*How an electronic system can generate and gather data, to profile people based on risk factors and lifestyle choices.*

Introduction

For this dissertation 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 will look at Artificial Intelligence (AI) and Deep Learning Systems, to generate questions and write them to databases to identify “risk factors” in a person’s lifestyle based on information provided by the user.

To try and gather information such as age, family history, cigarettes smoked, alcohol consumption. activity levels and compare the reported to the recommended.

With an system that can be taught different values and score the user based on the information they provide.

Computer systems are used every day and can be seen in many different varieties including audio and digital recording, photoshop, banking, email and other systems that can track and monitor a person’s walking.

This system will try to look at factors that can affect a person’s health and profile people based on their inputs. It will have a series of questions that a person can fill out and it can tell them if they are in danger of certain types of disease based on their lifestyles and habits.

It will focus on the following:

1. Diabetes
2. Coronary Artery Disease
3. Stroke/Heart Attack
4. Liver Damage
5. Risk of Cancer

Smoking for example, is never recommended, a healthy balance diet is recommended for every person and alcohol consumption should be limited. Diet and lifestyle play an important role in a person’s health. However, even with a healthy balanced diet and regular exercise there is always a risk of a person developing a disease. This system is intended to give people a baseline of what they need to change and in the future an system like this may be used to track and simulate disease and changes in a person’s health.

To use computer learning system as a predictor of future health.

This app will score a user’s answers into “Low risk” Medium Risk” and “High Risk” based on the guidelines provided by the Health Service Executive (HSE) and the World Health Organisation (WHO).

The Aim of the project:

The aim is to write a prototype system that will profile users based on the answers they provide. Research into disease and the causes of disease has been carried out and the questions are based on this research.

The scoring system will be set depending on the input for example a question like do you smoke will register a score of 1 if true and 0 if false. The next question then will be how many do you smoke? if the answer is 1 cigarette the score will be 0 (the lowest score) if the answer is between 2-10 the score will be (1) and if the answer is 10+ they will receive a score of 2. These answers will be tallied up at the end to decide if a user is low medium or high risk based on their answers. While one cigarette a day is a mild addiction these people would be at considerably less risk than a frequent smoker.

It is being developed as a prototype to gather and generate data but the same type of system could be implemented as a pre-assessment for hospital dissertation. It could have questions, be set up for internet access and to comply with HL& standards, however this is not the project for the moment it is just a different concept for this idea.

As this is a prototype it is setting the way for a bigger idea of this kind, if a team of software developers were to work with specialists in a filed eg, a cardiologist to write the questions and scores based off their knowledge and expertise in the subject.

Literary Review

For this dissertation, literature on the following topics were researched and explored.

Starting with search terms such as Artificial Intelligence (AI) & Computer Sciences, Deep learning systems, Data mining, Standards and Accreditation, Electronic Health Records, General Data Protection Regulations (GDPR) and patient privacy (autonomy) and building from there.

From here it was important to look at the diseases mentioned above to find signs, symptoms and causes

One of the main topics is Artificial intelligence and the term Artificial Intelligence belongs to a broad spectrum. Exploring AI from an early concept to present technologies.

Artificial Intelligence

Artificial intelligence as 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.” (Collins, 2018)

The aim is to write an system using computer software for coding languages Python/Spyder.

To create questions and different variables that a user can interact with.

The systemme could be used to look for patterns such as 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, unusual meaning outside a normal balanced diet), activity levels, alcohol use.

For example, a person suffering from heart problems can have their data analysed to check for a pattern to see what may be causing the problems. A person with a heart condition can have their data checked against other people who have the same condition, again to look for more patterns and similarities such as their diet and any family history of the disease.

AI can be used to help interpret 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.

The definition of data according to the Collins dictionary, in terms of AI;

“Data is information that can be [stored](https://www.collinsdictionary.com/dictionary/english/store) and used by a computer system.” (Collins, 2018)

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 [system](https://www.collinsdictionary.com/dictionary/english/program).” (Collins, 2018)

This kind of technology is used very successful within social media and marketing campaigns as they can tailor advertisements based on a user’s input. An system 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.

Artificial Intelligence was spoken about as early as 1967 in a book called “The Shape of Automation for Men and Management”. This book speaks on topics relating to the distribution of work and how automation can help to distribute work more evenly. This paper refers to the fears people had at the time concerning automation. Meaning they feared automation as it would reduce the amount of available work. This however, is not true as automated services in many cases still need an operator to make sure a process will work, and that should any problems occur an operator is able to resolve them. As discussed in the book above it remains the case today that while the nature of work is changing and requiring people to “upskill” or re-train in areas that are becoming more automated.

Machine intelligence refers to smart systems in a computer/machine and includes automation. Robotics is a good example of AI but for this paper information systems and deep/computer learning is the focus. This will help examine the current state of AI.

Artificial Intelligence had seen large advancements by the 1980’s-2000. A paper written by David Welham explores how AI can benefit training and support. The abstract from his paper Welham states that:

“Since the beginning of the use of technology to support training and learning there has always been the belief that such new technologies would be able to add value either by reducing costs or increasing effectiveness. The 1980s and early 1990s were a period of enormous optimism as to the promise that such technology could bring. The governments of Europe and the US were generous in their funding of research in this area. In Europe research and development system such as ESPRIT, DELTA, RACE, ERASMUS and COMETT, to name only a few, funded a wealth of initiatives aimed at advancing the use of technology. At the margins of the early initiatives was the belief that AI must have a part to play in these developments. This paper reviews the early initiatives and suggests reasons why the potential for the use of AI in education and training has never been truly fulfilled.” (Welham, 2008)

This is a good example of what people may want to be achieve through AI systems versus what has been achieved but this paper is still a few years old. The results found that training can be achieved through AI but was not a cost-effective means to deliver training. The problems faced at the time this paper was published included a lack of memory available to a machine or system as well as computers not being as “mainstream” at the time, meaning computers were not as fast or available compared to the technologies we have today with an explosion in technology and the growth of the internet.

Deep learning & AI

Deep learning, regarding Artificial intelligence systems, refers to a computer’s ability to work with the data we feed it, interpret it and make decisions based off this information.

One such papers relating to this topic c called “Artificial intelligence for analyzing orthopedic trauma radiographs: Deep learning algorithms--are they on par with humans for diagnosing fractures?” (OLCZAK et al., 2017)

This paper researches diagnoses via the use of deep learning, although this paper is from 2015 it is one of the most recent papers that are available. This paper was written to compare AI against humans for diagnose based on medical images of fractures in patients. They proved that with up to 80-90% accuracy, their code could process images and make a diagnosis.

Their testing was accurate as the only images they report not being usable were due to poor image quality or uncertainties.

They only tested against two Senior Practitioners. Having more senior members being tested against the AI may have altered the data, but for the purpose of their experiment it worked.

They were able to tell their system what to look for and how to categorise the images it was presented.

The term rubbish in rubbish out is true when it comes to AI and machine learning. The paper above showed that when AI is given a purpose and clear set of demands and rules it can function as good as a human.

Another paper focused on the use of data mining to improve customer satisfaction in public transport.

Written by Ma and Capri they describe what their system does as:

“Data mining techniques use a broad family of computationally intensive methods that include decision trees, neural networks, rule induction, machine learning and graphic visualization.” (Ma and Capri, 2014)

This paper showed how broad and sophisticated it can be to gather and interpret data. Their study was based on the population of Beijing.

GDPR, Privacy and the use of data

When looking to use and interpret people’s data it is important to consider General Data Protection Regulations (GDPR)

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 any other form of processing which violates the GDPR’ 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” (Data Protection Commission, 2018)

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

General Data Protection Regulations, is the right to own your information. Information regarding one’s self cannot be shared or used without prior written consent (Personal Data). This means that companies that may want access to a person’s data cannot gain access without authorisation and cannot share this information for any reason or purpose.

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.” (Data Protection Commission, 2018)

To bypass this a person would have to give consent for their data to be used, be able to enter their own details if they wish (or their GP could do so with written consent) into a database that could be linked up with Electronic Health Records, that could all be stored in one place, where medical information can only be accessible by an account number, as well as GP details (GP name and address of GP office) to protect personal data but still be able to enter medical data. This also ensures that the data will be relevant/accurate as if it is entered in a GP office it can be verified as it is entered.

Data intended for the use of study and analysis would have to be anonymised to protect a person’s right to confidentiality and for the benefit of studies as data such as name and address might not be useful. In order to deal with this issue a warning will appear in the system stating that by using the system, the user gives consent. This leads to the topic of Health informatics and Health Level 7.

Health Level 7

One of the biggest contributors to health informatics and relating interoperability is Health Level 7 (HL7). HL7 sets the standards for the interoperability and transfer of information between healthcare systems. On their website they state that they focus on the 7th tier of Open Systems Interconnection (OSI).

"Level Seven" refers to the seventh level of the International Organization for Standardization (ISO) seven-layer communications model for Open Systems Interconnection (OSI) - the system level. The system level interfaces directly to and performs common system services for the system 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)

Interoperability is an ongoing problem within healthcare as many different types of machines can generate and store data.

An Electro Cardio Graph machine (ECG) for example can take and monitor a person’s health rate and vital signs while electronically storing this information.

If this information could be sent to a different server/database that relates to a patient, it could prove useful in the future for checking previous vitals against current to see if overall health has changed much. If a person’s heart rate is higher or lower than their previous reading it could be stored in the database and be attached to the patient profile for future analysis.

Clinicians could look for different heart rates and patterns to keep an overall profile on the condition of a person’s heart, the same could be done for blood pressure, lung capacity/function, glucose level, weight and heart rate.

This idea ties in with the Electronic Health Record but in a bigger scope. If every detail of a person’s medical history is recorded and stored in one central location It could prove useful in providing diagnoses and looking for causation into diagnoses as a bigger profile can be built electronically.

The biggest problem is interoperability. The system being created could be developed in the future to have different extensions added in so that no matter the source of the information the system will be able to sort through it and convert it into a useable function (to meet HL7 standards).

For this dissertation the focus is to have an system that can ask questions of a user and store that information to give out a reading of risk factors and if further developed could be integrated into a healthcare system in a hospital. Another use of this type of system would be for pre-assessment in a hospital. If developed into a tablet/portable electronic device it could speed up the sign in process in a hospital, instead of nurses carrying large files for each and every patient, the information stored electronically could be recalled on demand.

ISO 13485: Medical device standards

If this system were to be developed further for use in a “portable device” or for use within a hospital/GP setting, then it would need to regulated and standardised. It would class as a medical device and so would fall under the guidelines set out in ISO 13485

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 will not 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)

The problem with diabetes is a person is either born with it as type 1 as it is hereditary or they develop it over time due to poor diet and lack of exercise, this is known as Type2.

On the website “Diabetes Ireland” they state the following on the disease:

“The term ‘diabetes’ means excessive urination and the word ‘mellitus’ means honey. Diabetes mellitus is a lifelong condition caused by a lack, or insufficiency of insulin. Insulin is a hormone – a substance of vital importance that is made by your pancreas. Insulin acts like a key to open the doors into your cells, letting sugar (glucose) in. In diabetes, the pancreas makes too little insulin to enable all the sugar in your blood to get into your muscle and other cells to produce energy. If sugar can’t get into the cells to be used, it builds up in the bloodstream. Therefore, diabetes is characterized by high blood sugar (glucose) levels.” (Diabetes\_Ireland, 2019)

In Type 1 Diabetes the body reacts to and destroys beta cells in the pancreas. These cells are used to produce Insulin and regulate the amount of sugar in one’s blood. A person suffering from type 1 will have to rely on insulin injections for the rest of their lives so that their body can regulate their sugar levels.

People with Type 2 don’t react to insulin as well as they should and in later life do not respond well enough to the levels they do produce. This leads to chronically high levels of sugar in the blood

Diabetes may go undetected for up to 12 years with a person showing no signs or symptoms.

In an attempt to stall the onset of diabetes amongst young people in Ireland the Irish government introduced a sugar tax, which came into effect on the 1st May 2018.

In an article published by the Irish times it states:

“It is aimed at tacking spiralling rates of obesity and will see the price of some popular drinks increase by as much as 60 cents for a two-litre bottle. The thinking is that higher prices will lead to lower consumption, and not only will people be incentivised to opt for healthier drinks, but the soft drinks industry will reformulate products to reduce the added sugar content and therefore the tax.” (Pope, 2018)

The tax was introduced to try and combat the growing rate of obesity seen in Ireland over the last few years. The world has seen a rise in the rates of obesity with the leading country being the United States of America, however almost every Western country is seeing a rise in rates of obesity. Below is a graph of obesity over time based on different countries.

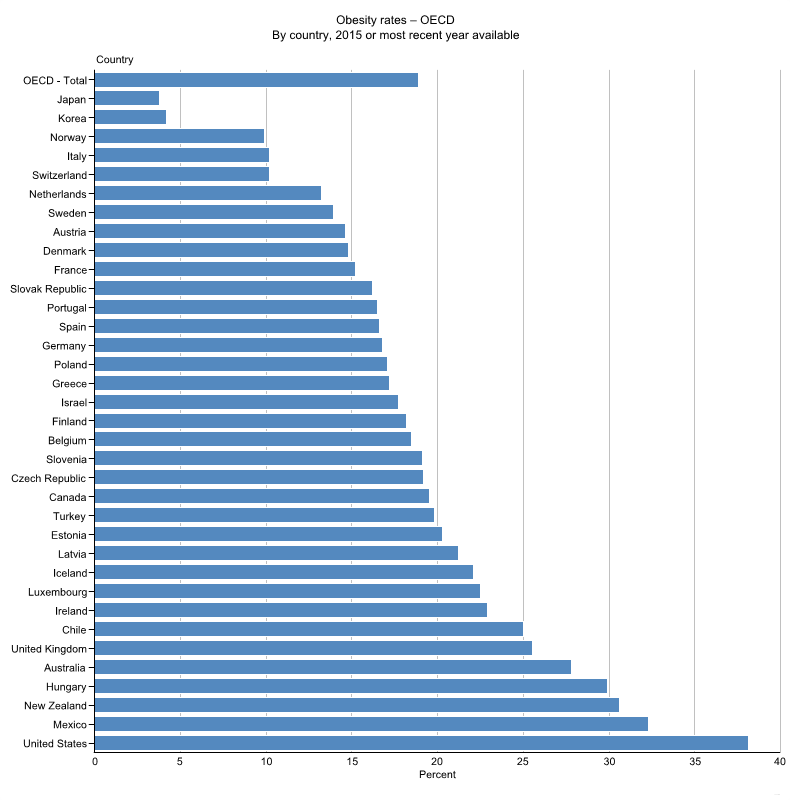


Figure 1. Diabetes by country

High consumption of sugary foods and takeaway food consumption is also linked with Type 2 Diabetes and Coronary Artery Disease (CAD). A study conducted on school children aged from 9-10, based on their weekly takeaway consumption has shown an increased link with Type 2 Diabetes, poor nutrition and CAD.

The result of the paper state the following:

“Among 1948 participants with complete data, 499 (26%) never/hardly ever consumed a takeaway meal, 894 (46%) did so <1/week and 555 (28%) did ≥1/week. In models adjusted for age, sex, month, school, ethnicity and socioeconomic status, more frequent takeaway meal consumption was associated with higher dietary intakes of energy, fat % energy and saturated fat % energy and higher energy density (all P trend <0.001) and lower starch, protein and micronutrient intakes (all P trend <0.05). A higher frequency of takeaway meal consumption was associated with higher serum total cholesterol and low-density lipoprotein (LDL) cholesterol (P trend=0.04, 0.01, respectively); children eating a takeaway meal ≥1/week had total cholesterol and LDL cholesterol 0.09 mmol/L (95% CI 0.01 to 0.18) and 0.10 mmol/L (95% CI 0.02 to 0.18) higher respectively than children never/hardly ever eating a takeaway meal; their fat mass index was also higher.” (Donin *et al.*, 2018)

Both diseases are preventable with proper diet and activity levels. However, type 1 disease as mentioned above is hereditary and is caused by genetics.

Both types of diabetes effect a person’s insulin levels.

The system will do the following:

* Flow/State Diagram
* UML Class Diagram
* DataBase Diagram

IF YES

While

“Finished” == False

**Start**

Finished =True

Write Patient to database

If No

If Yes

If there are any questions left

Update Field in “Patient” Class

Answer Valid

Validate Answer

Not Valid

“Print not valid Try Again”

Enter Answer

Print Question [i]

IF NO