Centralized Health Databases: Lessons from Iceland*1

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[Slide 2] The Iceland is exactly the size of the State of Ohio in the United States. 102,000 km^2 to be compared with around 380,000 km^2 of Japan. As you can see, the population is dispersed along the coast because the inlands are mostly highlands and glaciers. We also have volcanic eruptions every 5 years on average, some of them are small, but others are of international proportions. I would like to give you some figures in the demography and history of the country, which are relevant to these issues.

[Slide 3] The population is small as you can see; 320,000 individuals, and 8% are foreigners. It was one of the last countries in the world to be inhabited by humans. First colonists arrived around the year 850, and there were no inhabitation of any kind before that time. The origin of the colonists was believed to be mostly Norwegian, but it was later confirmed by DNA testing that they came both from Norway and the British Iles. Some of them were married and already brought their wives with them, and others who

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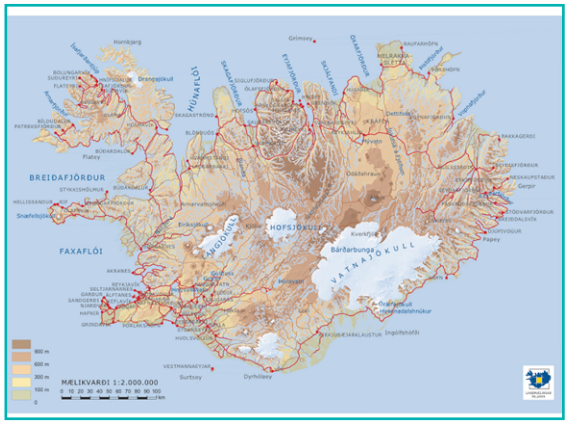

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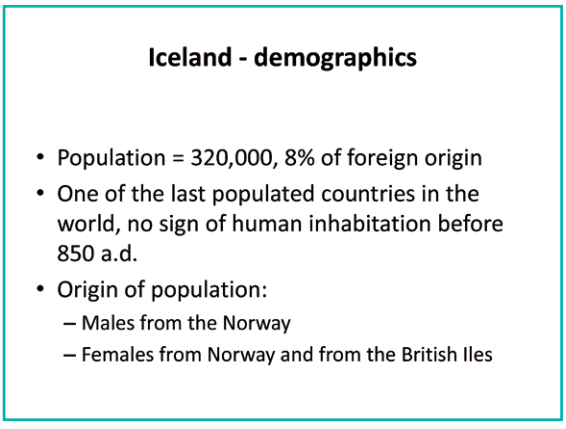

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*1 This article is based on the lecture at the JMA Conference on Medical Information Technology held on February 8-9, 2014.

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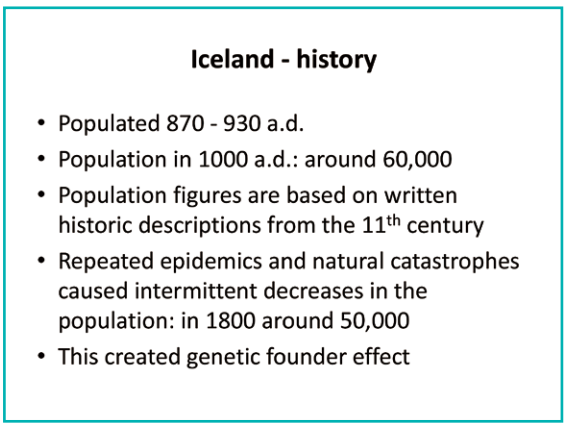

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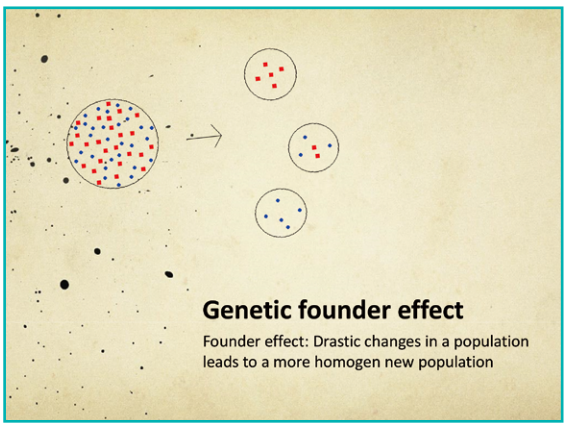

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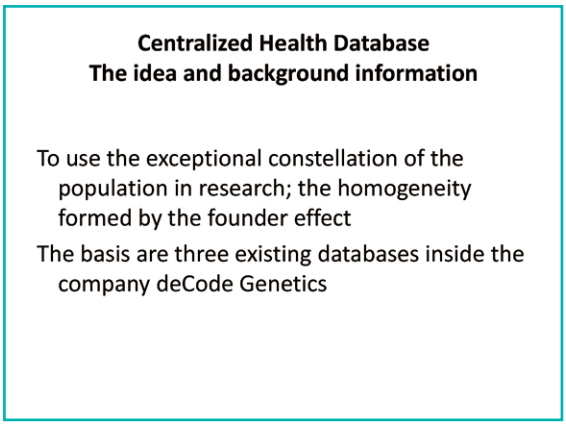

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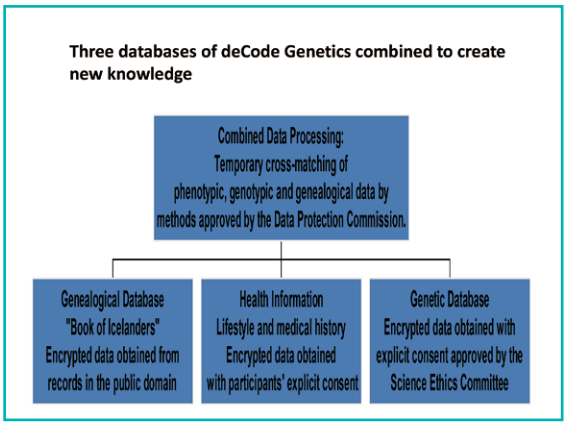

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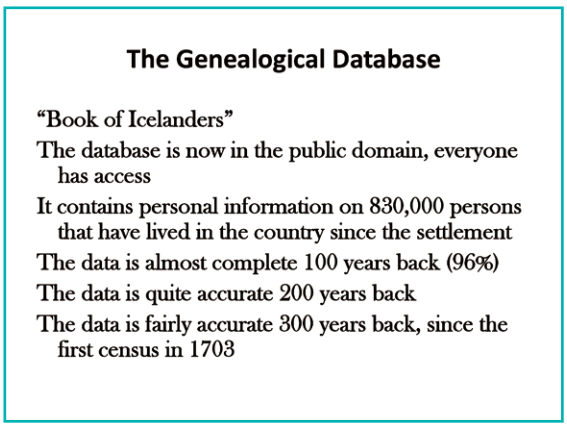
were single captured females from Norway and the British Iles and brought them to Iceland.

[Slide 4] The history of the country, as you can see, is short. It was inhibited during the times of 870 to 930. The populations around the Year 1000 was 60,000. Since then, there were many difficult times for centuries, and I would like to dig a little deeper on that.

We have evidence of natural catastrophes and epidemics on several occasions for centuries, and the population was diminished by 25-30% each time. So, the population at around 1800 had not increased a bit since the original inhabitation. This created what is scientifically known as a founder effect. **[Slide 5]** When a population of humans or other animals is hit by a catastrophe, the population size diminishes significantly. When it happens repeatedly, the population experiences a founder effect, making the population more homogeneous that it originally had been.

[Slide 6] This is the basis of the idea of the *centralized health database* (hereinafter referred to as the CHD)—to use the exceptional constellations of the population in research, and to use the homogeneity formed by the founder effect that is very specific in this country. The basis for this was the existing database inside a private company called the deCode Genetics, which still exists as one of the biggest genetics research facility into the world.

[Slide 7] Inside the company, they established 3 distinct databases, which I will describe further. These databases can be linked—technically. However, they are under strict supervision by the data commission. The situation inside the company has not created any problems because they have been working with the Ethical and Technical Commission, and later with the Data



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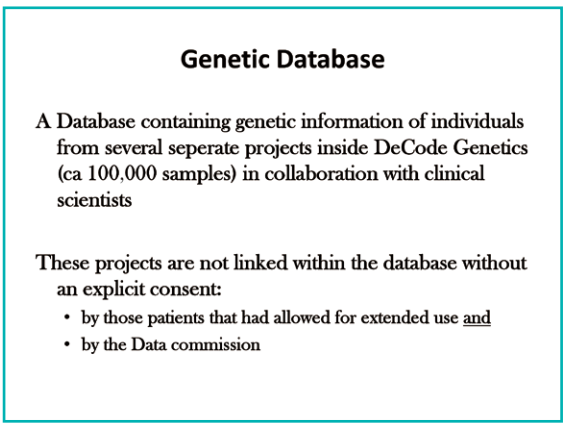

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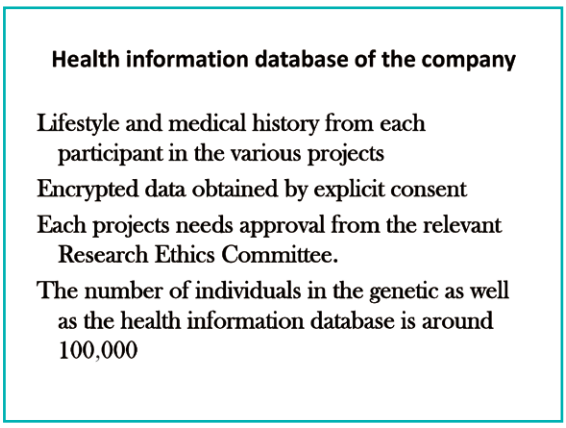
Protection Commission and the Science Ethics Commission. So there were no problem in this regard, and many research facilities and companies follow the same procedure more or less.

I will now describe specific databases in more details. **[Slide 8]** The genealogical database contains not only all living individuals in the country, but also the information dating 1,000 years back that we have access to. We have almost complete population data for the 20th Century. The data are quite good 200 years back, and fairly good 300 years back since our first nation-wide census conducted in 1703. This population data book is called the *Book of the Icelanders* and is open to the public; you can create an account and see to whom you are related. However, you are only able to look up from your own perspectives. You cannot look up 2 separate individuals to see if they are related; so you can never be a third-party. One novelty that came out of this is a software application for mobile phones, which became very popular among young people as a small entertainment in the evening hours to see who you are related to. Although it was not the initially intended use of the data, the application became very popular. So, this database became very popular in research, both inside and outside the deCode Genetics.

[Slide 9] The next database is all about genetics. The company has in-house samples from about 100,000 citizens, which covers roughly 1/3 of the nation. There is a statistical technique called imputation, which can be used in 2-steps. You can use it by having information for the whole gene sequencing from an individual and extrapolate into other individuals whom you only have limited amount of genetic information, a blood sample for example. This is the first step, and imputation in this manner is quite secure; it is around 99%. The second step of imputation is to use, again, the whole gene screening of an individual, and using that information along with the genealogy of an individual of known relationship, and through imputation you can obtain the genetic constellation of the second individual who is not participated in the research. This is now debated in our Parliament regarding a new legislation allowing or not allowing this to happen. The projects that use this genetic database is supervised by the Data Commission and the Ethics Committee, so the use of this genetic database does not cause any problems.

[Slide 10] The third database contains health information provided by the individuals participating in specific research projects. They gave explicit consent as well as bio-samples and blood samples, along with their general information. This, too, does not cause problems because it is inside the framework of the Data Commission and the Ethics Commission. However, when it comes to the CHD, a problem arises.

[Slide 11] The idea of the CHD was first presented in 1998. The idea was to extend the database inside the deCode Genetics to incorporate all health information of every citizens. The company presented the idea to the Department of Health with political backup. The politicians worked for a speedy process inside the parliament and presented a proposal for a new legisla-



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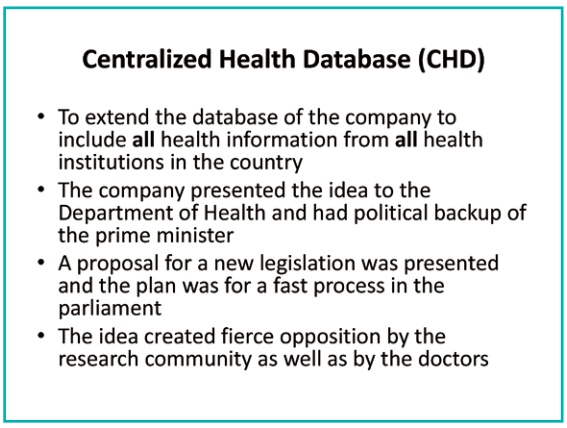

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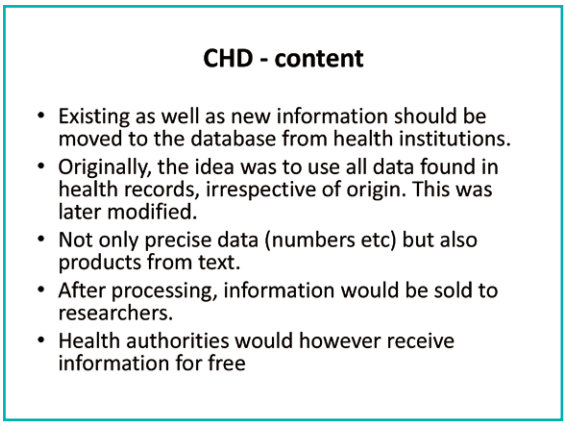

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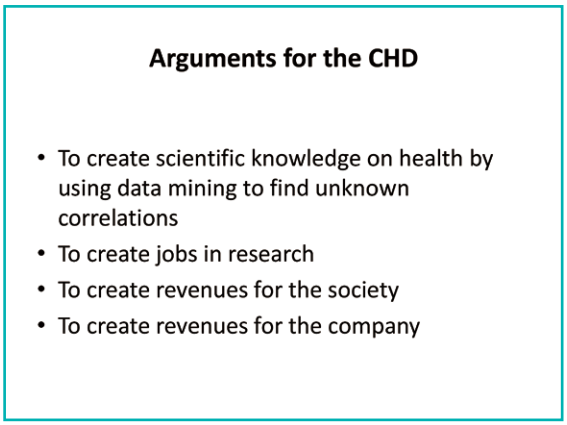

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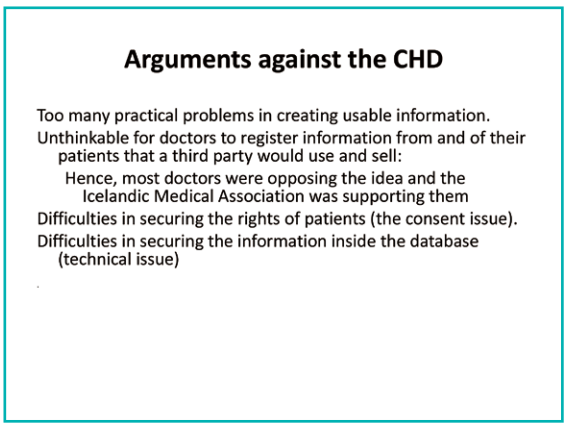
tion in the spring of 1998. However, their plan did not work due to the fierce opposition by doctors and research committees in general.

[Slide 12] In the proposal of the CHD, both the existing and future information will be transferred from health institutions to the CHD. Some of the information at that time were already stored as electronic data, but others were still paper-based. The original idea was quite far-stretching, attempting to put all information from heath records—not only the accounts of doctors but nurses or social workers, and even hospital priests. But soon, those who proposed the idea realized that the idea was not practical, and during the next 6 months, some changes were made.

The idea was not only to enter numbers, but also to produce *products* from *text*. After processing inside the database, pieces of information can be sold to anyone who is willing to purchase and meet the standards. That was to be accounted for by independent regulatory committees. One of the most notable event was that the Minister of Health expelled the existing Ethics Committee and produced a new one—so the debate extended to the worlds of research, ethics, and politics. One of the ideas was for the health authorities to have free access to the information; they already had plans of a mutual health records for the whole population.

[Slide 13] There were some arguments supporting the CHD. It would create scientific knowledge on health by using various data mining to find unknown correlations. It will also create jobs in research communities. It will create revenues for the society, which was one of the most popular arguments for the CHD. The deCode Genetics, of course, will gain revenues



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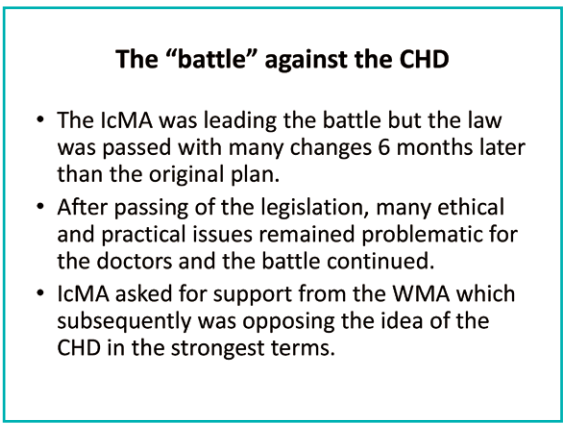

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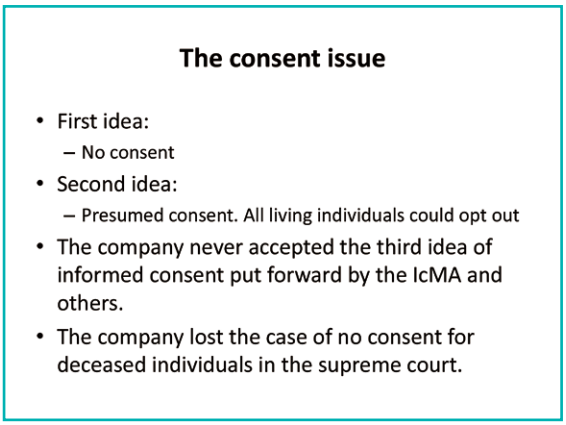
from the CHD, but this point was not put forward very much in the debate.

[Slide 14] There were also arguments against the CHD. There were too many problems in creating useful information. It was quite unthinkable for most doctors that their patients' information will be sold to third-party companies by a private company every time they see a patient and put information in his/her record—just unthinkable for the majority of them. So, those doctors fiercely opposed the idea through the Icelandic Medical Association (IcMA). There were, of course, the issue of informed consent since it would be difficult to secure the right of patients. There were technical issues as well since it would be difficult to securely store only correct information inside the databases.

[Slide 15] So, the battle started. We managed to delay the legislation by around 6 months, and the bill was changed drastically from the original plan. But still, the bill passed, leaving many ethical and practical issues unsolved. So, doctors were not confident of its implementation. The IcMA sought support from the WMA, this topic received serious consideration inside the WMA. In meetings after meetings, committees and workgroups were presented with this issue, and both the president and CEO of the WMA visited Iceland twice. The effort continued for 4 years, until the WMA adapted the *Declaration on Ethical Considerations regarding Health Databases* in 2002.

[Slide 16] Allow me to review the informed consent issues. The deCode Genetics' first idea of consent was not to require any consent, but



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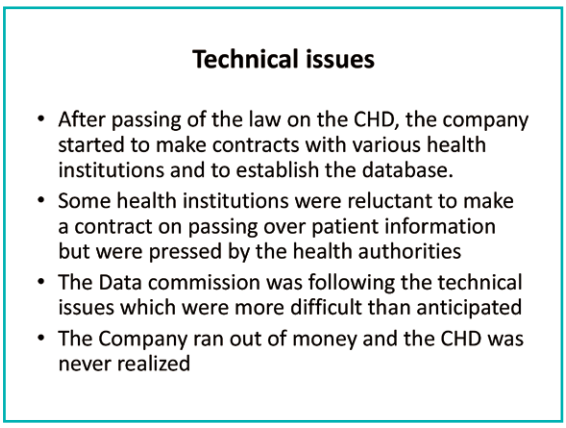
it was then changed to presumed consent for the living individuals. The company never accepted the third way of informed consent put forward by the IcMA and others. Then, the company run into a problem. A daughter to a deceased father took the case to a court, claiming that she should be asked whether or not her father's information should be entered into the database. She won the case in the supreme court, which meant that there is a serious issue in accessing the information that were collected from deceased relatives of living individuals, which are already contained in the database. That was a huge blow for the company.

[Slide 17] There were also technical issues. After the bill passed, the company started to make contracts with various health institutions in order to establish the database. Most of them participated, but some that were reluctant were



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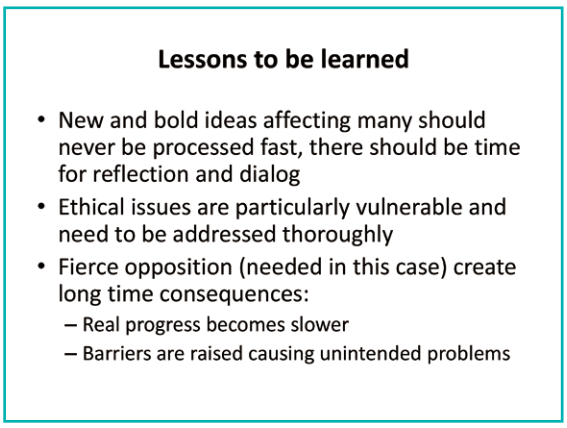

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pressed to participate by the health authorities. The Data Commission worked hard to find an acceptable technical solution. But these technical problems were not resolved after 2 years, and the company run out of money. So, the CHD in Iceland was never realized.

So, this is what happened in the past. Now, let me talk about the lessons to be learnt. **[Slide 18]** New and bold ideas affecting many should never be processed fast; there should be time for reflection and dialog. Ethical issues are particularly vulnerable, and need to be addressed thoroughly. Fierce opposition, as in this case, creates long time consequences. Real progress in the technical field becomes slower because there are so many obstacles standing on the way. Barriers are raised causing unintended problems.

[Slide 19] Ethically, there are considerable ethical issues creating and using big health databases, and I know that this has been the main topic of this seminar in the last 2 days. It is extremely important to create a balance between patients' rights for consent/information and practical issues. Sometimes, practical issues tend to override patients' rights—but we need to realize this tendency and be aware of the balance. This was an issue in my country 12 years back, but it is a hot issue today in some other countries. For example, the UK government has plans on population-based health information databases. In Denmark, there are several nationwide databases covering many deceased individuals, and the government now has a plan to combine these databases for the purpose of creating jobs and selling the information. Most important of all, people need to be able to trust the safeguards and use of health data. We must not forget that it is easy to lose trust but difficult

to regain it.

[Slide 20] Lastly, let me summarize the situations in Iceland 16 years after the CHD was proposed. It was 1998 that the CHD was planned, and it is now 2014. The CHD was never realized. Actually, there were plans in 2007 or 2008 to reinstate this 10-year old idea, but in another form. It was not realized because of the economic downturn, but the plan is still there, and it will be reinstated in the coming years. In my country and some neighboring northern countries, it seems that data protection in the health service is stronger than in other sectors of society, always creating problems and complicating a process. However, we also see that some databases have a firm ethical and technical basis. There are quite many of those, and they were not questioned.

Databases are very strong tools for research. But we must handle with care!