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Challenges and Opportunities when Collecting or Generating Data for Digital MDs

Pat Baird, Philips

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Need more than Data, we need Knowledge

We live in an era of DATA. We are generating over 3.5 quintillion bytes of data every day. That is over 3,500,000,000 gigabytes! Per day!

However, to build safe an effective products, we need more than data – we need a good understanding of what that *data does mean* and *does not mean*. We need more than data, we need context, we need knowledge.

Source: https://wpdevshed.com/how-much-data-is-created-every-day/

Does the Data tell the story you think it is telling you?

I was talking to an owner of a McDonald's restaurant and he had an interesting story about data. He was curious about how many customers ask for a cup of water. Normally, he can get a report from the cash registers about how much of a certain product is sold every month, but since water is free, it did not show up on the sales summary for the month. His restaurant didn't sell fish sandwiches, so he asked his employees to use the "Fish Sandwich" button whenever some asked for water.

After doing this for a few weeks, he started receiving a shipment of tartar-sauce packets from McDonald's supply – they automatically send shipments of things like napkins and paper cups and straws and sauce based on sales, and they saw that he was selling a lot of fish sandwiches so they sent him sauce to help him out.

How does this apply to us? I know of several instances where the patient had a certain medical condition but their insurance would not cover treatment. So the physician lied on their medical record because the insurance would give treatment for this other condition.

Examples of Data without Knowledge

At a previous company, I was involved in product support and analysing postmarket data. One of the data sources was to look at sales of replacement parts to hospitals – sometimes as hospital would repair a device but not tell the manufacturer that something failed, so we looked at parts replacement orders as a quality indicator.

I noticed that a few hospitals had a sudden increase in buying parts in November and December. I thought it was perhaps related to the weather becoming colder in the winter – but the parts ordering was back to normal (or even lower) in January and February.

I reached out to one of these hospitals to ask what is causing the higher rate of failures – their response was that their yearly budget is “use it or lose it” – if there is any money left in their budget, they use that money to buy more parts, otherwise management would take the money back.

Examples of Data without Knowledge

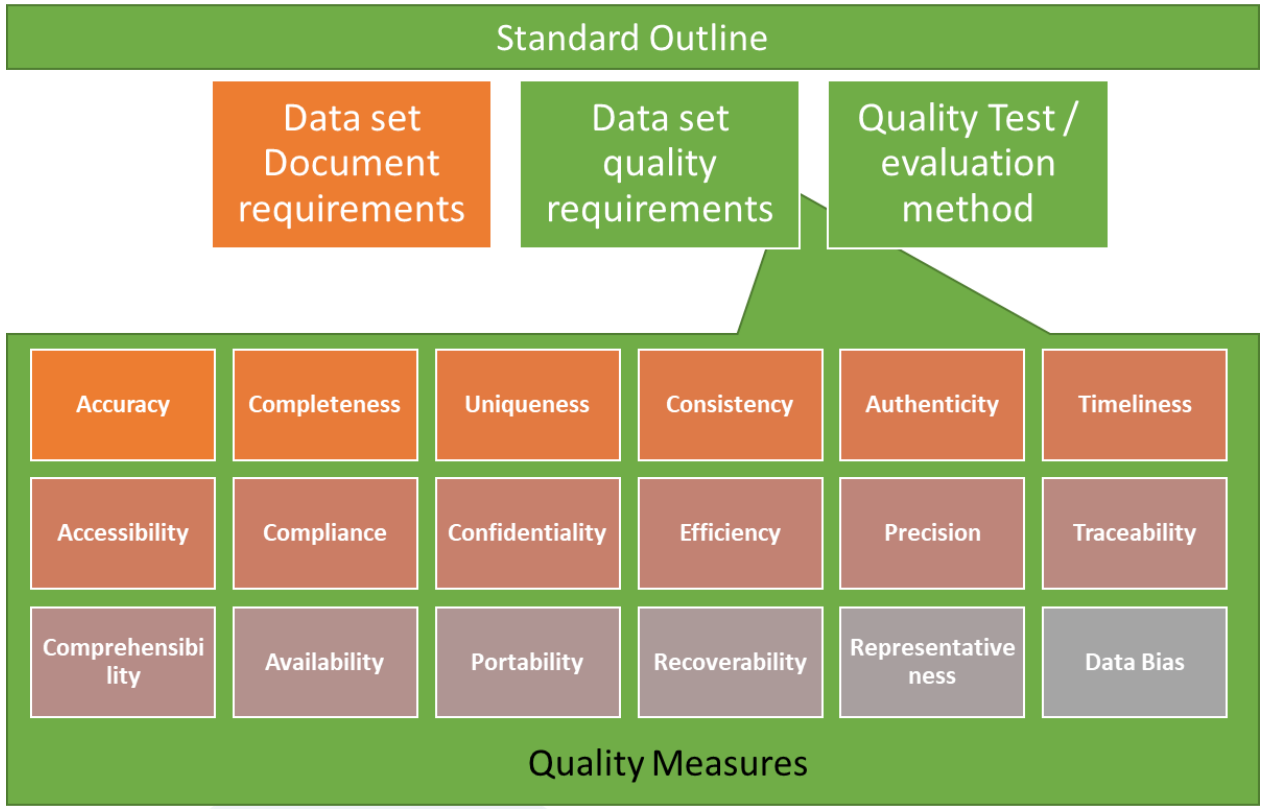
There was a ML system trained to help pneumonia patients get the right kind of treatment, based on risk. Because patients with asthma are high risk when they get pneumonia, healthcare providers treated them more aggressively.

This led the software to conclude that asthma patients must be low risk, because their survival rate is much higher.

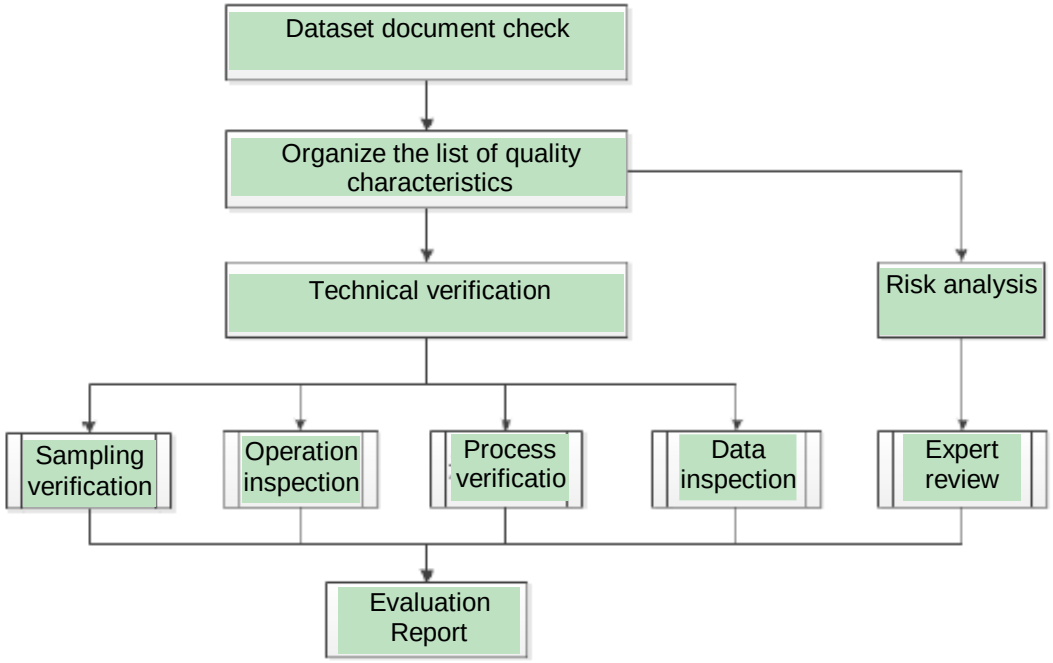
The software looked at data, without knowledge, and came to a conclusion that is opposite of reality.

Quality Management of Dataset

People realize that data quality is important and there are standards that have been developed or are being developed to try to address the quality of the data. Below are some examples from *IEEE P2801 Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence*



18 Quality Measures for Data set



Dataset Evaluation Process

It should be noted that for systems that continue to learn, the new data needs to follow the same quality requirements.

Challenge: Conflicting Needs

Data quality is a key point of pre-market reviews, is mentioned often in regulatory guidelines, and is the subject of many standards. One of the challenges that we see across the world is the conflicting needs of high quality data vs. ensuring data privacy. We might not be able to properly develop and tune ML models because of this conflict.

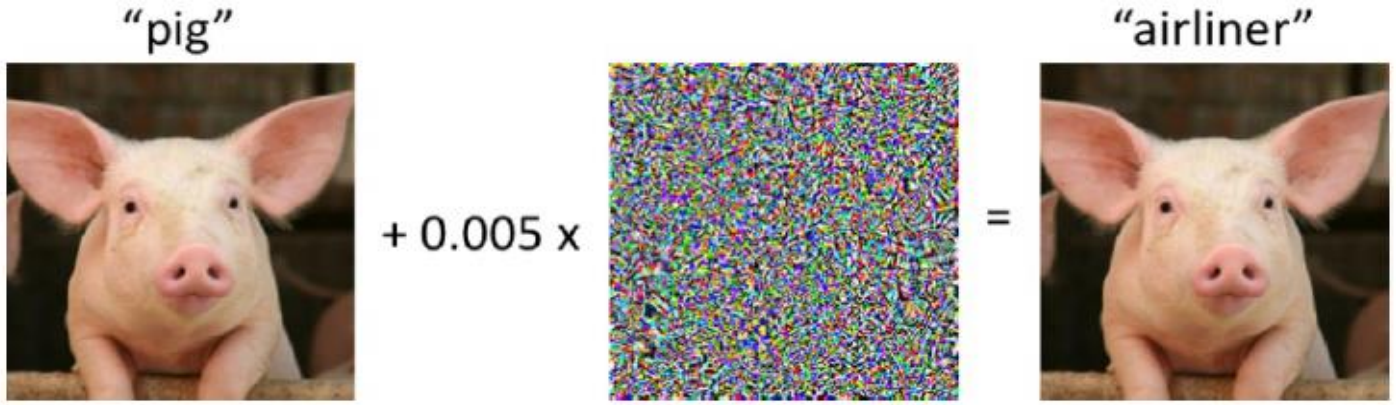
This could affect system performance by failing to identify factors that impact a patient's risk, because those factors have been removed from the data. Even if it is legal, some hospitals are reluctant to share their data with manufacturers due to security and privacy concerns.

There are also export restrictions on patient data which can make it difficult since ML software often runs on remote servers.

Challenge: Cybersecurity

ML systems have a lot of data. Potentially very attractive data. This data is often handled by multiple stakeholders as it is passed from one system to another.

Due to the nature of how ML systems work, it might not be obvious that there have been a security issue.



“Example of adversarial perturbation used to evade classifiers”;
Draft NISTIR 8269 A Taxonomy and Terminology of Adversarial Machine Learning

Opportunity: More Data!

As previously mentioned, we have a lot of data, and it is rapidly increasing. With the introduction of wearables, we have even more data. It is estimated1 that there will be 41 billion connected IoT2 devices generating 79 zetabytes of data (79 trillion gigabytes) by 2025. https://www.idc.com/getdoc.jsp?containerId=prUS45213219

This is a very attractive amount of data for developers – there are many different types of analysis that can turn data into evidence.

Regarding wearables – it should be noted that someone's normal heart rate, body temperature, and other key signals vary from person to person, and there have been studies where data from a wearable was able to successfully identify early stages of a disease – much earlier than waiting for the aggregate triggers that have been set for the entire patient population.

Need for Collaboration

Several years ago I was in a meeting where we were developing a standard about medical device interoperability, and we spent over an hour arguing about the phrasing of a single sentence. I then realized that before we can get *machines* to talk to each other, we need to be better at getting *people* to talk to each other.

I think there is a similar lesson here – before we can be successful in *artificial* intelligence, we need to create and sustain a forum to share our *collective* intelligence.

What assumptions do we share and what advice do we have for the developers?

THANK YOU / QUESTIONS

Pat.Baird@Philips.com

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