CPME 2006/115 EN

TITLE / TITRE

CPME reaction to the DRAFT eHealth Interoperability Staff Working Paper "Connected Health: Quality and Safety for European Citizens" of 2 May 2006

AUTHOR / AUTEUR

Dr Daniel Mart, CPME President

CONCERNING / CONCERNE

All members

PURPOSE / OBJET

INFORMATION

DATE

07/07/06

KEYWORDS / MOTS CLEFS

e-Health

CPME Reaction to the

DRAFT eHealth Interoperability Staff Working Paper

"Connected Health: Quality and Safety for European Citizens"[1]

CPME agrees with the statement of this working paper stressing that "the importance of **patient safety** is viewed as the crucial and overriding rationale that underpins eHealth interoperability". Therefore CPME welcomes that the paper points towards the accessibility and timely availability of medical data, improved workflow, facilitated disease management, and new clinical applications as advantages obtained from eHealth.

However the implementation of **Identification and Authentication Services** is essential. To achieve this on a European level with the relevant legal framework is the prerequisite for eHealth implementation as the whole system is patient centred. Identification and authentication of health professionals should follow the same guidelines.

Without services such "as privilege management, access control, tracking of information and processes, accountability, integrity and confidentiality services, policy management, and audits", CPME cannot adhere to other developments addressed in this paper.

CPME wants to stress that E-health has to service the system, not the other way around

Also CPME insists on keeping the safeguards of the current systems in the e-health environment, as "the eHealth revolution has as many serious implications for healthcare regulators, policy-makers, lawyers as for medical professionals and patients." If there will be serious changes to the way health care is delivered, these scenarios will need to be discussed with all stakeholders before implementation to ensure that these changes are in the interest of the patients and/or citizens. Physicians cannot accept changes to the systems for the only sake of e-health applicability.

As the paper clearly states, interoperability regards not only technical matters, but it also concerns legal, ethical, economic, social, medical, organisational and cultural matters.

Of all these points CPME considers that the lack of a **legal framework** to back this ambitious agenda has to have the highest priority.

---

[1] Brussels, 2.5.2006

Ethical issues like for example organisational matters are not to be underestimated and a thorough "state of the art" evaluation on implementation level has to be followed by educational measures to achieve a necessary "e-health culture".

Legal framework

CPME agrees with the need and encourages the development of a European legal framework which has to define minimal conditions, including issues such as: responsibility and data protection, legality and financing of on-line medical acts, and on-line pharmaceutical information and product supply, as described in the 2002 Communication.

Logging and access control varies greatly from country to country, sometimes even from region to region. <u>CPME underlines the need of a **common European legal framework** on this issue</u>

It is also important that these issues are addressed and promoted at European level in order to stimulate traditionally technology-resistant health care professionals to adhere to this new technology.

Benefits: Patient safety

CPME considers that the introduction of interoperable eHealth solutions constitute a contribution to the improvement of the delivery of health and social care, and therefore, to patient safety.

It is suggested that health professionals be encouraged to document incidents. CPME could endorse this proposal under the strict condition that, in order to enhance this process and bring it into practice, **<u>a blame free reporting system is implemented at European level, including the necessary legal framework</u>**.

E-Health can play a positive role in the improvement of quality and efficiency of services. In order to achieve this, it is necessary to bear in mind that **<u>medicine still needs to be practised in a eye-to-eye doctor-patient relationship. The de-humanising evolution in other technology dominated areas would be a disaster for the medical environment as it justly and heavily relies on interhuman communication and relationships.</u>** Telemedicine will only be a reasonable solution for some specific, well-defined applications.

Regarding containment of costs, however, CPME thinks that these should be compared to the necessary, sustained investment. If correctly implemented this investment could very well considerably exceed the projected amounts. A global reduction in cost is not necessarily proven and should not be the primary goal compared to the essential priority of patient safety and quality healthcare. The paper rightly states that implementation of eHealth interoperability is a long-term process requiring a sustained commitment with respect to political involvement.

The paper mentions data available in North America about "best practices", the quality of care and the impact of unavoidable accidents in the medical field. Although illustrative it is important to keep in mind the particularities of the American health care system in relation to the European systems and approaches.

Therefore CPME disagrees with the concept of a "universal best practice", and considers that the concept of "best possible treatment for a particular problem of a particular patient in a particular setting" should be used instead. Best practice recommendations should always be guided by quality and safety motives and resist pure financial and rationing logic.

It is of paramount importance to protect the principle of **professional autonomy of physicians**. Professional autonomy is first of all intended to protect the rights of patients as modern health care is based on the interaction between the empowered patient and the autonomous physician.[2]

Interoperability

It is important to bear in mind that most national health information spaces are far from having achieved interoperability. Therefore, a step-by-step approach, with a clear and well-defined framework is indispensable.

In developing e-health interoperability, CPME considers it essential to address the following issues with the priority as listed:

1. **infrastructures**
2. **identification architecture**
3. **other health related services**
4. **patient summary**

CPME believes that Interoperability should promote and define common extraction and communication platforms and layers. Example: download and display medical imagery independently from operating systems and applications and regardless where it has been created and where it is stored.

Therefore, interoperability should not be addressed solely through patient summaries and emergency data sets. CPME also draws attention to the fact that there are no common definitions of these concepts (or of "electronic health record") or a regulatory framework for this standard.

Then again, unique European identifiers are absolutely necessary to make interoperability possible.

CPME would like to stress the importance and need of intensive involvement of "the field", meaning continuous consultation of the ones that practice medicine on a daily basis and not only of health professionals involved in e-

---

[2] CPME 2006/101 Final and CP 1999/020 Final.

health. This is crucial in order to obtain useful information on the viability of applications, and to reach acceptance and real implementation.

Patient summary and emergency data set

For CPME the separation of patient summary and emergency data set is artificial and therefore we cannot agree to it. What is the difference between essential information to be contained in a patient summary and emergency data?

CPME has come to the conclusion that there are too many uncertainties and unsolved issues to agree to consider the "patient summary" approach as the ultimate solution. We draw attention to the fact that this involves not only a re-design but also a new way of working in the health care environment and thus implies considerable educational, financial and ethical changes.

A lot of manpower and many regulatory procedures will be needed to create patient summaries / emergency data sets. This also requests an analytical process by a professional and regular updating. This means that in the end doctors will have to edit, maintain, update, correct and take responsibility for such a patient summary. Doctors do not consider this one of their core tasks and the proposal is contrary to the current organisation of the dataflow between doctors. The necessary blind trust in very variable data that are treated as given and fixed values in this proposal is not brought forward by physicians working in a real life environment.

It will also create **responsibility issues,** such as access control, storage, lack of completeness, relevance of information dependant on the reader, relevance of information dependant of the author, degree of certainty of data, crucial importance of timely updating, reliability of semantic interoperability etc.

The patient summary could be replaced by **the universal availability of a given set of patient data** (under his/her control).
The utility and desirability for a longitudinal life-long patient-record has to be discussed with the relevant stakeholders as it comprises the undeniable risk of data overkill and thus inacceptance.

Considering all the necessary efforts to put this in place, considering the interoperability issues and the very little real world benefits, we strongly argue against considering emergency data sets to be a priority Issue.

It is important not to forget that doctors often have to act before they hook up to a computer and try to retrieve data. It should be remembered that even if a patient carries a card with his/her blood group, this will be tested again, for instance.

For physicians the limit between patient summary such as they are insufficiently described and emergency data sets is a floating one. Emergency data would be contained in patient summaries if they would be compact enough to fulfil their role. Is there really a need for both?

Access

Access control is of utmost importance. In any case the access to data (except in case of an emergency) should be under the control of the patient (citizen) submitted to login procedures and surrounded by a relevant legal framework to guarantee application and follow-up of the rules.
Access control in institutions, hospitals and networks has to follow the same rules as those applied in other sectors. Generalised and predefined access rights have to be proscribed.

Standardisation

CPME encourages the voluntary use of open and formal standards by the industrial actors, as pointed out in the paper.

Semantic Interoperability

Apart from the difficulties of interlanguage interoperability the enormous amount of abbreviations and the not only country specific, but also institution-specific idioms, will require a tremendous educational effort in order to implement semantic interoperability
There is also a big risk of loss of the richness of the medical language.

Feasibility of eHealth interoperability

As a general remark CPME wishes to highlight the importance of including the input from the real time working medical profession. For example, the "scenario-cases" presented in the Annex of the document are rather disconnected from the real practice and therefore they need to be discussed in further detail.

This document relies heavily on IT-experts, officials and R&D personnel. If it is wished to receive large scale and real time implementation which involves 2 million doctors in Europe, CPME strongly recommends deviating from the theoretical framework.

Physicians can not accept changes to the systems for the sake of e-health applicability. This type of MAJOR paradigm shift will not be imposed or distilled top down. Therefore transformations of health systems and their implications will have to be discussed and agreed upon.

A collaborative effort, implying educational and regulatory issues, has to be made. Physicians, as users of the system, should be an important partner in this process. CPME is ready to participate in this collaboration.