IT coding for information exchange on Medication and Vaccination

1. Introduction

Wouldn't it be nice….and how convenient it would be for an individual for a mother of children who have to be vaccinated, for the son of an elderly parent who needs (hospital) care, for a child with a rare disease, to have complete personal health records easily accessible and at hand.
Where is the "uber-app" that covers this all?

Shwachmann Diamond Syndrome (SDS), is a rare condition with Exocrine Pancreas Insufficiency (EPI), Neutropenia and Skeletal dysplasia , first features present in early childhood. Laboratory tests will confirm the diagnosis. Due to the lack of pancreas enzyme, fat and fat-soluble vitamins are not absorbed in the gut. There is no doubt that pancreatic enzyme replacement therapy (PERT) is indicated in patients with EPI. Blood levels of fat-soluble vitamins should be measured, and supplementary therapy should be started if values are low. The family, carers and all healthcare professionals would benefit enormously from an (electronic) Personal Health Record for SDS patients. This PHR would contain international coding for the disease (ICD K86.81), lab tests (LOINC), and medication (ACT A09AA02 – pancreatine), which the the individual with SDS or the carers could authorise healthcare professionals to access. https://rarecare.world/disease/pancreas-insufficiency

Alas, nothing is as simple as some pieces of paper or a small booklet!
Exchanging private information in the e-era requires not only coding and structuring but also has to meet with extensive regulations and safeguards. Since the onset of IT forty years ago, all kinds of systems, languages, uses have been developed – usually from small scale upwards, in countries, in professions, in practices, in industries. Governments often limited their role as to regulating and safeguarding.

Whilst different kinds of systems continues to spring into life and grow, so did the demand for exchange of information between various healthcare professionals on diagnosis, treatments, vaccination, medication, etc.
And after almost a decade since the first initiatives to enable interoperability, there now seems to appear some clarity in the field of internationally interoperable systems, resulting in the possibility of international information exchange in healthcare. Between professionals, but also between patients and professionals.

Here the importance of allowing every system, language, and database to exchange with any other cannot be underestimated. All existing products, coding and languages will be able to continue in their current role, thus avoiding the "Oh no-not-yet-another-system!"-syndrome.
The following chapters try to shed some light on the various players and products that are making this possible, in general and internationally, and for medication and vaccination for the Netherlands' situation in particular.

2. Standard for International Medicinal Product Codes - ISO Revised IDMP standards

A series of standards called IDMP (Identification of Medicinal Products) started a revision in 2017 and will bring a host of benefits to patients and the healthcare community. Implementing these standards should simplify the exchange of information between stakeholders and enhance the interoperability of systems in the medical field.

IDMP standards and technical specifications support the activities of medicines agencies worldwide. These cover a variety of regulatory activities related to the development, registration and life-cycle management of medicinal products, as well as pharmacovigilance and risk management.

Christian Hay, Senior Consultant ISO Healthcare, explains: “IDMP standards are essential for the world’s increasingly integrated healthcare. They provide the precise architecture for the computerization of information on medicinal products all around the world. When regulators adopt IDMP, their capacity to interoperate with each other makes for safer patient care; this is, for example, a huge benefit for adverse-event reporting and for documenting medication in patient records.”

To meet the primary objectives of the regulation of medicines and pharmacovigilance, the reliable exchange of medicinal product information in a robust and consistent manner is essential. IDMP standards fully support this and that is why a revision of the standards was deemed opportune.

ISO IDMP standards cover the following aspects to describe a medicinal product:

- Medicinal product name (ACT)
- Ingredient substances
- Pharmaceutical product (route of administration, strength)
- Marketing authorization
- Clinical particulars
- Packaging
- Manufacturing

Using ISO IDMP within regulatory activities brings benefits to regulators, industry and, ultimately, patients. “The trend towards global standards continues to increase. I cannot imagine the world without IDMP, whose implementation programme is going to last several years. Without IDMP, the existing information fragmentation by country or region would cause increasing risks to patients globally – not only those who travel, but those who are faced with mobile health or because of the globalization of supply chains,” explains Christian Hay.

3. European Medicines Agency (EMA) and IDMP Implementation Guidelines

To facilitate the phased implementation of the IDMP standards the EMA and the EU Regulatory Network have founded an EU IDMP/SPOR Task Force which comprises of participants for both Human and Veterinary medicinal products from the European Medicines Agency (EMA), Member States, experts nominated by European Pharmaceutical Industry Associations, Software Vendors and interested parties. The task force is responsible for advising on the planning, development, implementation and maintenance of the ISO IDMP standards in the EU, in line with requirements defined at international level and based on agreed EU implementation principles.

In 2019 progress has been made as to the implementation of IDMP data standards in the EU, in particular at a substance level. Shared definitions of substances can have an international impact, as shown via a proof-of-concept project led by the Dutch regulator (Medicines Evaluation Board), on behalf of the European regulatory network. Benefits of data continuity were considered, exploring the enhancement of cross-border medicines management by descriptions/coding for complex molecules — for instance in scenarios where a patient loses their medication on holiday, or needs a new prescription, and a healthcare provider needs to check the active ingredients, and identify any contraindications or allergy implications.

This study demonstrates that the description of molecules in a consistent and agreed way, with common mapping, will provide significant support for data and process interoperability. Instead of individual professionals having to sift through dossiers to confirm the constituent ingredients of equivalent products, they could simply exchange the agreed identifier — much as people use their social security number to identify themselves as individuals to different government organizations. Here, the primary benefit is reduced risk of wrong medicines being issued (though the efficiency gains for all stakeholders, and the accelerated speed of decision-making, are clear sub-benefits).

The target go-live date for human medicines/IDMP compliance is 2023.

4. Federal Drugs Agency (FDA/USA) and IDMP

As FDA focuses on the challenges of the global supply chain and foreign sourcing of medicinal products, FDA continues to participate in the development of and to promote the adoption of international harmonized IDMP to ensure the safety of medications throughout the world.

FDA has been using standards and terminologies similar to the concepts presented in the IDMP standards. We have assessed internal operations and systems and determined that many of the terminologies and standards currently used in regulatory submissions across the medical product development lifecycle are compatible with the data concepts in Medicinal Product Identification (U.S. National Drug Code), Substance Identification (Unique Ingredient Identifier), and Units of Measure (Unified Code for Units of Measure). FDA will continue to collaborate with ISO, as well as other regulatory agencies to identify and use a central list of dosage form and route of administration terms referenced in the ISO 11239 standard. Lastly, FDA will continue to collaborate internationally and to enhance its operations and systems, as needed, to ensure conformance to IDMP standards.

https://www.fda.gov/industry/fda-resources-data-standards/identification-medicinal-products-idmp

5. Interoperability – exchanging electronic health records: HL7 FHIR

Fast Healthcare Interoperability Resources (FHIR) is a standard describing data formats and elements (known as "resources") and an application programming interface (API) for exchanging electronic health records. The standard was created by the Health Level Seven (HL7) healthcare standards organization. One of its goals is to facilitate interoperation between legacy health care systems, to make it easy to provide health care information to health care providers and individuals on a wide variety of devices from computers to tablets to cell phones, and to allow third-party application developers to provide medical applications which can be easily integrated into existing systems. (Wikipedia)

Medication https://www.hl7.org/fhir/medication.html

This resource is primarily used for the identification and definition of a medication for the purposes of prescribing, dispensing, and administering a medication as well as for making statements about medication use.

Representing medications in the majority of healthcare settings is a matter of identifying an item from a list and then conveying a reference for the item selected either into a patient-related resource or to other applications. Additional information about the medication is frequently provided for human verification, but a full representation of the details of composition and efficacy of the medicine is conveyed by referring to drug dictionaries by means of the codes they define. There are some occasions where it is necessary to identify slightly more detail, such as when dispensing a package containing a particular medication requires identification both of the medicine and the package at once. There are also some occasions (e.g. custom formulations) where the composition of a medicine must be represented. In these cases, the ingredients of the medicine have to be specified together

Using codes and code systems https://www.hl7.org/fhir/terminologies-systems.html

Many elements in the FHIR resources have a coded value. FHIR mentions the WHO ATC Classifcation as one of the code systems that may be used in the system element of the coding data type.

6. SNOMED CT

SNOMED provides the clinical language that facilitates electronic communication between healthcare

professionals in clear and unambiguous terms, and can be used to code, retrieve and analyze clinical data. SNOMED is comprehensive and provides clinical terms for all healthcare professions. The primary purpose of SNOMED CT is to encode the meanings that are used in health information and to support the effective clinical recording of data with the aim of improving patient care.

SNOMED provides the core general terminology for electronic health records. These are all in English. NICTIZ acquired the National Release Centre of SNOMED. The aforementioned general terminology is currently being translated into Netherlands by NICTIZ, which is stimulating its use in the Netherlands. (see below: 5. NICTIZ)
As of today SNOMED is not being used for medication, as the Netherlands' "G Standaard" is used to share

7. NICTIZ (NICTIZ) and MedMij

NICTIZ is the Dutch center of expertise for e-health. The organization monitors eHealth trends and interprets them to establish Netherlands' national policies for all parties concerned. NICTIZ enhances interoperability in healthcare through the development of a framework for recording and sharing of information.
Amongst others NICTIZ formulated information standards for safe data exchange between healthcare professionals and patients in a Personal Health Record(PHR): MedMij. Companies offering a digital PHR may apply to qualify for the MedMij label, supplied by NICTIZ.
NICTIZ promotes the use of HL7 FHIR for data exchange in healthcare. They set up the SNOMED National Release Centre and are currently translating the SNOMED core general terminology into Netherlands.

8. Identification of Drugs by XIS/PHR in MedMij

In information exchange systems, the identification of a drug is expressed as a "product code": a code that determines a drug and that may be sent by a XIS and retrieved by a PHR. Below is a list of different types of such codes, amongst others the ATC code. It is not clear if ATC effectively will be used by a XIS/PHR – it might be more likely to be through a HPK, PRK or GPK.
Companies providing PHR's do not (yet) have a G Standaard license, meaning they might be able to retrieve and administer codes, but they cannot tell which ATC it represents.

According to the MedMij Standard, product codes for drugs that may be used in information exchange are the following

- GTIN International Article Number
- KNMP article number = ATKODE (2.16.840.1.113883.2.4.4.8)
- Commercial product code - Handelsproductcode (HPK)
- Prescription code - Voorschrijfcode (PRK)
- Generic product code - Generieke productcode (GPK)
- Anatomic Therapeutic Classification code (ATC)
- Name of substance - Stofnaamcode (SNK)
- Name of substance with way of application - Stofnaamcode i.c.m. toedieningsweg (SSK)
- SNOMED CT code
- 90.000.000 number (eigen code instelling) (OID van instelling)

Merely ATC and SNOMED are internationally used and accepted codes.
ATC (WHO) is freely available, SNOMED requires a license for use.
ATC coding was never meant to identify drugs. It does not allow for strength, dosage, way of application, combination with other drugs. SNOMED is more precise on these aspects, although few countries are using SNOMED's medication chapter (England, Australia en Singapore). In the

Netherlands there is no link between the national drugs database G-Standaard and SNOMED.
As mentioned above (2. ISO IDMP), international standards for drug identification are being developed. These standards are apparently available, but for the moment cannot be used in PHRs since there is no international database with drugs coded in the IDMP way. In the Netherlands this database already exists: the G Standard.

9. The G Standaard

The G-Standaard is the database of 40 years for drugs in the Netherlands, developed by the profession of pharmacists initially for their own use, and nowadays used by all parties in healthcare, including physicians, pharmacists, wholesalers, manufacturers, health insurance companies and the government.

The G-Standaard supports all kinds of processes in healthcare, like prescription, dispensing, ordering, reimbursement and professional decision support. Software developers use the G Standard to realise operability in (hospital)pharmacies and interoperability between pharmacies, GP's and hospitals.

The G-Standaard database contains all products dispensed by or used in the pharmacy:

- licensed drugs
- unlicensed drugs (e.g. raw materials and compounding preparations)
- vitamins and other nutritional products
- homoeopathic products
- medical devices

The database contains information on all drugs to support the logistic process in healthcare.
For the (un)licensed drugs, the database also contains a structured drug terminology and information for safety assessment decision support. Decision support is linked to the drugs and integrated in the process of prescribing and dispensing. For more information: https://www.knmp.nl/downloads/g-standaard/GStandaarddecisionsupportversionoct2011.pdf

NICTIZ participates in a European project for international exchange of (medication)information. NL has a "receiving" role in the project – information from abroad will be translated to G Standard database. ATC and SNOMED are possible identifying codes, and NL has opted to do a mapping on ATC.

10. ATC - classification following chemical substance

In the ATC classification system, the active substances are classified in a hierarchy with five different levels. The system has fourteen main anatomical/pharmacological groups or 1st levels. Each ATC main group is divided into 2nd levels which could be either pharmacological or therapeutic groups. The 3rd and 4th levels are chemical, pharmacological or therapeutic subgroups and the 5th level is the chemical substance. The 2nd, 3rd and 4th levels are often used to identify pharmacological subgroups when that is considered more appropriate than therapeutic or chemical subgroups.

The complete classification of metformin illustrates the structure of the code:

A	Alimentary tract and metabolism (1st level, anatomical main group)
A10	Drugs used in diabetes (2nd level, therapeutic subgroup)
A10B	Blood glucose lowering drugs, excl. insulins (3rd level, pharmacological subgroup)
A10BA	Biguanides (4th level, chemical subgroup)
A10BA02	metformin

(5th level, chemical substance)

Nomenclature

- International nonproprietary names (INN) are preferred. If INN names are not assigned, USAN (United States Adopted Name) or BAN (British Approved Name) are usually chosen.
- A Biological Qualifier (BQ) is not part of the INN and the introduction of a new BQ will not have any implication on the ATC code for the specific INN. Further information about the Biological Qualifier can be found here: http://www.who.int/medicines/services/inn/WHO_INN_BQ_proposal_2015.pdf?ua=1

11. Future developments

Seamless data exchange between patient and healthcare professionals still seems to be some way off. Hospitals are offering their patients access to their health records through personal health records, where they can see their conditions, diagnosis, results of lab tests and screenings, therapies and medication. Third party applications ("apps") offer ways for patients to monitor certain aspects of health like fitness, diet, heart rhythm, steps. Applications that enable patients to register their own medication and share this information with healthcare professionals are operational in many forms and formats.
The "uber-app" which patients will use to connect, retrieve and share everything with everyone they deem useful is not here yet. Still, developments sometimes take big leaps foreward once certain hurdles are taken. In the meantime there might be demand and room for a RareCare App, in order to help patients with rare diseases manage the access to their health records wherever they are.

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