A study of quality assurance and quality management within the logistics of Covid-19 vaccines

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Agenda
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- Reasoning behind the study
- The virus, disease, pandemic, and vaccine
2. Our laboratory examinations
3. Quality assurance (QA) and quality management (QM)
- Reference information and requirements
- Application of QA and QM
4. Discussion
5. Conclusions

Reasoning behind the study: The need for personal decisions and measures as a quality of life issue.

The starting points of the study: The Covid 19 Pandemic started in early 2020, and the vaccine came into use at the beginning of 2021. Political and healthcare authorities and mainstream media communicated strongly about

- the dangerousness of the new virus and its fast worldwide spread.
- vaccination as the only solution to the pandemic.
- the necessity of many measures affecting society and people's activities

Local key medical doctors echoed these messages.

Our challenge: To make decisions and draw conclusions about the situation. The issue was discussed in an informal study group MKR (Multiprofessional Corona Group) of similarly interested people, and we began to investigate the matter in more detail incl.:

1. An overview of the Pandemic from the international references.
2. Vaccine related laboratory analyzes.
3. The study of applied quality assurance (QA) and quality management (QM) practices.

My personal study questions:

- In general: How to take an attitude to the Pandemic related activities and vaccines?
- As a quality expert: What could I know about the quality of that vaccine and its related quality assurance (QA) and quality management (QM)?

The virus, pandemic, and related measures created suspense, uncertainty, and risk in us.

Suspicious information from diverse sources:

- The Pandemic were very precisely planned in 2019 (“Plandemic”).
- SARS-CoV-2 was not a real natural virus but a patented man-made "virus”, and it had links to Gain-Of- Function activity.
- Covid 19 Pandemic was declared (2020) by WHO Director-General who has faced criticism and provoked mistrust. WHO is highly corrupt and financed by the pharma industry.
- Covid-19-diseace did not meet the criteria of general danger at any point..
- The Pandemic was largely based on PCR testing, which however, cannot be used to diagnose any specific viral disease.
- No SARS-CoV-2 virus was isolated from any patient, and PCR positive cases turned out to be other than Covid 19.
- In contrast to normal years, in 2020 no usual cases of influenza were reported at all.
- The political authorities launched questionable measures against the Pandemic without clear justification. They also brought up the urgent need to quickly start vaccinations.

We confronted with conflicting information and big uncertainty, which we understood as a high risk to make any final decisions and conclusions regarding the pandemic.

- Risk (ISO Guide 73, ISO 31000): effect of uncertainty on objectives.

The launch of the new mRNA vaccine for Covid 19 increased our doubts and uncertainty (risks).

What did we learn about the vaccine?

- The vaccine was introduced as an emergency solution with a special permission and promoted massively by the politicians, authorities, and main media.
- The development of the vaccine was carried out unusually quickly, and it was not subjected to the usual safety and effectiveness tests.
- The vaccine was based on a new mRNA technology that had not been used for humans before. Conventional vaccines were not available.
- In fact, these mRNA “vaccines" are not vaccines according to the traditional definition but classified as gene therapy products. The use of genetically modified organisms (GMO) in food is viewed with great suspicion.
- The lipid nanoparticles and s-protein of the mRNA vaccine, which spread throughout the body and remain for a long time, are toxic to humans.
- Vaccination was presented as the only solution to the Pandemic. Other medications and treatment protocols were abandoned or withheld.
- No detailed information was available from the authorities about the vaccine's material composition and its procurement details.
- One of the Covid 19 vaccines was withdrawn from market due to serious side effects.
- A few years earlier, swine flu vaccines had caused serious problems, and vaccinations had to be stopped.

Studying the composition* and effect* of the vaccine, which can be linked to the quality of vaccine

Chemical analyzes of vaccines:
- Samples were from around the country.
- Vaccine vials were not homogeneous.
- Vaccines contained a wide range of additives and impurities not mentioned in the product specification, e.g. graphene and parasites-
- C. 20% of the vials contained pure saline, not indicated on the vial label or in specifications.

Microscopic blood examination:
- Many vaccinated and non-vaccinated persons.
- The red blood cells of the vaccinated persons were strongly clumped together even several months after the vaccination.

We also received similar information from many international sources.

Communication with health authorities and university research units:
- We suggested more thorough further studies but the authorities were not interested and denied our results and all further research.
- The authorities had not investigated the vaccines in their own laboratory, even though it should have been part of their duties.
- The university's pharmacy department denied our results and did not allow us to use their laboratory services. They had no related research for reference, although one of their research areas was quality issues in the pharma industry.

As a result, I started looking into the Quality Management (QM) and Quality Assurance (QA) procedures of the vaccine.

Relevant viewpoints for the QM and QA study - Practical and conceptual challenges

Vaccine and vaccination logistics processes:

Many different actors: Decentralized and uncoordinated QM and QA accountability:

- Product development (USA). The product new, not produced or used before.
- Production (Europe).
- Distribution from production to vaccination stations.
- Regulatory measures (USA, Europe and Finland).
- Local injections of the vaccine into a lot amount of people over the country.
- Disposal of expired vaccines and vaccine residues.

Requirement and guidance references:

- Contractual documents between the producer and country/region agencies*.
- National/regional (Finland and EU) regulatory requirements.
- Sector specific standards of the Pharma industry, mainly QA, e.g. GMP, GLP.
- General ISO QM and QA standards, e.g. ISO 9004, ISO 901, ISO 10005.

Related concepts as defined by ISO 9000**:

Q – Quality

QM – Quality management

QA – Quality assurance

Findings from the QA and QM practices within the logistics processes

Findings from QA/QM requirements procedures, references, and discussions:

- No clear basis for QA because of the uncertainty and secrecy of the vaccine composition in product specification and procurement contract.
- No QA requirements and responsibility to the producer in the vaccine procurement contract.
- Vaccine's structural composition was not known or analyzed by the authorities in Finland. It wasn't even possible because the producer had banned it.
- EMA's assessment report revealed problems in the vaccine, which led to no actions.
- Vaccine's official batch control was not performed in Finland but based on actions of other European qualified laboratories. Producer's Qualified Person (QP) was responsible for the batch-specific quality of the vaccines.
- In the development stage, the approval testing of these vaccines by the producer in the US was fraudulent in terms of quality and QA. However, the buyers and regulatory authorities did not take any particular QA measures
- We have no information about the QA of transport, storage, or disposal of vaccines, However, there are special requirements for these in terms of temperature, time, and security.
- Information on the implementation of QA regarding the field vaccination process, vaccination management, personnel, and training show deficiencies in the operation, even though there are specific requirements for these.

General related viewpoints

The producer had continuous illegal activities and big fines regarding the launch and marketing of medicines.
- That was known by the regulators but did not lead to precautionary measures, e.g. risk management and enhanced QA.

Pharma industry is very conservative, and introducing new innovative solutions of QM is challenging. They apply sector-specific formal QA practices, even established by laws and regulation, which are not necessarily effective.

Pharma business is influenced by many strong economic, authoritarian, and political interests, including corruption.

Communication has not been open or transparent in the Covid-19 vaccine logistics.

New information on the matter is constantly emerging, which strengthens our earlier views

- Experts and authorities knew from the very beginning of the Pandemic that the vaccine does not prevent infections or the spread of the disease.
- Producer's test reports revealed that the vaccine had caused a lot of many kinds of serious diseases.
- Specialists in the field have demonstrated the biological mechanisms for the diseases caused by the mRNA vaccine. The same has also been proven with empirical tests.
- Statistics show a significant increase in deaths and many serious diseases after vaccinations (e.g. cancer "tsunami" and "turbo" cancers). These vaccines have caused severe adverse effects much more than any other vaccine before.

The pathologists have brought the connections between the vaccine and the deaths in their autopsies.

- Key persons among the authorities have questioned the Pandemic and e.g. talked about a political pandemic.
- There are ongoing legal cases regarding pandemic restrictions and adverse effects of vaccinations.
- Those who have criticized vaccines and the Pandemic have been targeted, blocked, and threatened.

Many experts and authorities still deny the revealed facts.

Summarized thoughts based on the case

Large-scale global, and traditional pharma business sector has drifted away from naturally integrated QM and adopted formal, complex, and ineffective QA practices. Also the regulatory authorities have contributed to it.

Major changes would be needed to the basic quality approach and practices, including the revitalization of the quality professionalism in the entire pharmaceutical and healthcare business ecosystem comprehensively, covering the pharma industry, regulatory bodies, political decision-makers, health care, research, and education, and even to the operational culture of the industry sector.

This should most naturally start from the industry's own initiative with individual active and respected persons.

More sector-specific QM/QA research and innovations are needed, open exchange of information, and unbiased scientific debate.

Risk management should be practiced within QM and QA methodologies. Risk management is a major practice in all the latest QM standards.

Particularly, bioethical aspects should be highlighted comprehensively, covering pharmaceutical companies, related regulatory organizations, political decision-makers, hospitals, research and education (medicines and health care), and medical personnel.

The communication of the authorities should be open and transparent, and the activities of the public media analytical and critical.

Conclusions

- The quality of Covid 19 vaccines and Pandemic treatments were not acceptable.
- Quality assurance and quality management have not worked or had the necessary effect.
- Risk management had not been implemented.
- Operations included ethically questionable aspects.
- A lot of difficult individual, economic, and social problems have been caused.
- Great mistrust heve been towards health authorities, public health communication, and the pharmaceutical industry.
- This study related to Finland but very likely similar findings can be obtained also elsewhere.
- The issue will very probably be discussed comprehensively still for a long time.
- Significant improvement measures in the entire medical and health eco system are necessary and possible but difficult to get happen.

An interesting question:

How do the quality professionals and community take a position on the subject and also prepare for the future in similar situations?

The researcher's own benefits from the case

I got the answers to my research questions and could act on my own justifiably regarding the Covid 19 Pandemic and vaccination and also to prepare for future similar events.

I could discuss the matter with experts and others in an argumentative manner

A topic for my wider ongoing research, the quality of society.