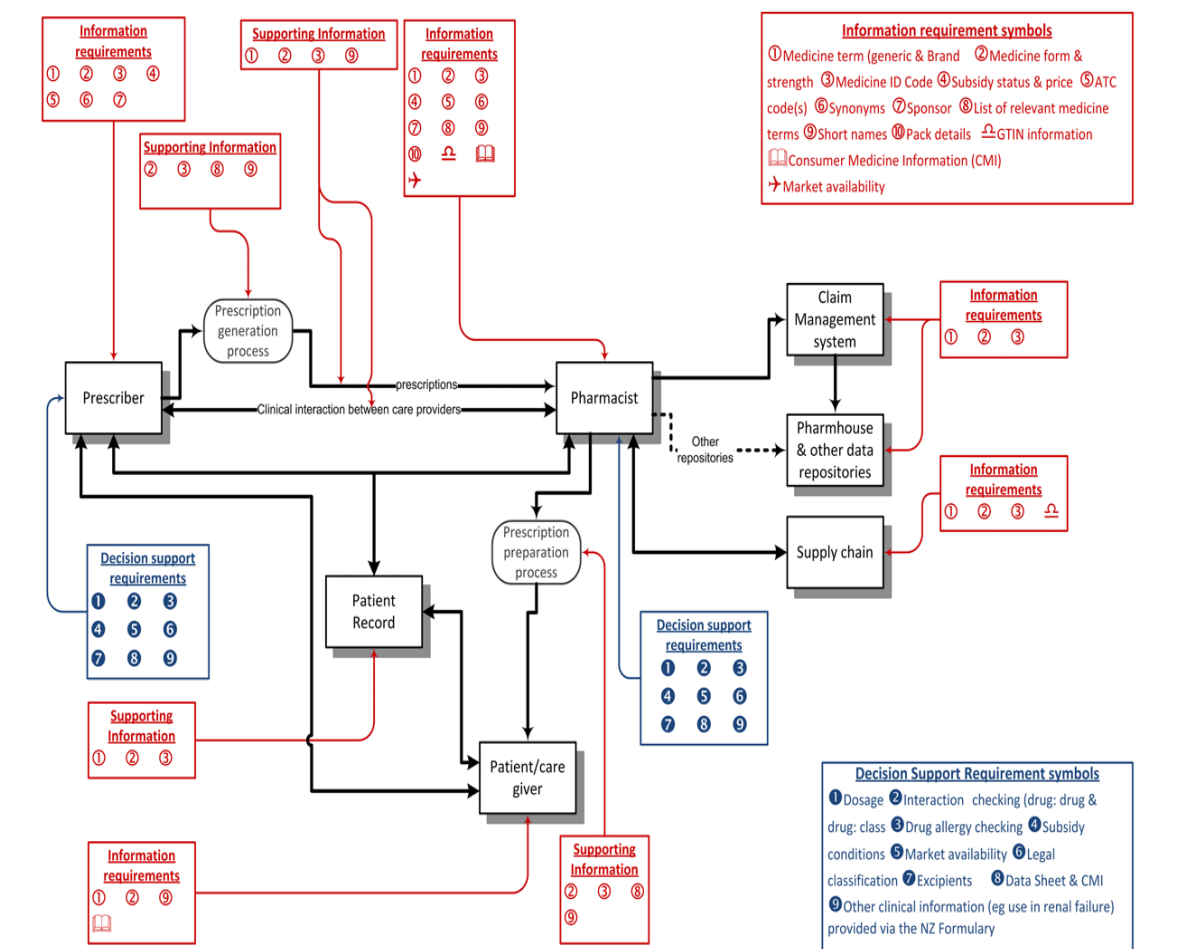


Figure 4-8 NZULM Information Flows (New Zealand Universal List of Medicines, 2011b)

4.5.4 Organisation and Management

The organisation was initially established as a project team to oversee the development of the terminology and the infrastructure. The project has now evolved to become a service provided by the New Zealand Ministry of Health.

A follow up report was prepared which compared the original recommendations to the project deliverables (New Zealand Universal List of Medicines, 2010b p. 8). The distribution of the terminology was the one noted exception. The initial plan was to create a software module that could be hosted by the end user and linked

to the application software. The plan was to maintain and update the database using internet access. This option was cancelled in favour of the solution providers distributing a subset of the data that was needed by their applications. The long term plan is to embed the NZUML as part of the solution providers' respective applications.

The NZULM files are available from the NZULM website. The files are a set of tables exported from a relational database. The NZUML is provided free of charge to all solution providers.

4.5.5 Interview with New Zealand

A email response to the interview questions was received from an technology expert from New Zealand on the 3rd August 2011. A paraphrased report of the interview is documented in Appendix 6. The interviewee stated that New Zealand was driven by the patient safety issue and the NZMT was part a strategy to address the issues. Engagement with community resulted with a decision not to start from scratch but too work closely with Australia, use standards including SNOMED CT, and as a result implement a terminology based solution.

However, the Australian model was not adopted completely and localisation was still required. The interviewee also states the needs to maintain expertise on the project. The implementation of the NZMT is at an early stage but New Zealand are taking a measured approach with the solution providers and starting on a small scale to test and verify the solution. Early experiences raised some questions on conformance to the editorial rules so quality may be an issue. The NZMT is still evolving and usage is expected to drive more requirements.

4.5.6 Conclusions

The study confirms that patient safety and the cost of medicines are primary motivators in New Zealand's healthcare. To address these concerns the New Zealand Government formally acknowledged the problem and established a strategy to deal with the issues and provided the resources for this activity.

Rather than reinvent solutions, the New Zealand strategy is to partner with others to learn and develop solutions based on international recommendations. The results of the study confirm the liaisons with Australia. Although New Zealand had been a charter member of IHTSDO, it was not until they considered the Australian approach that they formally decided to adopt SNOMED CT as their Clinical Terminology. The AMT data model was adopted for the medicines and drugs catalogue.

One unanticipated finding was the development of the NZMT into a NZUML linking with the databases used by the regulator and the reimbursement agencies. This approach varies with Australia, but it suits New Zealand's purposes. Another finding was the development of a relational database for the NZUML and the decision not to use the SNOMED CT physical architecture.

The decision on when to engage with solution providers needs to be timely. If the engagement is too early and the solution is not adequately developed, solution providers will take a negative view due to data inaccuracies.

Another interesting finding is the decision to launch a partially developed solution. A possible explanation for this, is to facilitate solution providers develop their applications to be able to use the NZMT and NZULM. The initial emphasis was not on e-Prescribing with clinical decision support but on other applications within the e-Prescribing area such as the e-Pharmacy and Medication Reconciliation. Developing these areas lays a foundation for future developments in e-Prescribing.

5 Findings and Analysis

5.1 Introduction

This study set out with the aim of answering the research question:

Using the knowledge and experience of other countries worldwide, why and how might Ireland develop and implement a medicines and drugs reference catalogue to support e-Prescribing?

The methodology used was a qualitative analysis of selected countries using case studies. The author prepared a summary critique at the end of each case study which reflected the findings for each country. The author then performed a cross case analysis using pattern and theme analytical techniques. The findings are presented under the following headings which are mirrored to the headings in the case studies:

- Background and Context see section 5.2
- Clinical Terminology see section 5.3
- Medicines and Drugs Catalogue see section 5.4
- Organisation and Management see section 5.5

5.2 Background and Context

5.2.1 Drivers for Change

The findings support the view that the problems with patient safety, medication cost and inefficiencies are pervasive and are motivators that initiate governments to take action. In the US and the UK, seminal reports were published. In Australia patient safety and divergent state and local health systems were inefficient and costly. In New Zealand, patient safety and cost were also the drivers for the government to respond. Each government looked to reform healthcare using e-Health and specific projects such as e-Prescribing as the agents of change. Government responses included enacting legislation, allocating resources and being active participants in the change, despite committing to a long term and difficult challenge.

5.2.2 Perceived Benefits of e-Prescribing

Each country identified that e-Prescribing could deliver the desired benefits. Within e-Prescribing the perceived benefits are categorised into clinical and cost benefits. The clinical benefits are introducing clinical decision support, a shared electronic patient medication record and medication review, interoperability such as transmitting an electronic prescription, and better regulatory and formulary compliance. The perceived cost benefits are managing reimbursement costs, reducing medication costs by switching to cheaper alternatives, reducing risk and consequential costs that might arise if there is an ADE, and eliminating the costs of maintaining multiple sources of drug information.

5.2.3 E-Prescribing As a Solution

The findings in each case study show e-Prescribing solutions are standalone. Therefore a medicines and drugs reference catalogue is needed by the solution to be part of a comprehensive interoperable patient medication record, summary of care record or to enable electronic transmission of prescriptions to the pharmacy.

E-Prescribing applications have inbuilt CDS solutions using their internal drug databases and are not dependent on the external catalogue to deliver this functionality.

5.3 Clinical Terminology

5.3.1 Clinical Terminology - Role in Healthcare

SNOMED CT is the foundation standard for clinical knowledge representation. Three of the four cases (UK, Australia and New Zealand) are using SNOMED CT. The US has adopted SNOMED CT but continues to use other terminologies. SNOMED CT includes medicines and drugs as part of its architecture and selecting it as a clinical reference significantly affects all e-Health applications. This includes e-Prescribing and medicine and drugs catalogue.

5.3.2 Impact of SNOMED CT on a Medicine and Drugs Catalogue

The impact is best illustrated by the UK Case Study. The UK (dm+d) catalogue had been implemented prior to the adoption of SNOMED CT. The UK adopted

SNOMED CT and subsequently had to develop a SNOMED CT version of the dm+d due to integration issues with the solution provider applications. The UK now is maintaining two full variants of their medication and drugs catalogue. In Australia and New Zealand, the AMT and NZMT are solely based on SNOMED CT.

SNOMED CT provides core functionality for e-Prescribing, CDS and Formulary. Despite this each country must develop a localised version of SNOMED CT to support the local variances because of language and different naming conventions. The US, UK, New Zealand and Australia have each created individual local medicine and drugs extensions to SNOMED CT. Each extension requires editorial rules and editorial software to help manage the data.

5.4 Medicines and Drugs Reference Catalogue

5.4.1 Implementation

The US has developed a complex model for its medicines and drugs reference catalogue RxNorm. However, for e-Prescribing only a subset called RxTerms is implemented. A catalogue to support e-Prescribing including CDS has yet to be published.

In the UK the dm+d is widely implemented to support the EPS project. The SNOMED CT UK Drug Extension catalogue is also published and used by those that are using SNOMED CT as the terminology. The retirement of the Read CT terminology will lead to changes in the population of users using the SNOMED CT UK Drug Extension.

Australia and New Zealand are each using SNOMED CT based catalogues and both countries are at an early implementation stage.

5.4.2 Medicines and Drugs Catalogue Usage

The findings show that the medicines and drugs reference catalogues are used in different ways and to a different extent in each country.

Firstly, as a mediate catalogue, i.e., as a reference for the application to use when information is shared with another remote application. The descriptions (or terms) used in shared files are based on the terminologies in the catalogue. This is the prevailing usage in the US, UK, New Zealand and Australia.

Secondly, the catalogue provides data supplied by other databases. The catalogue can contain the status and authorisation number for the medication as well as price information. The UK dm+d and NZULM support additional data.

Thirdly, the usage is for the purposes of building links to another database for additional information. The Australia AMT links to the NPC where the additional data is supplied. The NZUML will also link to the NPC as well as the regulatory database and the reimbursement database for this functionality.

The addition of a terminology affects the usage of the catalogue. The early implementations of RxTerms and dm+d were relatively straight forward from a data content perspective, but the use of a terminology complicates the data structures. Australia and New Zealand prefer to keep the terminology database independent of the other data used for reimbursement, supply chain and regulatory information.

While the catalogues can support CDS, the solution providers still prefer to use their internal drug files for this purpose. Australia has stipulated that their AMT is not to be used for CDS purposes. The UK, US and New Zealand favour including CDS rules in their plans, but the standardised CDS rules are the next step to be developed with the British National Formulary taking the lead. The value proposition of having standardised CDS rules or applications that must comply with a CDS rules warrants further study.

Finally, implementing a catalogue must consider the history of previous catalogues and how they were used. If patient records have been populated using the old catalogue, this legacy must be accommodated.

These findings suggest that the catalogue needs to be developed with a vision to the future applications. However, the usage, as shown in the case studies, is

incremental starting with small scale applications then building into a more complete adoption. A summary of the usages mentioned in the case studies is shown in Figure 5-1.

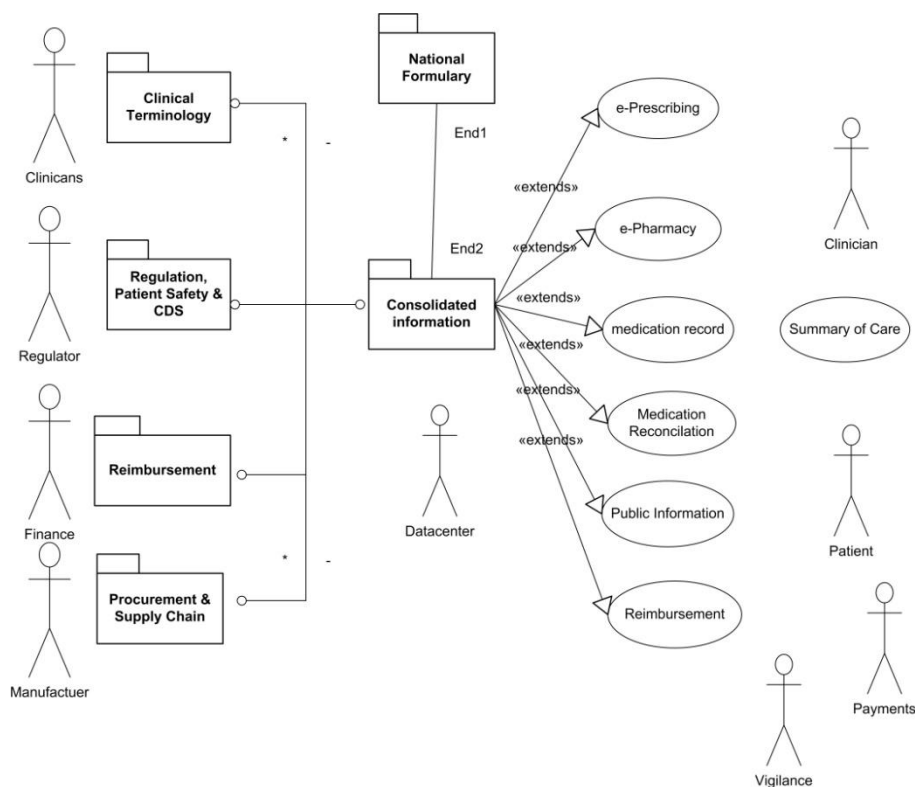


Figure 5-1 Summary of Case Study Usage

The diagram above refers to a “consolidate information model” which is the logical shape that is emerging on medicines and drugs reference catalogues. It is the opinion of the author that this consolidated information model will be based on a terminology database partnered with databases that provide other data for example, cost, regulatory data, other classifications and additional data not accommodated by the terminology. Ideally there should be no more than one additional database for this purpose. Both the Australian and New Zealand projects are progressing in this direction.

5.4.3 Data Model

The US data model, RxNorm, is the most complex with 14 concept levels and multiple relationships styles. The UK used a five level model with a simple relationship. Australia and New Zealand used a seven level model with a simple relationship. The UK, Australian and New Zealand models are very similar,

reflecting the close cooperation between the countries at the development stages. This suggests that the data model is evolving to a de-facto best practice. Table 5-1 compares the data model for each case study. The US model is unique and has been excluded from the analysis.

The data model is not SNOMED CT dependent. It can therefore be used independently of SNOMED CT. The UK dm+d is an example of this. However, when SNOMED CT is adopted there are linking concepts at two levels in the dm+d. The ingredient name (VTM), and the name, form, strength and dose (VMP) establish the relationship with SNOMED CT. The localised name of the product (AMP) is added to the SNOMED CT extension.

There are two levels missing in the UK model, Trade Name and Containered Trade Product Pack. These were originally contained in the dm+d UK bonus file and were mapped to the GTIN. The inclusion of the GTIN directly into the dm+d is now under review by the UK Terminology Centre.

The study concludes that the data model used by Australia and New Zealand, and possibly the UK, is the model that best represents the requirements for a medicines and drugs reference catalogue. The model does not imply a requirement to adopt SNOMED CT, but the compatibility with SNOMED CT is important in the event of a future migration.

Data Model Level Description	SNOMED CT	United Kingdom SNOMED dm+d	Australia AMT	New Zealand NZMT
Therapeutic Use	Product Class Drug/Product Class			
Therapeutic Use	Product Category (functionality)			
Ingredient Name	Virtual Therapeutic Moiety (VTM)	Virtual Therapeutic Moiety (VTM)	Medicinal Product (MP)	Medicinal Product (MP)
Virtual Common Name, form, strength and dose. (linked to localised representation)	Virtual Medicinal Product (VMP)	Virtual Medicinal Product (VMP)	Medicinal Product Unit of Use (MPUU)	Medicinal Product Unit of Use (MPUU)
Virtual Physical Pack Quantitatively equivalent with same ingredient, strength, form and pack size		Virtual Medicinal Product Pack (VMPP)	Medicinal Product Pack (MPP)	Medicinal Product Pack (MPP)
Branded product name			Trade Product (TP)	Trade Product (TP)
Localised Representation of Name/Brand – linked to the common form and unit of use “taken by the patient”	Actual Medicinal Product (AMP) (Localised extension)	Actual Medicinal Product (AMP)	Trade Product Unit of Use (TPUU)	Trade Product Unit of Use (TPUU)
Actual Pack given to the patient. Prescribed, dispensed, and reimbursed		Actual Medicinal Product Pack (AMPP)	Trade Product Pack (TPP)	Trade Product Pack (TPP)
How the medication is packaged, bottle, blister pack, vial			Containerised Trade Product Pack (CTPP)	Containerised Trade Product Pack (CTPP)

Table 5-1 Comparative Analysis of the Case Study Data

5.5 Organisation and Management

A significant finding in each case study is that a single organisation is responsible for all aspects of the catalogue including distribution. This may be explained by the fact that a trusted or authoritative independent body is the best option to satisfy all the stakeholders. This organisation determines policy and coordinates between the interested organisations.

The distribution process is similar in each country. Some countries require login validations while others allow open access. Online lookups using internet browser technology are also available. In all case studies, the catalogue is provided free of charge to the users.

How the data is structured and delivered varies from case study to case study, there is a complete lack of standardisation. The US uses delimited files, the UK uses xml for dm+d and delimited files for dm+d SNOMED extension, Australia uses the SNOMED CT structures and the NPC GS1 xml, and finally New Zealand uses excel data sheets exported from a sql relational database. Which option is the best is a topic matter for future study. While there has been much discussion on semantic interoperability, the syntax and messaging appears to have been overlooked by each country, leaving it up to the solution providers to develop different interfaces. Australia, using the SNOMED CT structures for the reference catalogue and the NPC GS1 message standard for other attribute data, comes closest to complying with international standards for messaging and syntax.

Despite the fact that the data models are almost standardised the file data content varies from country to country. The reason for this may possibly be due to the unique requirements driven by custom and practice as well as regulation in each country. This has practical implications for the international solution providers. A further study is required to determine the most suitable semantic model for Ireland. This study would need to consider the particular solutions that exist in Ireland. It also is a possible barrier for new solution provider entrants to the market.

Quality issues were highlighted in the US, UK and the New Zealand case studies. It is cautioned that, whatever solution is chosen and whatever organisation is established, a quality assurance process is required.

5.6 Conclusions

The findings are the potential factors to be addressed during the development and implementation of a medicines and drugs reference catalogue in Ireland. These will be discussed in the next chapter.

6 Recommendations

6.1 Introduction

This study has investigated, using case study analysis, the why and how other countries implemented their respective medicines and drugs reference catalogues. The findings suggest a number of recommendations which should be considered before developing and implementing a similar solution in Ireland. These recommendations are detailed in this chapter.

6.2 Strategy

One of the difficulties with a medicines and drugs catalogue is that it is a foundation standard for accurate reference data and interoperability but it needs a context in which it can be utilised. In this study the context was e-Prescribing and the case studies reflected that context. However, that does not preclude preparing for other initiatives based on a medicines and drugs catalogue.

Recommendation:

As part of an e-Health Strategy and to support a wide variety of applications including e-Prescribing, a national medicines and drugs reference catalogue should be developed and implemented.

6.3 Responsibility

In each case study, a government organisation was established to steer the development of the catalogue. This organisation reported to the government or a government department. Funding is provided as part of the healthcare budget.

Recommendation:

The government should establish an organisation, representing the key government agencies to oversee the development of the catalogue.

The catalogue is implemented by solution providers and is used by healthcare professionals.

Recommendation:

The government organisation should engage with the main stakeholders and potential users of the catalogue and consider the working structure to ensure that they are actively involved and support the initiative.

6.4 Clinical Terminologies

Clinical Terminologies play a significant role in healthcare. Furthermore, SNOMED CT is the favoured clinical terminology in each of the case studies (except the US for a medicine and drugs catalogue). The structure of a medicines and drugs reference catalogue is strongly influenced SNOMED CT.

Recommendation:

The government should indicate their plans for clinical terminologies and in particular the adoption of SNOMED CT as a national clinical terminology standard.

6.5 Data Model

The case study evidence supports a finding that the data model for the medicines and drugs reference catalogue has evolved to near mature state. The data model is robust and supports e-Prescribing. The findings also show that the data model will support summary of care records, medication review, referral and discharge.

Recommendation:

The data model implemented by New Zealand and Australia should be the data model for the medicines and drug reference catalogue in Ireland.

6.6 Supported Functionalities

6.6.1 General Structure

Each case study had used the catalogue and had decided on the purpose of the catalogue. All had determined that it was to be a mediate reference standard. Additionally it is used to support other data and or/to link to other databases where critical data is stored. This combined with a terminology has a significant impact on the overall architecture of the catalogue. These options need to be considered in more detail.

Recommendation:

The government organisation should review in more detail the solutions evolving in the UK, Australia and New Zealand where a pure terminology based medicines and drug reference catalogue has evolved based on SNOMED linked to databases that provide data to support reimbursement, regulation and the supply chain.

6.6.2 Clinical Decision Support

Solution providers prefer to use their proprietary databases and maintain their own CDS rules. Despite being one of the key reasons for implementing a reference medicines and drugs catalogue, standardise CDS has yet to be deployed.

Recommendation:

Firstly, it is recommended that Ireland should not develop a standard CDS solution until it has been tested and evaluated elsewhere.

Secondly CDS in the proprietary e-Prescribing solutions should conform to a standard. It is therefore recommended that future research is needed to determine the CDS standards for e-Prescribing, and the value proposition of the certification programme to those standards.

6.7 Organisation and Management

The author has already recommended that a government organisation should oversee the development of the medicines and drugs catalogue. This organisation should also consider the long term sustainability of the catalogue.

Recommendation:

The government organisation should consider establishing a sustainable organisation to provide governance, maintenance, future development and participation in the adoption of the catalogue in healthcare.

The adoption of the data model does not in itself determine how the catalogue will be published. Each case study had a different way of publishing the catalogue. This was determined locally to suit the local solution providers and users.

Recommendation:

Determine, under the auspices of the government organisation and the stakeholders, the most efficient way to deliver the medicines and drugs catalogue to the users.

6.8 Limitations of the Research

Already discussed in section 3 has been the debate on case study research. The author has taken remedies to address the academic rigour needed for qualitative case study. In this section, the author examines the limitations in respect of this particular study.

All of the case studies produced a significant amount of data that had to be synthesised to focus on the research question. This natural process of filtering selects the obvious while possibly ignoring the significant. It is possible to return to the data many times, reanalyse it and generate further nuances on the findings.

The interview modalities varied which raised a question of balance. Interviewing the interviewee in person, by conference call and by email affects the dynamics of the interview. The opportunity to observe a person's behaviour and to respond to behavioural signals is far superior to the impersonal engagement by email or telephone.

An interviewee bias was also revealed. The first interviewee, a pharmacist who had worked of many years in this area; the second, a senior operational manager with wide range of technical and clinical skills; the third, a senior technologist who has responsibility for the terminology database, all brought there different experiences to the responses given in the interview.

The research area is complex and there is no typical country or unit of analysis, therefore it is challenging to produce a simple answer. This study resembles an iceberg, where part is visible above the water but the danger lurks below as there are many factors that can influence the outcome. While this study was biased to healthcare and economy, other factors such as political, cultural, social, and demography were ignored.

However, despite the above it is the author's opinion that the findings can be trusted at least in a Popperian sense.

6.9 Recommendations for Further Research

The study has concluded with the above recommendations, however progressing the topic further will require additional research.

The research should be on delivering solutions using a medicines and drugs reference catalogue. E-Prescribing, researching both the Australia and New Zealand projects, and developing the medication record (O'Grady, 2010) into a Summary of Care Record are possible research areas.

The second area is how in Ireland a reference terminology could be published and integrated into the healthcare applications used in Ireland.

The third area of research is to examine the benefits that might be realised when using standardised CDS rules published centrally when compared to using the disparate rules embedded in the proprietary applications.

6.10 Conclusion

In the introduction to this study the author referred to both Peter Hinssen's definition and Benjamin Disraeli's rule on information. These quotations, while true in every context, but specifically in healthcare mean having the best information available to the clinician to treat the patient. A medicines and drugs reference catalogue is a technology that aims to deliver that goal.

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Appendix 1

Cimino's Desiderata for Terminology Databases

Introduction

Cimino, a leading expert in terminologies published an influential paper which defined a set of Desiderata or requirements that Controlled Medical Vocabularies should meet (Cimino, 1998). The Desiderata were developed on the need to have information that was shareable, served many purposes and accurate. The Desiderata expressed the properties needed for a terminology database. The properties Cimino established are documented below.

Cimino's Desiderata

Content	There is a need to add more and more content not in a haphazard way but in a methodical way. This is defined as "formal, explicit and reproducible".
Concept Orientation	This aims at removing vague terms. The concept must have "one meaning and no more than one meaning....., i.e, single coherent".
Concept Permanence	After a concept has been created, it cannot be then deleted. This ensures that evolution of the concept is supported and that there is migration path
Non-semantic Concept Identifier	Once a concept has been defined there is a need for it to have an identifier that is "free of meaning and hierarchy". A concept name is not sufficient as an identifier because it can evolve and change. However a non-semantic concept identifier linked to the concept remains permanent.
Polyhierarchy	This is needed to satisfy different users. Different users demand information in different ways and as a result a single classification will not satisfy everybody. This adds complexity, but by having multiple views the terminology will be of use to more users.
Formal Definitions	Formal definitions are created by combining concepts in a relationship to give meaning. Therefore, the computer to be able to combine these by a linking process or manipulated symbolically.
Reject "Not Elsewhere Classified"	This is a "catch all" term. These terms exclude possible formal definitions elsewhere in the vocabulary.
Multi-granularities	This allows the users detail what they need. A General Practitioners view of specify a condition is different from the specialist's view. The vocabulary must work to satisfy the needs of all its users. Creating levels of precision is achieved via using concepts to represent the medical knowledge.
Multiple Consistent Views	Care has to be taken to ensure that the views of the concepts in the vocabulary are consistent. Viewing something that has many parents has an identical appearance
Beyond Medical Concepts: Representing	Context is the environment in which the concepts are being used. There needs to be rules built on context built into the vocabulary.

Context	
Evolve Gracefully	Evolution is part of the challenge and there needs to be a way to manage that change. The changes have to consider the already existing records. Also there needs to be clarity of the reason for the change.
Recognise redundancy	Redundancy occurs when the same information is represented by synonymous. There is a balance between representing data by modifiers or codes and data with added using free text. Using synonyms also expression in the vocabulary.

Appendix 2

Interview protocol

TRINITY COLLEGE DUBLIN

Information Sheet for Participants

In Ireland, we are at an explorative stage on ePrescribing. Therefore the purpose of the research is to evaluate the qualities and to scope a Reference Catalogue for Medical and Medical Devices to support ePrescribing. As part of the research it was decided to research the experiences and knowledge of experts both locally and internationally in the area.

The particular areas of interest in the research is the importance of a drugs database or catalogue, its linkages with clinical terminologies such as SNOMED CT and standards such as ISO and CEN, usage of identifiers, how the catalogues are structured and maintained, the resources required to support the catalogue, the model used to disseminate the information, how solution providers have used the information for their applications, usage by the clinical profession and finally how effective are they in ePrescribing process.

The procedures relevant to the interviewee relate only to providing informed consent, participation in the interview to address the above and the signing the declaration contained within the consent form.

Please be advised that:

Participation in the interview is voluntary and that the interviewee may withdraw at any time for any reason without penalty.

Ideally the interview will be recorded, but interviewee has the option of declining and reverting to the interviewer taking notes,

Personal Data, save for purely communications purposes – telephone, e-mail, will not be retained within the meaning of the Data Protection Act. This data will be held secure for the period of time required by the college. It will not be disseminated for any other purpose or further processed.

All data supplied is treated confidentially.

If interviewee does not wish not to answer any specific questions these wishes will be respected by the researcher.

If there is any likely hood of a conflict of interest, the interviewee will declare it to the researcher as soon as it is recognised.

The professional integrity of others will be respected by both the interviewee and the researcher.

No mention about third parties should be made during the interview. If references are made accidentally or otherwise to third parties, they will be anonymised in the document.

The interviewee, should they require a debriefing, it will be provided by the researcher within 4 weeks of the interview.

If any illicit information is reported to the researcher, the researcher is duty bound to report it to the relevant authorities.

Audio recordings will not be identifiable unless written permission is received.

Ends

Trinity College Dublin

Participants Informed Consent Form

LEAD RESEARCHER:

Brendan Kernan

BACKGROUND OF RESEARCH:

In Ireland, we are at an explorative stage on ePrescribing. Therefore the purpose of the research is to evaluate the qualities and to scope a Reference Catalogue for Medical and Medical Devices to support ePrescribing. As part of the research it was decided to research the experiences and knowledge of experts both locally and internationally in the area.

The interview will be used for a qualitative analysis as part of a dissertation. The dissertation will then be submitted in partial fulfilment of the requirements for a degree of Master of Science in Health Informatics.

PROCEDURES OF THIS STUDY

The researcher has carried out an extensive literature review and a study of various similar projects in different parts of the world to answer the research questions. To ground the research and obtain factual current data from experts in the area, it was also decided to carry out a qualitative analysis. The research methodology will be to gather data for the qualitative analysis using semi structured interview techniques and analyse the data for themes.

A series of lead questions will be prepared and will be supplied in advance to the expert.

The expert will have a minimum of two weeks to review the questions and if needed will be able to contact the researcher in advance of the interview to discuss any issues.

If the interviewee has any difficulty with the topic or questions, he/she has the opportunity to decline to take part in the research.

The interview will take place over the telephone, Skype, or face to face and will be of a duration of no more than thirty minutes.

The interview ideally will be recorded and transcribed after the call. However, should the interviewee not wish to be recorded, these wishes will be respected and the interviewer will manually record the interview.

The source and content of the data will be anonymous as to respect the confidentiality of the opinions of the expert

The transcriptions will be analysed for themes and compared for the analysis.

An aggregated analysis of the results of the interview will be published in the dissertation

The records and workings of the dissertation will be retained and secured as required by the college for the period of time stipulated

PUBLICATION:

The publication of the aggregated results of the interviews will in a dissertation that will be submitted as part of a Master Degree in Health Informatics. The research may be used by others for academic research.

In addition the research outcomes are likely to be presented at selected conferences, seminars or workshops in Ireland.

DECLARATION:

- *I am eighteen years or order and am competent to provide consent.*
- *I have read, or have read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.*
- *I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.*
- *I freely and voluntarily agree to be part of this research study though without prejudice to my legal and ethical rights.*

- *I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.*
- *I understand that my participation is fully anonymous and that no personal details about me will be recorded.*
- *I have received a copy of this agreement.*

PARTICIPANTS NAME:

PARTICIPANT'S SIGNATURE:

Date:

Statement of researcher's responsibility:

I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that maybe involved. I have offered to answer any questions and fully answered such questions. I believe the participant understands my explanation and has freely given informed consent.

Drugs and Medical Devices Catalogue

Medicines Terminology and Drug (DMD) Reference Catalogue for e-Prescribing in Ireland

Timeframe: 30 minutes

Proposed Interview Questions

Interviewer introduces his understand from research to help position the status with respect to the thesis.

What were the chief catalysts that triggered the development of the DMD catalogue in your country?

Hints: Patient safety, reimbursement, regulation, interoperability, EHR, Medication Reconciliation, government or user community initiative, insurance industry, cost containment

Who/What were the main drivers for change

The legacy – a green field or many proprietary solutions – regional variances

What research and/or evaluations were carried out to determine best way to deploy the catalogue? What parameters and constraints were considered by the decision makers? Who were involved parties and what was the outcome?

Hints: Studies and reports published, imitation of another market , local considerations- language/ ethnic influences, linkages to other adopters, government, regulators, HCPs, sector association influences, and were there localisation issues?

Post implementation were Benefit Realisation studies carried out? What were the outcomes?

Did Health Terminology Standards, ISO and/or CEN Standards feature in stating your requirements? Did the standards help/support/hinder your process or did you have to develop national variations to suit your local needs?

Hints ISO, SNOMED CT, LOINC, ICD 10, ATC, Ingredient Names, identifiers, HL7 V2 or V3, barcode, RFID, XML, ICH, etc. Scope and structure of the reference

catalogue for different users, approach minimum dataset. Access to/from – lookup, messaging used to distribute the catalogue.

Regulatory Influences and Statement Product Characteristics(SPC) –

Local influences that might have influences changes to standards-Formularies, MIMS, other reference material

Interoperability with other jurisdictions e.g. European EpSOS, New Zealand/Australia

Plans for future migration

How was agreement reached?

What are and why were these organisational structures deemed necessary to (1) develop (2) deploy and (3) maintain the databases General Practitioner, Hospital prescribing, CPOE, pharmacies and administration and EHR .

Hints: government, private industry, regulatory, sector association, third party agency, maintenance, number of updates, notifications and alerts, retirements and cancellations

Quality Control and Validation

Distribution Schedule and maintaining synchronisation

Resource requirements (Cost and Manpower)

What is the relationship with the solution providers? How are they supported? Is the catalogue integrated as part of their applications? Are additional modifications used? Is there interoperability between solution providers?

Hints: Integrated versus reference standards, Accreditation of Solution

Providers applications,

Systems: GP, Hospital prescribing(CPOE), Retail and Hospital pharmacies, administration systems and EHR .

Identification- Terminology Structure

Clinical (SPC attributes- drug- drug reactions, contra-indications, allergies)

Supply Chain

Appendix 3

Telephone Interview with UK Expert

Paraphrased Summary

What were the chief catalysts that triggered the development of the catalogue in the UK?

The UK government started developing a catalogue of medicines that might support procurement and cost control, i.e., replace branded drugs with generic drugs. At the same time, a Summary of Care record became a priority under the Health Reform Programme. There were many suppliers of applications to General Practitioners. These applications were standalone and were not interoperable. Interoperability was a key requirement for Summary of Care record and having a standard description for medicines was need. Solution providers had supplied the capability to hospitals to build their own reference catalogues but it duplicated their work. There were also risk factors relating to liability.

What research and/or evaluations were carried out to determine the best way to deploy the catalogue? What parameters and constraints were considered by the decision makers? Who were the involved parties and what was the outcome?

The main driver was the Government (Pharmacy Section) through the National Health Service. The legacy of already having started a solution was the basis of the catalogue. The outcome was a reference catalogue structure and an organisation with a panel of experts to oversee the future development. The panel of experts have been insular when dealing with the users. Pragmatism must prevail over purism.

Did Health Terminology Standards, ISO and/or CEN Standards feature in stating your requirements? Did the standards help/support/hinder your

process or did you have to develop national variations to suit your local needs?

SNOMED CT was mandated to be the reference standard and the basis for the catalogue called the dm+d. The dm+d was to be a subset of SNOMED CT. It is hoped that SNOMED CT would become the global standard thereby there will be international recognition for the dm+d. Other classifications and terminologies are legacies that have to be included, but the decision on a single terminology standard is critical. There are limitations with SNOMED CT and therefore there are subtle variances between SNOMED CT and the original dm+d in how medicines are clinically described. It is not perfect and it is still evolving. The selection was for better or worse. The dm+d is just a dictionary for writing a prescription in different ways. The next step is to have it fully integrated with rules to support CDS. The British National Formulary is restructuring their databases to link the dm+d with CDS rules they have developed based on the SmPC. Solution providers have their own solutions for a drug file that supports CDS and are reluctant to change this until a better solution is available.

What are and why were these organisational structures deemed necessary to (1) develop (2) deploy and (3) maintain the databases General Practitioner, Hospital prescribing, CPOE, pharmacies and administration and EHR .

Within the UK Department of Health a small team of Pharmacists is responsible for updating and maintaining the dm+d. It was strongly felt that the dm+d needs to have real strong support from the community, government, clinical champions and Chief Executive Officers to increase adoption. Some aspects are good and some are not as good as they should be. The Organisation within the Department of Health has had to adapt to the market and consider the needs of the user more.

What is the relationship with the solution providers? How are they supported? Is the catalogue integrated as part of their applications? Are additional modifications used? Is there interoperability between solution providers?

Solution Providers use commercially available drug databases in their applications. They also have embedded the CDS rules based on the SmPC. The dm+d is included so that the clinician can use it to write a common description for the drug when e-Prescribing and send the e-Prescription to the Pharmacy. There are differences between the solution providers' drug files and the dm+d but they are coming closer together. The dm+d, however, has yet to replace the commercially available products. This may happen when there is linkage between the dm+d, the British National Formulary and CDS. The value proposition is not really clear yet.

Other comments

Priorities change at government level, it is important that there is a long term commitment. The dm+d is a long term programme with many difficulties and the benefits of a dm+d are not obvious prior to implementation, but once implemented there is no going back.

Appendix 4

Face to Face Interview with Australian Expert

Paraphrased Summary

What were the chief catalysts that triggered the development of the catalogue in your country?

The Australian government had worked on e-Health for over twenty years without success. Developments were hindered by separate regional health programmes and demographic constraints. There were diverse non-interoperable solutions, even when the same solution provider was used. In a new programme the emphasis shifted to a PCEHR of medically validated data. It is basically a summary care record held in a virtual database or cloud solution containing patient health data that could be verified and accessed by different clinicians. The overall objectives of the programme are to: improve efficiencies, reduce adverse events, improve quality of care, provide a knowledge base for clinical decision support, and implement interoperability between systems, better use of information and the medication programme. The reform programme looked to other countries to see what they were doing to address the health agenda.

What research and/or evaluations were carried out to determine the best way to deploy the reference catalogue? What parameters and constraints were considered by the decision makers? Who were the involved parties and what was the outcome?

Many expert reports addressing the whole healthcare reform issue had been prepared. The Health Authorities consulted widely with the eight states and governments, the College of Health informatics, the College of Surgeons and the College of Health Administrators. They also looked at the International Standards and what was happening in other countries. The particular focus was on the reasons, rationales, drivers and opportunities for reform in those countries. The outcome was the Health Reform Strategy and NEHTA an independent body was established to advise on e-Health developments. This resulted in a legislative

programme that sought to drive the implementation of e-Health. NEHTA was the body responsible for all eHealth reform for the entire Australian community. The need for the catalogue was identified in that context.

Did Health Terminology Standards, ISO and/or CEN Standards feature in stating your requirements? Did the standards help/support/hinder your process or did you have to develop national variations to suit your local needs?

NEHTA looked at all the international standards including ISO, HL7, ATC and other best practices. They advised that SNOMED CT should be the Clinical Terminology Standard for Australia. This was recommended and approved by the Australian National Standards body who oversee all Australian Standards. It was therefore decided that AMT should be built using SNOMED CT and then configured to suit the Australian domain. NEHTA worked closely with the UK, Canada and New Zealand on the catalogue requirements and on how their data model was to be structured. But to get consensus they needed to localise the standard. Other classifications were still relevant and also needed to be considered. These were still used and the scope needed to reference them. Some of the larger hospitals had already terminologies embedded in their applications.

What are and why were these organisational structures deemed necessary to (1) develop (2) deploy and (3) maintain the databases General Practitioner, Hospital prescribing, CPOE, pharmacies and administration and EHR ?

NEHTA is responsible for the programme. The AMT is centrally managed and controlled by them. The NEHTA organisational structure is indicative of the Australian commitment to the e-Health agenda and Regional and Federal governments are represented on the board. NEHTA provides the advice and recommendations on the formation of policy; the government makes the decision. Software solution providers are required to include the AMT in their solutions. The providers must update their applications to support the AMT and to maintain version control as there are regular updates. There is pressure on

solution providers to comply. Expenditure on the whole programme of Health Reform is significant.

What is the relationship with the solution providers? How are they supported? Is the catalogue integrated as part of their applications? Are additional modifications used? Is there interoperability between solution providers?

Previous experience has indicated that “Ripping out and Replacing” existing solutions does not work. Generally solution providers have looked to the NEHTA for guidance on how to comply with the regulations and standards. There are a large number of solutions and solution providers that need to be encouraged to use the AMT. The solution provider is responsible to their clients for ensuring that their applications use the AMT. Frequent updates are provided. CDS is a core functionality that the solution providers offer and this depends on the AMT.

Other Interview comments

Cloud based solutions for the PCEHR require standards to enable implementation.

Appendix 5

Interview with New Zealand Expert by Email

Paraphrased Summary

New Zealand prepared a formal written response to the interview questionnaire (A.N. Other, 2011). The responses received to each question are summarised below.

(Note A.N Other is a fictitious name to ensure compliance with the Ethics requirement of the University.)

What were the chief catalysts that triggered the development of the medicines and drugs reference catalogue in your country?

Other (2011) refers to the New Zealand government's long term objective to address the problems of patient safety and cost. The medicines and drugs catalogue, referenced in the New Zealand Medicines Terminology Recommendation Report (Health Information Standards Organisation, 2009), already cited in this study, was a component of that strategy.

What research and/or evaluations were carried out to determine the best way to deploy the medicine and drugs catalogue? What parameters and constraints were considered by the decision makers? Who were the involved parties and what was the outcome?

Other (2011) refers to the work of the Expert Advisory Committee (EAC) which looked in detail at the implications of a medicines and drugs catalogue. The members of EAC included health authorities, clinician representatives, solution providers, and the reimbursement and the regulatory agencies. EAC focused on using a terminology based solution and explored how that might be developed and implemented. EAC decided not to develop a medicine and drugs catalogue from scratch, but to align with International Standards and to work closely with their counterparts in Australia.

Did Health Terminology Standards, ISO and/or CEN Standards feature in stating your requirements? Did the standards help/support/hinder your process or did you have to develop national variations to suit your local needs?

Other (2011) identifies the closeness between Australia and New Zealand on healthcare policy. The alignment of policies on drug regulation and the advanced stage of the Australian AMT using SNOMED CT influenced the New Zealand choice of a medicines and drugs reference catalogue. The New Zealand and Australian data models are the same. However, Other highlights the decision not to use the SNOMED CT physical model, but to use a relational database instead. Other does not explain the reasons for this decision. However, Other (2011) is critical on standards conformance. There are some instances of divergence between the editorial rules and the naming conventions and as a result, local standards were developed.

What are and why were these organisational structures deemed necessary to (1) develop (2) deploy and (3) maintain the database.

Other (2011) indicates that the project requirements changed from time to time and that a pragmatic response was necessary in order to maintain the continuity of staff employed. Therefore New Zealand engaged the services of the same independent contractors from the development stage to the live stage.

What is the relationship with the solution providers? How are they supported? Is the medicines and drugs catalogue integrated as part of their applications? Are additional modifications used? Is there Interoperability between solution providers

Other (2011) states that the implementation strategy is to work with the solution providers on specific projects using the NZMT and to work with the other data providers. Currently, there are two areas where the NZMT is providing a common language, e-Pharmacy between the GP Practice Management System and the Pharmacy, and Medicine Reconciliation linking medicine charting and the patient discharge summary. In each area there are two different solution providers who both provide feedback on the performance of the NZMT. The NZMT is not sufficiently well developed to enable total integration with the solution provider

applications. Further additional development will include closer adoption with the other data providers, Medsafe and Pharmac.

Additional Comments

Other (2011) commented on some of the criticisms that arose during the development and implementation of the NZMT and the NZULM. These criticisms included issuing work in progress and inaccurate data, choosing SNOMED CT as the clinical terminology and maintaining the separate data structures of each of the data sources rather than integrating the data into one database. In response to these criticisms, the data should only have been data that had passed the editorial procedures. SNOMED CT was a policy decision that could not be changed. Interestingly, Other comments that the rapid development and deployment was possible only because of the strategy not to immediately integrate all of the data from the data sources. When viewed by the data sources, the quality of data source data may have been compromised.