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Recommendation on Cross-Border EHR Interoperability

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While much of Europe slumbered through its summer vacation, the program to build a pan-European e-Health network shifted up one notch, after the European Commission published a Recommendation on cross-border interoperability of electronic health record (EHR) systems.

At first sight, the Commission paper, released in July, appears lukewarm. A Commission Recommendation is a non-binding legal instrument. To many Eurosceptics in the healthcare IT industry, it is the equivalent of pulling out a BB gun, while other global actors are priming heavy-caliber hunting ammunition.

Devil in the details

And yes, the devil does (again) lie in the details. The Recommendation continues to seem lukewarm, even after a few readings.

Formally known as 'COM (2008) 3282 final', it comes less than a year after a draft which was published for public consultation.

That draft outlined both the salient points and the challenges - around the issue of e-Health interoperability: privacy and confidentiality versus security, its organisational contours and processes, the semantic, architectural and technical factors involved, and the final packaging (certification and accreditation, as well as monitoring and evaluation).

Structural Weaknesses

There were, nevertheless, two structural weaknesses in the draft. Both were significant, given the importance of interoperability to any meaningful European e-Health space (e-Healthscape, if one coins one's own bit of Eurojargon).

The first lapse concerned the definition of the draft as a document for 'informal' consultation. This qualifier of informality is reflected in the final Recommendation, which avoids any mention of such consultations who was consulted, how they were consulted, what they stated and whether or not their comments were taken into account - and why.

This is very unlike the practice in some other parts of the world (especially Anglo-Saxon countries), where considerable attention is given in public consultations to the viewpoints of actors outside the realm of a professional civil service.

In addition, several such exercises explicitly identify and provide either the text or the summary of such submissions (Australia being one good example).

Nanny Knows Best

Sadly, this lapse is a reflection of what many criticise as an ingrained propensity for secrecy in the corridors of the Berlaymont. The litany about the "Nannies in the Brussels Superstate" knowing what is best and never needing to explain why - is not just the preserve of British tabloids.

Of Sensitive Information and Competence ...

At Healthcare Information Technology Management, we were given a good example by the CEO of a top contract research organisation.

While increasingly paperless/cross-border clinical trials are an evident area of attention for e-Health, EudraCT, the European Union's 'e-Registry' of such activity, remains closed to the public.

So, he asked, should a European need information about 'stem cell trials' on the 'elderly' – and can there be more red alerts than these in a search phrase ?

Well, such a trial is taking place in an EU Member State. It has a EudraCT registration number (2005-002156-17), but access to the database (<http://eudract.emea.europa.eu>) remains closed to all but "competent authorities of the Member States, the Commission and the Agency," warns a document at the Website.

Uncle Sam Lends a Hand ...

Across the Atlantic, life is different, not just for Americans but Europeans too. Typing in the EudraCT number into the American government's counterpart to EudraCT (www.clinicaltrials.gov) not only provides detailed information about this sensitive European trial, but tens of thousands of others across the world.

From Interoperability and Vacations ...

In the final analysis, the draft Recommendation on the Titanic challenges of healthcare IT interoperability focused on four rather-trivial factors as its raison d'être:

- Ó The needs of vacationing EU citizens who fall ill in another Member State
- Ó Those who travel for medical care to another EU country.
- Ó Remote healthcare diagnostic services (a near-repetition of the previous two factors).
- Ó Transnational issues focused on "referral thresholds, admission rights, liability and recompense, and reimbursement" – again, more or less, a recap of all the above.

Via the Real World

The draft made little if any reference to other, more real-world and harder realities of global first-mover market-facing standards (European, American or even Asian), of scale, of pan-EU Best Practices benchmarking etc.

This then is the real world backdrop for e- Health and interoperability - of cross-border fast becoming borderless, of massed healthcare SoA teams at a variety of places around the globe, of Websites like Kiesbeter in the Nether lands - which allow patients to window-shop hospitals on the basis of performance, and more.

... To Interoperability and Travel

After all this, even the final Recommendation leaves much to be desired. Its third paragraph, once again, repeats the problems faced by "travelling persons" in Europe, as a need for cross-border interoperability for healthcare IT systems. The seven proposals in the Recommendation (final) are listed below:

1. The political level of cross-border interoperability of electronic health record systems.
2. The organisational level of cross-border interoperability of electronic health record systems.
3. Technical interoperability of electronic health record systems.
4. Semantic interoperability of electronic health record systems.
5. Certification of electronic health record systems.
6. Protection of personal data.
7. Monitoring and Evaluation.

The key issues of concern to healthcare IT managers are (3) and (4), namely technical and semantic interoperability. The others are little more than a rear-view rewrite of the Vision in the Draft, with a glut of references to issues like "financial indirect incentive mechanisms", to five-year programs (rather like the current FP-7), to the "governance process", "policies and incentives", to "mutually recognisable conformity" etc.

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Of Survey(s) and More Survey(s)

The biggest lapse, however, in the Recommendation is its advice to “undertake a comprehensive survey of existing technical standards and infrastructures that may facilitate the implementation of systems supporting cross-border healthcare and the provision of healthcare services throughout the Community, especially those related to electronic health records and exchange of information”, and to “analyse the use of standardised information models and standards-based profiles when developing and implementing interoperable electronic health record systems and services solutions.”

Indeed, someone in the Commission seems to have forgotten that the entire “comprehensive survey” of standards and infrastructures is actually over, and paid for (to the tune of 1.16 million Euros, by the EU, under FP-6, its Sixth Framework Program for Research). It was delivered in late 2007, both as a report to the Commission and on the Turkish National TV Channel, TRT2.

Riding an Overlooked Roadmap

The so-called RIDE project (Roadmap for interoperability of e-Health systems) is an encyclopedic exercise; its final report is 276 pages long. It took 24 months, and involved medical informatics organisations and experts from 7 countries (Belgium, France, Germany, Greece, Ireland, Italy and Turkey).

RIDE was mandated to lay the foundations for the Commission’s action plan on e-Health (COM 356) by explicitly studying and coordinating efforts on e-Health interoperability across Europe – with “special emphasis” on semantic interoperability.

The RIDE project investigated both the current state-of-play and techno-policy interoperability challenges in EHRs across a wide range of EU and other associated countries; the consortium was headed by Turkey’s Middle East Technical University. RIDE made an analysis of e-Health systems in 8 key countries (Austria, Estonia, Germany, Ireland, Netherlands, Poland, Sweden and the UK) and an in-depth survey of interoperability systems and practices in 14 countries: Belgium, Bulgaria, Cyprus, Hungary, Latvia, Luxembourg, Malta, Portugal, Romania, Slovenia and Spain, as well as Australia, Canada and the US. The RIDE experts also analysed specific challenges related to semantic interoperability in another four countries: the Czech Republic, France, Greece and Norway, and separately collated insights into both Current Practices and Best Practices at the EU level as well as a professional gap analysis for the future.

Crucially, RIDE acknowledged the impracticability of “a single universally accepted clinical data model.” They sought to both assess current limitations in the field and evaluate European best practices in providing semantic interoperability. The eventual aim – to “draw up a realistic road map” for “achieving interoperability” and “deploying interoperable e-Health solutions”.

Of USB Sticks, Cellphones and Health Records

In the final analysis, the debate on EHR interoperability in Europe seems to swing manic depressively between pies-in-the-sky and periods of total stasis. At the baseline, as one cynic told Healthcare Information Technology Management, the really crucial (and meaningful) health records of tourists could be easily accommodated on a USB stick or even a cellphone.

It is also unlikely that such basic data would pose concerns about security –least of all to a European holidaymaker requiring urgent medical attention at an - other end of the continent.

This is not to question the major, serious and laudable goals of an interoperable EHR in Europe. However, it is evident that the RIDE project was (and remains) a very good place to start.

It is puzzling why the Commission Recommendation mentions its action plan on e-Health (COM 356) in several footnotes, but has nothing to say about RIDE, which was “mandated to lay the foundations” for the very same COM 356, and by all accounts, appears to have done a laudable job.

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