Introduction

For this topic, it was important to look at what technologies are currently being developed in the Medical Technology sector. In an ever-expanding market it is important to look at what Is involved with bringing new technologies forward and the difficulties with regulations for newer and emerging technologies. This paper aims to examine the current state of Artificial Intelligence and Deep Learning Programmes, standards associated with medical devices (as devices are now capable of generating more and more data) and data regulations. This project aims to test the viability of machine aided diagnosis/artificial intelligence as a diagnostic aid through data mining software by creating an algorithm that can search through a database and mine relevant data concerning disease while examining the cause of disease.

Artificial intelligence defined in the Collins dictionary

“Artificial intelligence is a type of computer [technology](https://www.collinsdictionary.com/dictionary/english/technology) which is [concerned](https://www.collinsdictionary.com/dictionary/english/concern) with making [machines](https://www.collinsdictionary.com/dictionary/english/machine) work in an [intelligent](https://www.collinsdictionary.com/dictionary/english/intelligent) way, similar to the way that the human [mind](https://www.collinsdictionary.com/dictionary/english/mind) works. The [abbreviation](https://www.collinsdictionary.com/dictionary/english/abbreviation) [AI](https://www.collinsdictionary.com/dictionary/english/ai) is [also](https://www.collinsdictionary.com/dictionary/english/also) used.”

The aim is to write a code using computer software for coding languages Python/Spyder.

To create databases with different variables that can be/are associated with disease.

The programme could be used to look for patterns in family history of disease to try and predict possible health complications in later life. Considering variables such as age, family history, smoker/non-smoker, dietary choices (poor, balanced and extreme/unusual diet like vegetarian and vegan, referred to as extreme in the database, extreme meaning outside a normal balanced diet), activity levels, alcohol use.

AI can be used to help interoperate this kind of data at a much faster level. If done correctly it has the potential to be very useful for gathering and understanding data and information.

Data being defined in terms of AI as “Information that can be [stored](https://www.collinsdictionary.com/dictionary/english/store) and used by a computer program.”

Information in terms of AI; “Information consists of the facts and [figures](https://www.collinsdictionary.com/dictionary/english/figure_1) that are [stored](https://www.collinsdictionary.com/dictionary/english/store) and used by a computer [program](https://www.collinsdictionary.com/dictionary/english/program).”

This kind of technology is used very successful within social media and marketing campaigns as they can tailor advertisements based on a user’s inputs. (FIND PAPER) A programme that could do the same based on health information and history would be very beneficial in terms of saving time when compiling research into disease causes and treatments.

**Literature Review**

1.1 Formatting data in healthcare:

The Continuity of Care Document (CCD), associated with HL7 (Health level 7), is the standard when it comes to formatting information for medical use.

HL7 standards are produced by Health level 7 international. They are an international organisation that aim to provide standards and they work with other standardisation organisations like the ISO (International Organisation for Standardisation).

The 7 in HL7 stands for the seventh tier in the operating system, as per their website, Health Level 7 describes themselves and what do they as the following:

"Level Seven" refers to the seventh level of the International Organization for Standardization (ISO) seven-layer communications model for Open Systems Interconnection (OSI) - the application level. The application level interfaces directly to and performs common application services for the application processes. Although other protocols have largely superseded it, the OSI model remains valuable as a place to begin the study of network architecture.” (Health Level 7 International, 2018)

Standards are set by Standardisation Organisations so that all other organisation/companies/manufactures that wish to get involved have guidelines to follow.

In a paper called “Web services of transformation data based on OpenEHR into Health Level Seven (HL7) standards” they refer to the role of the HL& organisation and make it clear that while they set the standards they do not create the software :

“HL7 does not develop healthcare or hospital software application, but it only develops the concepts, methodology, specification, and standard, so exchanging data among different application is possible to be done.” (‘Web services of transformation data based on OpenEHR into Health Level Seven (HL7) standards’, 2017)

1.2What is a standard?

A standard is defined as: A level of quality or attainment. In terms of business it relates to a level of quality that must be met to consider a product or service fit for the purpose intended. Many standards relate to the Medical Technology sector and its various entities as outlined above HL7 is the standard for the transfer, processing and use of data and information.

A major Authority in regards standardisation for are the International Organisation of Standardisation.

On 23rd February 1947 the “International Organisation for Standardisation” or “ISO” was founded. Their headquarters are in Geneva, Switzerland.

The ISO works with 162 countries worldwide and their aim is set up global standards to promote trade between nations.

Their role is important, as standardisation means everyone is following the same documentation or guidelines regarding the provision of products or services.

As of November 2018, the ISO have set and defined over 20,000 standards ranging from food production to Medical Devices.

From their website the ISO outlines what they do and why they do it:

“ISO creates documents that provide requirements specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose” (International Organisation of Standardisation, 2018)

1.3 ISO standards for medical devices

ISO 13485:2016 Relates to the safe and regulated production of medical devices. Anyone wanting to make or produce a medical device for the market must adhere to ISO 13485:2016 for their products to be recognised.

Devices that do not meet the requirements out lined will not be permitted to sell their products as there are rules outlines by the ISO that must be followed.

The ISO does not enforce that their standards are met as this is up to the individual companies to make sure they are being followed.

From their website regarding Medical devices the standards set in ISO 13485:2016 are as follows:

"ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.” (International Organisation of Standardisation, 2018)

They state that all companies regardless of size or type of device they must follow the guidelines.

When it comes to medical devices it is important from a patient/user safety and for financial reasons that guidelines are followed.

If they are not it can lead to more problems down the line and patient/user safety must be top priority. If a company fails to follow the guidelines it can mean either a withdrawal of services for noncompliance and this could make trying to get into the market more difficult as any noncompliant devices won’t make it to market and any items that do that are found to be faulty (outside the specs) may have to be recalled which would cost a company time and money as well as damaging their reputation.

“If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to ISO 13485:2016 reflect any exclusion of design and development controls.” (International Organisation of Standardisation, 2018)

ISO 13485:2016 is the most current version of the ISO standards adopted in Ireland for medical devices and the full title of the document is:

And the number of the document is:

The standard number = I.S EN ISO 13485

Overseen by ISO, CEN & CENELEC

ISO: International Organisation for Standardisation

CEN: The European Committee for Standardisation

CENELEC: The European Committee for Electrotechnical Standardisation

In the document they state

“This European standard has been prepared under a mandate given to CEN/CENELEC by the European Union and the European Fair Trade Association to provide a means by which a manufacturer may demonstrate conformity and by which the Notified Body may assess the manufacturers conformity, with the requirements of the directive 93/42/EEC (as amended) on medical devices.” (International Organisation for Standardisation, 2016).

1.3 GDPR, Privacy and the use of data

As data regulations are strict and using real information may have been an ethical/legal issue, the information in this database has been generated randomly. The information provided in this database is to be used to show a proof of concept and so has been randomly generated to avoid this issue. However, as GDPR is relevant to this concept it is worth mentioning.

GDPR, General Data Protection Regulation. GDPR was introduced on 14th April 2016 and became enforceable on the 25th May 2018.

The following is the official guideline to GDPR as per their website,

‘One of the requirements of the GDPR is that, by using appropriate technical and organisational measures, personal data shall be processed in a manner to ensure the appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage. What is meant by “destruction” of personal data should be quite clear: this is where the data no longer exists, or no longer exists in a form that is of any use to the controller. “Damage” should also be relatively clear: this is where personal data has been altered, corrupted, or is no longer complete. In terms of “loss” of personal data, this should be interpreted as the data may still exist, but the controller has lost control or access to it, or no longer has it in its possession. Finally, unauthorised or unlawful processing may include disclosure of personal data to (or access by) recipients who are not authorised to receive (or access) the data, or as stated in Article 29 DATA PROTECTION WORKIG PARTY. In the official document they refer to themselves as “This Working Party was set up under Article 29 of Directive 95/46/EC. It is an independent European advisory body on data protection and privacy. Its tasks are described in Article 30 of Directive 95/46/EC and Article 15 of Directive 2002/58/EC. The secretariat is provided by Directorate C (Fundamental Rights and Union Citizenship) of the European Commission, Directorate General Justice, B-1049 Brussels, Belgium, Office No MO-59 03/075” ( (http://ec.europa.eu/justice/data-protection/index\_en.htm, 2017))

Under the guidelines set out in the GDPR documentation they have clear guidelines on what to do with a persons data and how data may be shared used.

“In order to use Data that would be protected under these guidelines data can be anonymised. According to the Data Protection Commissioner ‘"Anonymisation" of data means processing it with the aim of irreversibly preventing the identification of the individual to whom it relates. Data can be considered anonymised when it does not allow identification of the individuals to whom it relates, and it is not possible that any individual could be identified from the data by any further processing of that data or by processing it together with other information which is available or likely to be available.

‘There is a lot of research currently underway in the area of anonymisation, and knowledge about the effectiveness of various anonymisation techniques is constantly changing. It is therefore impossible to say that a particular technique will be 100% effective in protecting the identity of data subjects, but this document is intended to give guidance on identifying and minimising the risks to data subjects when anonymising data. In the case of anonymisation, by 'identification' we mean the possibility of retrieving a person's name and/or address, but also the potential identifiability by singling out, linkability and inference.” (https://www.dataprotection.ie/docs/Anonymisation-and-pseudonymisation/1594.htm, 2018)