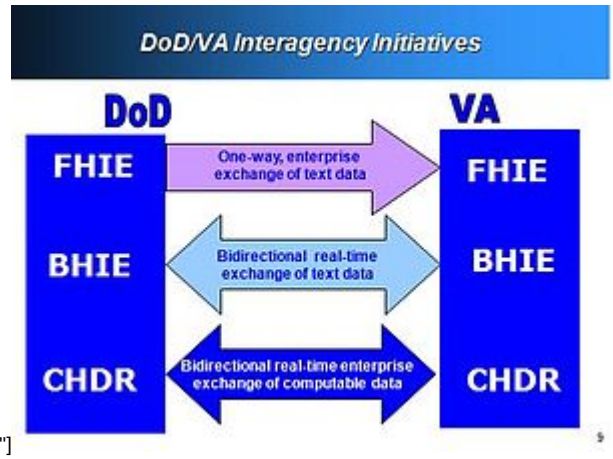
Are medical software standards in the EU mandatory?



[caption id="" align="alignright" width="300"] English: Electronic Health Records flow chart.jpg (Photo credit: Wikipedia)

In the United States there is a great push from the government to implement medical informatics standards. But is there in Europe? In specific, are there any European countries who mandate some kind of standard for digital medical records? Does the EU have any legislations to control medical software standards?

I have done some superficial investigation by asking people experts in the field, and i found out that most likely there are no mandatory content formats for electronic health records at EU level or at the Member States level. However, since health care is mostly organized at the regional level, there are many projects which follow a standard (or an adapted variant of a standard), for example ISO 18308, 20514.

> *Apparently there is no legislation at the EU level. At Member States level, we know that for Sweden, Czech Republic and Denmark, although we do not have access to their health projects, they do have specific content formats in their projects which are required. But generally speaking, there is no legislation on content formats, there are only technical requirements for such formats per project.*

The EU Commission of march 1 2012 Annual European standardization work program 2012 http://ec.europa.eu/enterprise/policies/european-standards/files/standardization/swd-2012-42_en.pdf states that there are three independent European standardization organizations (ESO) – CEN, CENELEC and ETSI, who are the organizations to deliver standard by 2020 according to a Communication 'A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020'. This document is to be read, as it seems interesting.

See Also:

- CEN TC251 is the organization corresponding to ANSI in Europe.
- In many national procurements, HL7 standards are mandated as part of an EHR tender.
- CDA is part of the epSOS specifications for cross-border e-Perscription (www.epsos.eu)
- http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/
- http://www.cenelec.eu/
- http://www.medicaldevicedirective.net/