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Participant information sheet: Challengers

How a formally organised Developer Challenge facilitates the development of clinically impactful, interoperable health information technologies

Principal Investigator Dr Karen Day

I am a health informatics researcher at The University of Auckland. I have been invited to collaborate with the HL7 NZ to co-host the 'Developers on FIHR' Challenge, to conduct research on how the process enables the development of interoperability solutions.

Healthcare services are going digital, from recording clinical care to providing services using information and communication technologies (ICT). Clinical care is complex and ICT enables clinicians to do more than simply record what they are doing, or find information electronically to support their work. There are opportunities to change the way we organize and manage healthcare delivery to positively impact the outcomes achieved, e.g. increase safety.

Some patients experience adverse events related to clinical interventions, e.g. serious allergic reaction to medication. Under the National Adverse Events Reporting Policy of 2017, health services are obliged to report serious adverse events according to a specified protocol, within 15 days of the event occurring. Most adverse events are originally documented in medical records, managed either by general practitioners (GPs) or hospitals. Since most medical records are digital, it should be possible to collate data digitally into a structured reporting format for submission. However, the record is not a single software application (programme) – it consists of several applications that function according to specific aspects of clinical care, e.g. medications are managed in an application that attaches to the basic information about patients. Efficient reporting is hampered by the lack of standard data formats, because each medical record system has its own proprietary approach to data storage. As a result, some data can be shared but most of the data cannot, i.e. data has to be collected from each separate application. It becomes a challenge to report adverse events that require data from several applications that are not interoperable (unable to share data).

HL7 New Zealand, the local affiliate of an international standards setting organisation that specialises in standards for data interoperability, is hosting a 'Developers on FIHR' Challenge. FHIR (Fast Healthcare Interoperability Resources) is a draft standard that makes use of data formats and elements structured as 'resources' which are shareable through Application Programming Interfaces (API). For the 'Developers on FHIR' event we are inviting those actively involved in software development, user interface development, system architectures and clinical care delivery to form teams and build applications to solve interoperability challenges associated with reporting adverse events. The research questions is therefore ***'How does a formally organised developer challenge facilitates the development of clinically impactful, interoperable health information technologies?'***

What does the study involve?

The Challenge was announced in early November 2017 and participants began registering right away on the HL7 NZ website. The in-person event will occur on 17 March 2018. Two webinars were planned

for late December and early February. People are being encouraged to form teams and start building their solutions as soon as possible, and work together in-person or online at their discretion. They are communicating via an online communications tool called Zulip – these are technical software discussions. Data will be gathered in the following ways:

1. Field notes by Karen Day of her experiences of the planning, and her attendance at the webinars.
2. Field notes by Karen Day of her observations of the in-person event in March, e.g. team sizes and constitution (clinician-developer mix), mentoring activities by FHIR experts, nature of solutions (size and mix of your team, things you are discussing, how you are progressing, detail about the interoperability problem you are solving and the solution your group is developing).
3. Interviews with consented participants (the two HL7 organisers, the event judges, and those who registered and attended the in-person event). This will be done after the event in appointments that suit the participants.
4. Evaluation survey of strengths and weaknesses of the Challenge process and associated activities and expert support.

How are you involved?

As a registered member of the Challenge (Challenger) you are involved in forming a team or being a member of a team.

Your contribution to the research data involves permitting Karen Day to make notes about the Challenge planning and activities, and your team's work as indicated above in points 1 and 2. Your contribution also involves participating in an interview (up to one hour long, at a time and place convenient to you, in-person or by phone or by video conference), and completion of the online evaluation survey (up to 15 minutes long) in the week after 17 March 2018.

Participation is voluntary

Your participation in this research is voluntary.

The co-hosts of the Challenge have the right to withdraw permission for the research at any time without giving a reason. At that point all research activities will discontinue.

You have the right to withdraw from the research at any time without giving a reason. You will not be able to withdraw your evaluation survey response after submitting it as the response will be anonymised on submission. I will make field notes about things I observe in the preparation activities for the Challenge, and during the 17th March 2018 in-person event. The notes will be anonymised at the time of writing, and cannot be withdrawn later. If you don't want me to make notes about your contribution to the group's work, please say so when you see me on the day.

During our interview I will use a digital voice recorder to record our discussion so that I don't miss anything when analysing the interviews. If you want aspects of the discussion to be excluded from analysis, please say so and I will pause the recorder until you are ready to start recording again. If after the discussion you want to further exclude or adjust aspects of the interview, please let me know before 1 June 2018 when data analysis will begin. The interview will be transcribed by a transcriber who has signed a confidentiality agreement. I will send you a copy of the transcribed interview if you want to see it (please indicate on the Consent Form).

Privacy and confidentiality

The interviews will be analysed and reported with no identifying details. It is possible that a quote used from your interview (in the published report) may be recognised by someone who knows you or worked on the Challenge with you and heard you say something similar. We will do our best to mask your identity in our publication. We will not publish details of your team's solution (other than the problem you're solving and the name of your solution).

How can people benefit from participating?

Participating in research results in reflection on what people do and how they do it. Your interview will involve reflecting on your experience of this Challenge and may improve how you participate in similar Challenges in the future. The analysis of the evaluation survey should provide information on how future Challenge events can be improved. We will publish this research in a peer reviewed journal so that others may benefit from your experiences. We will publish a one-page summary of the research results in the online discussion in Zulip.

How will the data be stored?

I will keep a digital copy of all the data in my password-protected account in The University of Auckland's computer network. In the unlikely event of needing to print aspects of the data to help me analyse it, I will shred the printouts on a university shredder once I have completed the analysis. I will keep the digital data (on the computer network) for six years, after which time I will delete it.

Who to contact with questions?

For further information about the study, you are welcome to contact me by email at k.day@auckland.ac.nz, or by phone on 09 923 3870.

You can also contact my Head of Department of Health Systems, Dr Tim Tenbenschel, by email at t.tenbenschel@auckland.ac.nz, or by phone on 09 923 9001.

For any queries regarding ethical concerns you may contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Research Office, Private Bag 92019, Auckland 1142.

Telephone 09 373-7599 ext.83711.

Email: ro-ethics@auckland.ac.nz

This research has been approved by the University Of Auckland Human Participants Ethics Committee on 14 March 2018 for three years, reference number 020754.