To Be or not to Be a Medical Device: Is the Regulatory Framework a Safety Rope or a Fetter?

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Software as a medical device, stand alone software, medical devices/legislation and jurisprudence, medical devices/standards, regulatory affairs

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With the current Guidance for Industry and Food and Drug Administration Staff for Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices [1] and for Mobile Medical Applications [2] of the of the U.S. Food and Drug Administration (FDA) the everlasting discussion has been re-fired: Is (this) software a medical device? If so, in an informatician’s world of rapid prototyping and short release cycles the bureaucracy of regulations will kill innovations.

On the other hand: It finally spread the recognition that medical software and clinical information systems can improve patient care and patient safety - not just facilitate the work or serve administrative purposes. Thus, the ancient medical wisdom shall apply: No effect with no side effect, no benefit without risk – errors may occur with the use of software associated with risk to the patients.

That this threat is real, proves a look at the ‘Manufacturer and User Facility Device Experience (MAUDE) data’ database of the FDA. MAUDE contains 643 records where a product problem is classified as “Computer Software Issue” in the last five years. In 69 records is the event type “injury”, and four records have the event type “death” (Table 1). Searching for the Product Class: “Software, Transmission And Storage, Patient Data” 110 records are reported, including 52 with the event type “injury”.

In 2010 Magrabi et al. systematically analyzed and edited such software associated errors [3, 4].

If software or clinical information systems have a positive impact on patient care, they must be as reliable as drugs or other medical devices. This results in an ethical responsibility for manufacturers, operators and users of the systems: We expect manufacturers that they implemented a quality management and risk management system. We expect that the product has been developed in accordance with the state of science of usability and patient safety, and that all aspects of life cycles were considered and complete documentation was created. Risks and errors should be documented and communicated to all operators and users.

Nothing else is available in the following standards:

- IEC 62304: Medical device software – Software life cycle processes
- IEC / CD 82304: Health software – General requirements for product safety
- IEC 62366 Medical devices – Application of usability engineering to medical devices
- ISO 14971: Medical devices – Application of risk management to medical devices

Table 1 Records found in searching product category = ‘Computer Software Issue’ in the ‘Manufacturer and User Facility Device Experience (MAUDE) data’ database of the U.S. Food and Drug Administration (FDA). (Search executed at 04/04/2015, timespan 01/01/2010 to 02/28/2015*)

<table>
<thead>
<tr>
<th>Product Problem: Computer Software Issue</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Type</td>
<td>2010</td>
</tr>
<tr>
<td>Death</td>
<td>4</td>
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<tr>
<td>Injury</td>
<td>69</td>
</tr>
<tr>
<td>Malfunction</td>
<td>569</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
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<td>Sum</td>
<td>643</td>
</tr>
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</table>

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ISO 13485: Medical devices – Quality management systems – Requirements for regulatory purposes.

Certainly, adhering to the standards listed above massively increase administrative overhead in research and development, extend the “time to market” and causes increased costs. However, this is the price to pay for success to reach the goal: Impact on patient care.

Therefore, the answer to the question in the title of this article is: Software can be a medical device and from this point of view, we have to accept administrative overheads – and the regulatory framework can be a useful guideline.

References