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Digital questionnaire platform in the Danish Blood Donor Study

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ABSTRACT

Objectives: The Danish Blood Donor Study (DBDS) is a prospective, population-based study and biobank. Since 2010, 100,000 Danish blood donors have been included in the study. Prior to July 2015 all participating donors had to complete a paper-based questionnaire. Here we describe the establishment of a digital tablet-based questionnaire platform implemented in blood bank sites across Denmark.

Methods: The digital questionnaire was developed using the open source survey software tool LimeSurvey. The participants accesses the questionnaire online with a standard SSL encrypted HTTP connection using their personal civil registration numbers. The questionnaire is placed at a front-end web server and a collection server retrieves the completed questionnaires. Data from blood samples, register data, genetic data and verification of signed informed consent are then transferred to and merged with the questionnaire data in the DBDS database.

Results: The digital platform enables personalized questionnaires, presenting only questions relevant to the specific donor by hiding unneeded follow-up questions on screening question results. New versions of questionnaires are immediately available at all blood collection facilities when new projects are initiated.

Conclusion: The digital platform is a faster, cost-effective and more flexible solution to collect valid data from participating donors compared to paper-based questionnaires. The overall system can be used around the world by the use of Internet connection, but the level of security depends on the sensitivity of the data to be collected.

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1. Introduction

The Danish Blood Donor Study (DBDS) is a prospective, population-based study as well as a biobank (www.DBDS.dk). DBDS was established in 2010 [1]. By the fall of 2015, 100,000 Danish blood donors had been included. The eligible participants are adults aged 18–67 years, who are donors at the Danish blood banks. The donor population in Denmark consists of more than 230,000 donors (5.4% of the Danish population aged 18–67 years), who give around 300,000 blood donations annually (www.bloddonor.dk). The nationwide Danish blood bank is an integrated part of the Danish healthcare system financed by local and state taxes. The Danish healthcare system is administered by democratically elected assemblies from national state institutions, regions and municipalities. The Danish blood banks are non-profit organizations owned and operated by each of the five regions in Denmark. The blood banks have a national board to structure collaboration across regions on recruiting donors, processing and distributing the blood for the Danish population. DBDS is building upon the structured Danish blood bank system in the regions responsible for administrating donation sites at 27 hospitals in addition to five mobile donation units using 180 selected sites nationally (e.g., large companies and universities). Of the 100,000 blood donors who agreed to participate in DBDS, 40,000 were included from mobile sites and 60,000 were included at the hospitals.

At the blood donation centers and attached laboratories, the entire necessary infrastructure needed for the collection of structured data and biological samples is in place. Both blood plasma and DNA are available from all donors. The blood bank infrastructure already has laboratory facilities with educated staff (nurses, technicians, IT specialists and physicians). In addition, the blood bank has staff for the subsequent testing of the blood for a variety of biomarkers and expertise in large scale storage of biological material.

Access to participants at the blood banks is fundamental in our study. Blood donors are asked to participate and sign an informed consent when they visit the blood bank. This consent allows us to use the blood samples from their donations to study the impact of genetic and immunological factors on current and future health and disease. Information on outcome and demographic factors is merged with the Danish health registers [2].

From March 2010 until July 2015, all participating donors had to complete a four-page paper-based questionnaire with questions of self-experienced physical and mental health including the 12-item short form (SF-12®) standardized health survey [3], smoking habits, alcohol intake, exercise, food intake, supplemental iron intake, height, weight, and waist circumference.

As a follow-up to the initial paper-based questionnaire, we have developed and implemented a digital and flexible tablet-based questionnaire platform, using the open source survey software tool LimeSurvey [4]. This enables a rapid, easy, and cost-effective procedure to collect valid data on health traits from the participating donors prospectively at the donor sites. The digital questionnaire is more focused on research including the following questionnaire domains: allergy, ADHD, migraine, hidradenitis, depression, Restless Legs Syndrome. It also contains questions from the paper-based questionnaire; SF-12, smoking habits, alcohol intake, height and weight.

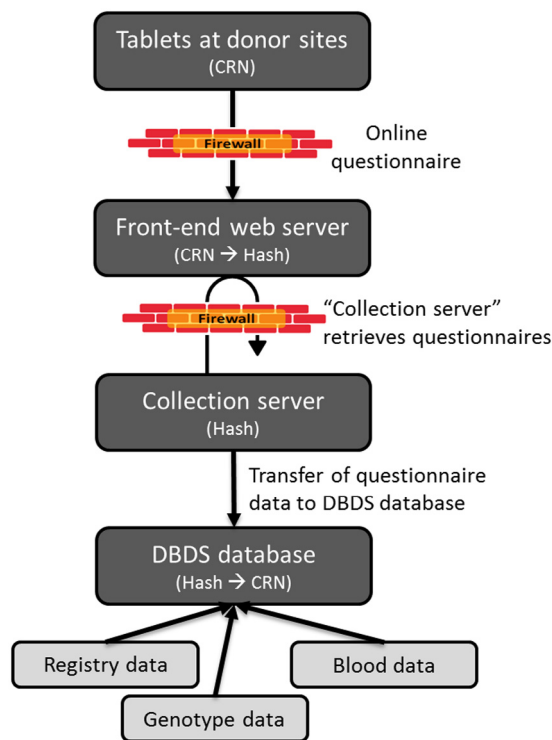


Fig. 1 – Description of dataflow.

The electronically based platform can facilitate personalized questionnaires, presenting only questions relevant to the specific blood donor by hiding unneeded follow-up questions on screening question results. At the same time, such flexibility also makes it possible to implement subgroup-targeted questionnaires, personalized from previous answers to questionnaires or biological measurements.

2. Methods

All participating blood donors complete a digital questionnaire on tablets during their visit to a blood bank (Fig. 1). The questionnaire is accessed online using a homepage at the front-end web server and will be saved following completion by the blood donor. The collection server retrieves the completed questionnaires and subsequently deletes them from the front-end web server every hour as an additional safety precaution to protect the person-identifiable data. The questionnaire data are frequently transferred from the collection server to the central DBDS database. Data from blood samples and verification of signed informed consent are then transferred to and merged with the questionnaire data in the DBDS database.

3. Systems

We chose a platform consisting of free and open source software that can be acquired at little or no cost. The questionnaire is built in LimeSurvey [4] (<https://www.limesurvey.org/> Version 2.06±), which is run on a Red Hat Enterprise Linux Server (ver.6.7)

using the Apache web server (ver.2.2), MySQL database (ver.5.1) and PHP (ver.5.3).

4. Description of security regarding civil registration numbers

One of the major design challenges is the level of security and restrictions incorporated into the system while providing a user-friendly questionnaire to the blood donors. The identification of participants relies on the Danish Civil Registration Numbers (CRNs)—a 10-digit personal identifier listed in the Danish civil register monitoring all individuals living in Denmark.

The participants access the questionnaire over a standard SSL encrypted HTTP connection (HTTPS), using their personal CRN (Fig. 1). Upon login, the CRN is converted to a hash code with a collision-resistant cryptographic hash function (used to uniquely identify secret information, e.g., sha512). Part of the hash is subsequently used as the token (id) for the questionnaire. The exact hash function is hidden by compiling a binary executable, e.g., sha512 (CRN + “pepper”)^(n times). By making it hard to learn the exact hash function, we make it difficult to trace the CRN from the hash. The collector server retrieves the data at regular intervals and deletes the questionnaires from the front-end server to reduce the amount of data available at the front-end server. Only answers with a valid CRN matched with a signed consent form can be used in studies. Using the CRN number is one of the key features of our approach, which can only be used under stringent security, giving subsequent data access to the national registers.

As the tablets require Internet access, connectivity has shown to be a limiting factor. Difficulties may arise in attempting to connect the tablets to a hospital’s in-house wireless network, as most networks in public hospitals must be accessed with a personal account. If a mobile data connection is used, signal strength may be poor within the local blood banks. Connection problems can be disturbing for the participants, and connection outage may force them to start over on the questionnaire, with a subsequently increased risk of losing the participant.

5. Results/discussion

DBDS relies on the existing infrastructure of continuous collection of blood samples to the Danish blood banks and on the local staff in the blood banks who acquires the questionnaire data during blood donation [5]. The questionnaire is currently being integrated into the daily clinical routine at blood bank sites across Denmark.

The digital platform was initiated at a few blood banks in August 2015. In June 2016, the platform is implemented at 24 hospitals and five mobile units in all regions of Denmark. 16,400 Danish blood donors have completed the digital questionnaire on the 31st of May. Only 30% of the participants were included at the mobile units due to difficulties of setting up robust Internet connections.

The advantages of a digital platform include lower costs (e.g., digital data collection removes the need for manual data entry and validation), improved data integrity (fewer human errors

from validation of scanning errors), and less time consumed for both the staff and the participants. Specifically, the participants gain a time advantage because the digital questionnaire can be completed with only one hand in real time, i.e., while the donor is actually giving blood.

Furthermore, it is easier to remove a group of questions or add new questions to the existing implemented questionnaire if, for example, the preliminary results require more specificity. The system is optimized to ensure that new questionnaires are easily implemented and that ongoing questionnaires can be terminated and removed when the desired number of participants has been recruited.

The digital platform also allows the results to be available for immediate analysis for all researchers involved since all questionnaire data easily can be exported to any desired format (CSV, Excel, Word) or directly into several statistical programs (R, STATA, SPSS).

Blood banks in Denmark have digital standard health questionnaires for donor screening to be filled in either at home or at the bleeding facility. They use a national safety facility (NemID) also used by banks, insurance companies, public authorities, etc. We are challenged by the fact that DBDS is a national study implemented across 5 different regional blood collection systems. The regions differ in the way they record routine questioning of donors for donation purposes. Furthermore, since DBDS legally and economically is separated from routine blood collection, it was needed to implement a new independent questionnaire system. Thus, participants answer this questionnaire as research participants rather than as blood donors. Since the system is Internet based and uses the civil registration numbers, the questionnaire can technically be filled wherever convenient; however, we have chosen to only allow participants to fill out the questionnaire at the blood donor facilities as we have experience with higher participation rate. 90–95% of all donors invited agree to participate in DBDS. The inclusion rate is to a large extent a measure of invitations from the staff in the blood bank, depending on the work load at the individual donor site. First time blood donors are not included as participants in DBDS. This is due to both practical issues at the blood bank with an extended examination of the donor, and a priority of repeated donors giving more information to the study.

All participants in our study are voluntary unpaid blood donors and they have no incentive to cheat to participate by for instance hiding diseases. Donors can answer incorrect but qua civil registration numbers and Danish registries to hospital contacts, in- and out-patient hospitalization can be checked—and it does not concern to illness hidden. The present version of the questionnaire does not include questions that could cause donor deferrals, but if more sensitive questions are to be included, further explanations on the independent nature of the study would need to be provided.

When new projects are initiated in DBDS not covered by our original ethical approval, we need to apply the Danish Ethical Committee. They decide if the proposed study is covered by our signed consent from the donor. The statistical analyses done by scientist in DBDS are done after coding securing that the scientist does not know the identity of the individual donor. Donors will not be re-contacted if tests indicate a potential higher risk for illness or existing illness. The individual donor will not benefit from our science, but their participation in the

study is a gift like their blood donation. Each of the included blood donors will be followed for 20 years, until termination of the Danish Blood Donor Study in 2050, but participants can at any time request removal of their entire dataset.

The tablet computers have a simple one-touch interface, making it possible for both young and elderly blood donors to complete the questionnaire. This characterization is supported by a previous studies comparing tablet or computer-based questionnaires with paper-based questionnaires for an elderly population (median age 64) and a Cochrane study in the general population [6,7]. The results showed no substantive influence of the questionnaire medium on the content of the collected data [6]. In fact, electronic questionnaires in the Cochrane study were reported to result in more complete records than paper-based questionnaires [7]. When the processing and validation of the paper based and digital questionnaire has been finalized, the two approaches will be studied comparing differences in completeness and consistency.

In conclusion, the digital platform is a faster and more flexible solution than paper-based questionnaires. With the digital platform, it is possible to monitor progress in real time instead of manually counting the answered questionnaires upon collection across the blood banks. Additionally, new versions of questionnaires will be immediately available at all blood collection facilities when new projects are initiated.

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