CF Consulting Firm Ltd.

John Doe <erise-casestudy@disi.unitn.it>

Notes for the HCN Project

"CF" Partner <erise-casestudy@disi.unitn.it> **Wed, May 25, 2011 at 13:14 AM**
To: Consultants <erise-participants@disi.unitn.it>

Dear Colleagues,

I think I just about to bring a bit unfortunate news for you :(, but let's see this as a new challenge and new business opportunity.

In recent meeting, our client, from the healthcare authority of CityVille, feels the need to be able to monitor and manage Adverse Drug Event (ADE) in the CityVille. As you might know; in recent years the CityVille has became one of the most prominent cities in EU that in the pharmaceutical industries. We can see the growing number of new openings of some pharmaceutical companies and some laboratories & research institutes.

One of the most central issue from the healthcare authority is:

"Recently, there have been many adverse events that occur in the society related to some drugs reaction. These might be caused by drug trials done by pharmaceuticals/research institutes OR due to usual drug therapy in the hospital. However, these result in increase of our medical costs. We need to be able to monitor and quickly response to these events".

In the literature , Adverse Drug Event (ADE) is defined as an injury/death resulting from the use of a drug; it includes

• harm caused by the drug (e.g., adverse drug reactions and overdoses);

• harm from the use of the drug(e.g., including dose reductions and discontinuations of drug therapy).

Detail can be found at http://www.pbm.va.gov/vamedsafe/Adverse%20Drug%20Reaction.pdf

To achieve this end, the CityVille thinks to extend the usage of their Healthcare Collaborative Network (HCN) in addition to handling the Public Health Alert (PHA). I realize such new usage will require us to revisit our security and privacy analysis that all of you have been doing. Thus, in this memo I'm requesting to you to adapt your current analysis considering the new usage of the HCN, and of course protecting the information security and privacy in that system because after all this is the reason why we are involved in this project

For details of the ADE use case in HCN, you can consider the following information:

Participating Organizations

This use case involves various organizations, such as the CDC (Central Disease Control Agency), the Healthcare Authority, Hospitals, GPs (General Practitioners), Laboratories & Research Institutes, Pharmaceutical Companies, Health Insurers, and FDA (Food and Drug Agency). Here are the roles of the actors:

- FDA is the national agency responsible in monitoring the drugs
- The Healthcare authority and Health Insurers are interested because they have some share in paying some parts of the medical cost when an ADE occurs
- Pharmaceutical Companies and Labs monitors the info exchanged in the network to learn about their drug trials
- Hospitals need to be up to date regarding the ADEs for the sake of patients' safety
- Pharmacies need to collect more details of the patients when they use the drugs that are subject to the monitoring. Moreover, pharmacies need to ensure the patients' safety when they provide the drugs to the patients.

ADEs can be reported

- Voluntary - by consumers or practitioners
- Mandatory - by pharmaceutical companies or labs

Those two modalities are well established in the FDA and the authority. Thus, it is safe to assume that they are not the object of this project, and more details can be found at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm

This report then must be reviewed by the FDA/the authority (or any institution pointed by the FDA/the authority). If the report is valid, then the FDA/the authority issues an ADE. Moreover, an ADE can be originated from the surveillance done by the FDA/the authority upon medical data exchanged in the HCN.

Essential Process

- Monitoring Administration Process – when organizations decide which medical data that they need to monitor from the network. Currently, every therapy done by GPs and Hospitals and every drug delivery of monitored drugs done by pharmacy are published in the HCN. However, the HCN needs to protect the privacy of the patient;
- Data Collection Process – each organization can collect required medical data that are required for detecting possible ADEs. For drug trials, the organizations need to obtain the consent from the patients
- Analysis Process – it is an internal analysis process of a single organization to analyze & detect any possible ADEs.

Information Security and Privacy Concerns

- Ensure all Confidentiality, Integrity, Availability and Non-Repudiation issues of the information so that the healthcare authority/FDA (together with insurers) can reduce the medical cost due to ADE, and of course to protect the citizen safety
- Protect patients privacy from any parties that might benefit from sharing these medical data/information
- All organizations are responsible to protect patients' privacy at their ends
- Ensure all ADEs are reliable

For privacy issues, you can consider the following EU codes at the following resources:

- http://ec.europa.eu/justice/policies/privacy/index_en.htm
- http://www.dataprotection.ie/documents/conferences/McClelland.ppt

Sincerely yours
--
John Doe
"CF" Partner
Consulting Firm, Ltd
erise-casestudy@disi.unitn.it