Electronic Data Capture for Injury and Illness Surveillance

A usability study

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Abstract

Despite the development of injury surveillance systems for use at large multi sports events (Junge 2008), their implementation is still methodologically and practically challenging. Edouard (2013) and Engebretsen (2013) have pointed out that the context of athletics championships feature unique constraints, such as a limited data-collection window and large amounts of data to be recorded and rapidly validated. To manage these logistical issues, Electronic Data Capture (EDC) methods have been proposed (Bjorneboe 2009, Alonso 2012, Edouard 2013). EDC systems have successfully been used for surveillance during multi-sport events Derman et al. (2013) and its potential for surveillance studies during athletics championships is therefore interesting. The focus for surveillance during athletics championships has this far been on injury and illness data collected from team medical staff in direct association to the competitions. But the most common injury and illness problems in athletics are overuse syndromes (Alonso 2009, Edouard 2012, Jacobsson 2013) and knowledge of risk factors associated to these problems is also relevant in association to championships. A desirable next step to extend the surveillance routines is therefore to include also pre-participation risk factors. For surveillance of overuse syndromes, online systems for athlete self-report of data on pain and other symptoms have been reported superior to reports from coaches (Shiff 2010). EDC systems have also been applied for athlete self-report of exposure and injury data in athletics and other individual sports and have been found to be well accepted with a good efficiency (Jacobsson 2013, Clarsen 2013). There are thus reasons for investigating EDC system use by both athletes and team medical staff during athletic championships.

This thesis used a cross-sectional design to collect qualitative data from athletes and team medical staff using interviews and “think-aloud” usability evaluation methods (Ericsson 1993; Kuusela 2000). It was performed over 3 days during the 2013 European Athletics Indoor Championships in Gothenburg, Sweden. Online EDC systems for collection of data from athletes and team medical staff, respectively, were prepared for the study. The system for use by team medical staff was intended to collect data on injuries and illnesses sustained during the championship and the system for athletes to collect data on risk factors.

This study does not provide a solution in how an EDC effort should be implemented during athletics championships. It does however points towards usability factors that needs to be taken into consideration if taking such an approach.
Keywords: Usability, electronic data capture, injury surveillance systems, athletics championships, injury and illness, overuse injuries, risk factors, usability, questionnaire, graphical interface, data entry
Acknowledgements

I would like to thank my supervisor Toomas Timpka for providing the opportunity to tackle this challenge. It has been a very rewarding process of learning.

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David Karlsson

2013
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1 Introduction

Athletics (or track and field) is probably the most popular individual Olympic sport and practiced on all continents. International Championships are held every two years at which up to 2000 athletes compete. Systematic injury surveillance during these events is challenging and the injury surveillance system (Junge et al 2008) needs to be designed and implemented in an adequate way (Mechelen 1997). Until today, data collection during such events has been performed using paper-based forms handed out during the event to team representatives. However, manual distribution of questionnaires and entering or scanning data into a database is associated with risks for errors (Drummond 1995; Pouwer 1998). And perceived challenges, unique to multisport events due to the limited data-collection window and the great amount of data to be recorded and processed very quickly (Engebretsen 2013), can create logistical issues when using paper-based methods (Junge et al 2008). EDC systems can offer a convenient time-effective approach for entering, managing and reporting data (Walther 2011) and have shown to be reliable and easily accessed for clinicians during the Paralympic Games (Derman et al 2013). Schmier et al (2005) concludes however that if the intended respondents have trouble or are reluctant in completing EDC questionnaires, these problems can even outweigh the benefits of EDC’s compared to paper-based methods. Furthermore motivating response is an acknowledged challenge for injury surveillance studies during track and field events (Junge et al 2008). And an EDC questionnaire, that is initially too difficult to use, might discourage data reporting and consequently lower data quality and completeness (Caro et al 2001). However, providing adequate system training to athletes and physicians is not possible during an in-door athletics championship because of the high number of medical physicians and short-term setting (Junge 2008, Engebretsen 2013). Thus investigating usability defects of the system and how it can be accessible for athletes and team medical staffs during track and field events is crucial for a successful EDC deployment. Usability is for the study defined as the extent to which a system can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use (ISO 2002). A secondary goal was to examine respondents’ general opinions and attitudes towards using EDC methods.
1.1 Issues and contributions
Data collection in this thesis took place at the 2013 International Athletics Championship in Gothenburg which was a sensitive setting where disturbing the competitors and team medical staff needed to be avoided. Even the possibility of acquiring participants for evaluations and interviews was no sure thing. Therefore it was necessary to use a method that would be fast and straightforward.

A wide range of usability testing practices and tools are available. There are very elaborate usability testing laboratories with recording devices and one-way mirrors for use in large commercial industrial applications, but few EDC systems are of a scale that warrants such expensive approaches. However, there is a collection of simple, inexpensive techniques known as discount usability engineering that can yield valuable results for systems. The goal of these approaches is not to find the absolute best, most usable design, but to improve the usability of a system enough to yield valuable user productivity improvements. “Think-aloud” methods (Ericsson 1993; Kuusela 2000) is one of those methods. It is fast and straightforward method that has shown to be able to extract rich information about the usability defects (Virzi et al 1996).

As described previously, the standard procedure in injury surveillance studies is to have team medical staff report injury and illness during the championship. But this study also includes data collection on risk factors from athletes. This is because high prevalence of overuse injuries and the perceived interest of aetiological factors of those injuries in connection to track and field events (Alonso et al 2012). Including this was done to build upon the latest findings in injury surveillance studies.

1.2 Issues
The work in this thesis set out to investigate EDC system usability with the criteria to be self-evident. An assumption was made that there was no possibility to provide the intended users on-site training in EDC systems use. Secondly because of the importance of respondents’ motivation in responding to the injury surveillance study forms, attitudes and perceived values regarding accessibility and usefulness are investigated. Thus the work in this thesis was oriented around two overall questions.

The first overall question was about how the team medical staff and athletes would perform and experience the task of reporting through an EDC graphical interface for
data entry. This was investigated with preparation of systems evaluated with usability evaluations methods to explore respondent’s performance and experiences during data entry.

How would team medical staff and athletes’ perform when completing EDC system questionnaires to report data of interest for injury surveillance during track and field events?

What implications does their performance and experiences have on future design of EDC questionnaires for use during athletics championships?

The second was how they perceived the EDC system to be useful and accessible for data collection during track and field events. This was investigated through enquiries focused on attitudes towards, and perceived value of, EDC usage.

How do team medical staff and athletes perceive using EDC system questionnaires for reporting of data for injury surveillance studies during athletics championships?

What implications do team medical staffs and athletes’ perceptions have for future implementation strategies of EDC questionnaires for use during athletics championships?

1.3 Contributions
The EDC system evaluated with athletes was developed as part of this thesis, however the system evaluated with team physicians were not. The infrastructure for the developed system includes a server, database and the files for displaying the questionnaire to the user. This can freely be copied and further developed in future EDC efforts for injury surveillance including risk factors during athletic championships. The ambition was to provide a design that would make reporting data for athletes easy and self-evident.

The usability evaluations aimed to provide knowledge on critical factors in the data entry interface design when little or no time is available to learn the system. Understanding defects in the design helped determine future design strategies (Nielsen 1994).

The interviews aimed to map the respondents’ attitudes and perceptions about electronic data entry during athletics events. This provided insight about potential methodological challenges in using EDC during injury surveillance studies.
1.4 Delimitations
Modern EDC systems are often used in the field of clinical trials and are usually web-based, meaning that they can run in a web browser which makes them available to a variety of platforms and devices. EDC replaces the traditional paper-based data collection methodology to streamline data collection. An EDC system typically have three components, a graphical user interface for data entry, a validation component to check user data and a reporting tool for analysis of the collected data. However if the graphical user interface for data entry is too difficult to use by the respondents, the value of the other two components might be eliminated. For this reason, this study only focuses on EDC data entry from the respondents.
2 Thesis outline

2.1 Background
The background presents how injury surveillance studies during athletics championships are conducted and what challenges it entails. It includes a justification why an EDC system might be appropriate for data collection in injury surveillance studies. Secondly it is presented why it is adequate to collect data from both team medical staff and athletes.

2.2 Methods and materials
This chapter presents the EDC questionnaires and evaluation methods used to elicit rich accounts of the experience from the participants. It explains the EDC systems used including design strategies in the developed system.

2.3 Implications
This section is divided in two parts, one for each EDC system. The goal is to outline implications for design and implementations strategies for successful data entry from athletes and team medical staff during track and field events.

2.4 General discussion
The results are compared to the previous research in injury surveillance and on EDC deployment. A discussion is held about the overall implications of design and strategies if to deploy an EDC system during athletics events. It is also elaborated on the advantages and disadvantages about the choices of using one commercial EDC system and developing a novel system for evaluations.
3 Background

3.1 Epidemiology in sports
In the medical literature, epidemiology is the study of distribution and determinants of disease. In sports medicine, most epidemiological studies regard acute and chronic injuries as "disease," and the results have broadened our current knowledge in many ways. Specifically, these studies have helped identify causes of injuries, determined the effectiveness of preventative measures, quantified the risks of various sport activities, and identified long-term injury trends in sport. This provides data that can enable management and treatment plans for common injuries to be developed, and proactive measures can be designed to prevent common and catastrophic injuries to this population.

Surveillance is usually the method of these epidemiological studies i.e. collection of injury and illness data during training season or competition. This means collecting and analysing data on occurring injuries and illness among athletes. To collect accurate data, injury surveillance systems (ISS) have been developed with varying constellations (Harrison and Price 1992; Finch et al 1999; Junge et al 2004, 2006, 2008) depending on the sport and setting. Each ISS have its own procedures, protocols and tools. These systems provide epidemiological data that are indispensable to identification and subsequently reduce injuries and illnesses in high-risk sports and disciplines. Mechelen (1997) describes that a general sports ISS is useful for answering questions about incidence and severity of the sports injury problem in various subsets of a population. However, he also conclude that if the purpose of injury surveillance is to identify aetiological factors\(^1\) or to assess the effectiveness of the preventative measures, then ISS’s tailored to the specific sport and research setting is required.

3.2 ISS during athletics championships
Junge et al (2008) developed and validated an injury surveillance system for use during athletics championships. How injury surveillance project is conducted today is based on that system. To collect data on occurring injuries or illnesses, paper questionnaires are distributed during the athletics championship to team medical staff. They are asked to report all newly incurred injuries or illnesses (or non-

\(^1\) The cause or origin of a disease or disorder as determined by medical diagnosis.
occurrence of injuries) daily on the provided injury questionnaire. But organizing the use of a paper-based method has its inherent problems. A paper-based system can only be organized in a single way, cannot be easily searched, cannot be easily modified, and cannot be accessed remotely. And when the analysis is conducted incoming answers are scanned or manually entered into the database which is time consuming and also adds the task of checking for scanning or keying errors. Studies indicate that manually entering or scanning individual questionnaires into a database often results in increased error rates (Cella 1995) and concerns about the logistical difficulties on distributing the paper questionnaires during athletics championships have been emitted (Edouard 2012; Engebretsen 2013). Current study procedures (Junge 2008; Junge 2009; Alonso 2010; Engebretsen 2013) for distribution during athletics championships are that questionnaires are printed out by the research team which then tries to maintain their availability for the medical staff during the championship. This means continuously printing out new copies and making sure that physicians have the report forms available. The research team also needs to check the returned injury report forms on a daily basis. Secondly the forms should be checked for double entry. In cases of double reporting by the team physician, the data should be compared and the discrepancies should be clarified. It can also be important to analyse the number of injuries reported from different countries in relation to the number of registered athletes of the respective country to check if the injury rates are as expected. It is of great advantage to control the completeness and quality of the injury documentation during the championships, as the team physicians can immediately be contacted, open questions clarified and missing information added.

EDC can streamline most of these tasks by providing a system where data can be overviewed and checked in a very efficient way. It can also eliminate the distributional problems of paper-based methods by making electronic questionnaires available on varying devices. In quality of life research, Drummond et al (1998) conducted a randomized crossover study where forty-six patients, aged 17-81 years, suffering from gastro-intestinal disorders, used both paper questionnaire and electronic questionnaire to report quality of life. The result showed that data were more complete on the electronic questionnaire (100%) than on the paper (99.1%) and that data procedures were greatly simplified. Drummond et al (1998) concludes that major benefits in completeness of data, speed of data flow, and data handling workload can be obtained from the use of electronic questionnaires.
Walther et al (2011) compared four EDC methods with the conventional approach with respect to duration of data capture and accuracy. It was performed in a West African setting, where clinical trials involve data collection from urban, rural and often remote locations. It was concluded that EDC have the potential to produce similar data accuracy compared to paper-based methods and that they can reduce research-associated costs because of the considerable reduction in time from data collection to database lock. EDC methods have also been introduced for surveillance during multi-sport events. Derman et al (2013) conducted a study at the London 2012 Paralympic Games. Overall, 3565 athletes from 160 of the 164 participating countries were followed daily over a 14-day period, consisting of a pre-competition period (3 days), and a competition period (11 days). Daily injury and illness data were obtained from teams with their own medical support (78 teams, 3329 athletes) via the WEB-IISS and data quality and completeness was high. Thus there is reason to consider EDC use for collection of epidemiological data, such as injury and illness occurrence, during athletics championships.

### 3.3 Respondents

Athletics championships include the track and field disciplines consisting of running, jumping and throwing and also race walking, cross-country and road running. The sport is governed by the International Association of Athletics Federation (IAAF) (http://www.iaaf.org, accessed June 10th, 2013). International Championships are held every year at which up to 2000 athletes compete. Competition at top-level athletics poses risk of suffering from injuries and illnesses (Junge 2009; Alonso 2009; Alonso 2010) and protecting and helping athletes to avoid injury and illness is a task highly prioritized by the International Olympic Committee (IOC) and the International Olympic Association of Athletics Federations (IAAF). As one would imagine, the proportion of injuries is dependent mainly on the sport in question. For example in contact sports, such as football, there are a higher proportion of acute traumatic injuries, whereas in noncontact sports, such as athletics, there is a higher proportion of overuse injuries. The injuries sustained in athletics are widely varied but commonly delineated into two distinct categories: acute traumatic injuries (“macrotrauma”) and insidious overuse injuries (“microtrauma”). Although these types of injuries are inherently different, they both result in debilitation of an athlete’s performance and are therefore considered significant by most epidemiological studies. However, during athletics championships the focus has this
far been on injury and illness surveillance and the data have been collected from team medical staff.

The next step is to extend the data collection to include also risk factors for injury and illness during athletics championships. Overuse syndromes are the most common injury and illness problems calling for prevention in athletics (Edouard 2012, Jacobsson 2012), and knowledge of risk factors associated to overuse problems have also been deemed relevant in association to championships (Alonso et al 2010; Alonso et al 2012). But team medical staff might not be the most qualified in answering questions about risk factors for the athletes. For study of overuse syndromes, online systems for participant self-report of data on pain and other symptoms have been reported superior to reports from athletic trainers (Schiff 2010). Correspondingly, EDC systems have also been applied for athlete self-report of exposure and injury data in athletics, and other individual sports, and were well accepted with a good efficiency (Jacobsson 2013; Clarsen 2013). Jacobsson (2012) used web-based questionnaire assessing self-reported injury data from athletes. The web-based system was based on a commercial product for the collection of survey data and the collection period was a year. The study found acquired sufficient data to find and determine high injury prevalence among elite track and field athletes. Clarsen (2013) used a new method, including a novel overuse injury questionnaire, which was developed and validated in a 13-week prospective study of injuries among 313 athletes from five different sports, cross-country skiing, floorball, handball, road cycling and volleyball. All athletes completed an online questionnaire by email each week to register problems in the knee, lower back and shoulder. Standard injury registration methods were also used to record all time-loss injuries that occurred during the study period. The new method captured a more complete and nuanced picture of the burden of overuse injuries. The result in these studies show that risk factors could, with good efficiency, be reported from athletes.

In conclusion because of the logistical problems inherited by paper-based methods it is reason to consider EDC methods as a tool in future injury surveillance systems deployed during athletics championships. And due the perceived value of risk factors, collection from both athletes and team medical staff might be necessary. However the important question is how data can be successfully collected from those respondents.
3.4 Motivating response
Injury surveillance is dependent on respondents’ efforts to provide the required data for a successful study (Junge 2008). Junge et al (2008) conclude that respondents should be motivated and that the study leader should be available throughout the events to provide motivation to respondents. Thus the success of any injury surveillance study during track and field events is dependent on motivating response. It is vital to success of an injury surveillance project that respondents comply with reporting the data. When investigating implementation of Electronic Health Records (EHR) systems, the value of understanding user motivation in using the system is deemed crucial (McGinn et al 2011, McGinn 2012). McGinn et al (2012) have concluded that the success of electronic report system is greatly dependent on the perceived value from the intended users of the system.

Thus investigating attitudes and perceived values from the athletes and team physicians can provide knowledge indispensable on how to make the system accessible for them during events.

3.5 Restrictive environment
Previous studies have been conducted to investigate the use of EDC during sports events. Ranson et al (2011) used an electronic system for injury surveillance during the ICC Cricket World Cup 2011 which was deemed a successful endeavour. Ranson et al (2011) concluded that the attained completeness of data attests to the efficacy of using networked electronic data collection as opposed to most other similar programmes in other sports that have relied upon paper based data collection, which although effective, are likely to require significantly more collection and processing human resource. But Engebretsen et al (2013) and Edouard et al (2013) have pointed out that athletics events provides unique constraints, such as limited data-collection window and great amount of data to be recorded and processed very quickly. This can create logistical issues, such as limited communication between researchers and physicians, affecting the success of data collection (Junge et al 2008). Furthermore an EDC questionnaire, that is initially too difficult to use, might discourage data reporting and consequently lower data quality and completeness (Caro et al 2001).

3.6 Point of departure
The point of departure was that the short-term data collection context during athletics events differs from the longitudinal setting, i.e. by that the study population is culturally homogenous and that little or no time is available for
learning to use the EDC system before entering the data. Furthermore motivating data contributions during athletics championship is a known challenge (Junge 2008; Engebretsen 2013).
4 Method

The work in this thesis set out to build upon already known methodological strategies and challenges in injury surveillance during athletics events, thus it was important that the EDC questionnaire extended from already established and validated paper questionnaires. Injury questionnaires have been developed over the years and have been implemented at the Osaka 2007 Championships (Alonso 2009) and the Beijing 2008 Olympic Games (Junge 2008; Junge 2008), which was extended to include an illness survey (Engebretsen 2013; Mountjoy 2010). Consequently, this was employed in the EDC investigated with team physicians.

The pre-participation question have not been developed and validated to the same extent, see appendix 2. This questionnaire was however used during the Gothenburg 2013 Athletics Championship and is the latest effort to include data collection on risk factors. The system evaluated with athletes was based on this questionnaire.

The preparation process of the EDC questionnaires was different as it was decided to use a commercial EDC system for collection from team physicians. The motivation was that the system had established back-end security and because it was open-source it could be redesigned and improved later on. However for the questionnaire on pre-participation data from athletes, a more thought out design process could be included prior to evaluations. Design research is the process of design, a process where design methodologies are applied to solve specific problem. Faste and Faste (2012) argue that different approaches can be categorized as design research. One of which is the activities to plan and evaluate experimental designs. It was possible to look at the design of the paper questionnaires on pre-participation and develop an appropriate design accordingly.

For evaluations this study used a cross-sectional design to collect qualitative data from team physicians and athletes using interviews and “think-aloud” usability evaluation methods (Ericsson 1993; Kuusela 2000). Data were collected during the 2013 European Athletics Indoor Championships in Gothenburg, Sweden.

4.1 EDC on injury and illness

OpenClinica, an open source software package exclusively designed for EDC and compliant with Good Clinical Practice (GCP) requirements, was the software of choice. OpenClinica is a web-based application ideally suited to wireless client-server
implementation and is available for free or as paid edition, which includes product support. Its purpose is to be a cheap and powerful tool for data collection in clinical trials. In this system the team physicians could record an injury or illness report.

4.2 EDC on pre-participation
To develop this partial EDC system the open source tools, JavaScript, HTML5, CSS3 and a NoSQL database called MongoDB (http://www.mongodb.org, accessed June 10th, 2013), were used. The infrastructure for the system included a server, database and the files for displaying the questionnaire to the user, see appendix 3. All required data entry fields was determined from the pre-participation paper questionnaire on risk factors, see appendix 2.

The design goal was to provide an interface for data entry that would be self-evident and easy to use. To achieve this, the main focus was to allow the athletes to complete the pre-participation questionnaire without having to do any typing i.e. only using the mouse. Evaluations of EDC systems have, for example, proved that single select questions have lower error rates compared to free text and date fields (Walther 2011). The web form application contained standardized input methods
such as drop-down menus, checkboxes and scales. This was sufficient for most questions but the paper forms on pre-participation ask the athletes to provide injuries or illnesses occurring the month prior to the event. This also needed to be employed in the electronic form. Thus a novel design was developed to allow the athletes to enter different injuries and illnesses and the duration of selected ailment, see figure 2.

Figure 2: The buttons (1) allows to select between three general categories for the injuries and illnesses. (2) displays two lists, different for each category. The athletes can select from both list for the categories injury and illness, but only from one for pain. This was communicated with “OR” or “AND” (3). In the drop-down menu (4) the athletes could select duration of health issue. And (5) shows a list of the added health issues which can be removed by clicking the delete icon.

4.3 Data collection
The recruitment of participants was based on the saturation principle, i.e. that additional participants were invited as long as new phenomena were revealed in the collected data. A laptop with a 15.4 inch screen containing both systems was used.
The evaluations with team physicians took place in the warm-up area in the arena and with athletes at different areas locations.

Evaluations were done through think-aloud usability test methods (Ericsson 1993; Kuusela 2000) with team physicians and athletes at the athletics championship in Gothenburg. Before each session, the participants were briefed about the systems purpose i.e. for data collection in injury and illness surveillance studies during athletics championships. They were then presented with the task of completing the report form and informed that no data entered to the database would be analysed. Qualitative and usability data were gathered from the evaluations through observations, audio-recordings and field-notes. Each session were complemented with questions about the task difficulty, usefulness of the system and opinions about reporting data online.

### 4.4 Respondents
7 team physicians were acquired working for 7 seven different national teams. Most of them had previous experience in working at athletics events and were familiar in the procedure for reporting data for injury surveillance studies. 8 athletes were acquired with a national distribution of 5 from Sweden, 1 from Norway, 1 from Denmark and 1 from the United Kingdom.

### 4.5 Questionnaire
The following table is a rundown of the schedule for interviews after each think-aloud session. A semi-structured format with an explorative approach was taken for the interviews. Further clarifying questions or prompts were used when necessary to facilitate understanding. Due to the limited time window when interviewing the physicians and athletes because of their schedules and stressed environment, the interviews were kept short.

### 4.6 Schedule for interviews
The following table is a rundown of the schedule for interviews.

<table>
<thead>
<tr>
<th>Table 1: Schedule for interviews with team physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is your general impression of the data entry system?</td>
</tr>
<tr>
<td>What are your general impressions of the online questionnaire?</td>
</tr>
<tr>
<td>What, if anything, did you find difficult or frustrating with completing the task?</td>
</tr>
</tbody>
</table>
What, if anything, did you find easier with completing the task?

Do you think an electronic system for reporting could limit you in your work during international athletics championships?

Do you think an electronic system reporting could ease your work situation during international athletics championships?

Would you report injury and illness through the online questionnaire if it was available at the next championship you participate at? (Yes/No)

If this questionnaire was available during an athletics championship, what device would you most likely use to complete it?

Do you have worries about integrity or security when providing health data online?

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**Table 2: Schedule for interviews with athletes**

What are your general impressions of the online questionnaire?

What, if anything, did you find difficult or frustrating with completing the task?

What, if anything, did you find easier with completing the task?

Would you complete the online questionnaire if it was available at the next championship you participate at? (Yes/No)

If this questionnaire was available during an athletics championship, what device would you most likely use to complete it?

Do you have worries about integrity or security when providing health data online?

---

### 4.7 Data analysis

The interviews, including think-aloud session, lasted between 15-25 minutes ($\bar{x} \approx 18$ min) and were recorded and transcribed. Two analyses were carried out, content analysis (Krippendorff 2004) was done for qualitative data from the interview
questions and usability analysis (Nielsen 1994) was done for the interaction data captured from the tasks done by the participants. The focus was on identifying opinions and judgments about system use and detect if features prevented task completion, caused delays, confusion or generated suggestions for improvements. Meaning units were defined as sentences containing aspects of relevance for usability and for the aim of the study through their content and context. The meaning units were then coded by assigning them one or two keywords. Manifest interviewee statements as well as latent interpretations of factors related to system usability were used. The codes could be abstract or concrete and were used to facilitate understanding and to compare meaning units in the different system evaluation aspects that were kept as categories.
5 Results

The physicians were generally positive to the system and of the opinion that it would be useful and even an improvement for collecting data during athletics championships. Filling out injury or illness data was deemed easy, however navigation in the system was not. The physicians displayed different interactive problems during the task, some of which could hinder task completion.

The athletes were positive and experienced the interaction as easy. Few errors were made and they completed the task with ease. However some of the questions were thought of as ambiguous and they felt an uncertainty about what to answer.

The result is presented in three sections for each EDC questionnaire, first general opinions about using EDC for data entry during athletics events is presented, and then the participant’s opinions about interacting with the questionnaire is reported and lastly the identified usability defects, that hindered or hampered task completion, is presented.

5.1 EDC on injury and illness

5.1.1 Perceptions

All physicians (n=7) were in favour of using electronic report forms instead of paper-based forms. They thought for different reasons that the system would make reporting faster and increase efficiency in data collection during events.

_We can do it at home on our computer and it’s already there which makes it easier for us and for you guys. (Team physician)_

The citation above shows how one physician explained that the reporting of data could be done on their own device and sent in online thus eliminating the need to hand it in manually. This was thought to make their and the researchers work easier during injury surveillance studies. This was also the general opinion of the participants. They (n=7) believed that it would be better to report data through the EDC than using paper forms. The reason communicated was that it enables easier management of data during surveillance studies. This was deemed positive by the participants with the argument that a better understanding on the extent, cause and severity of injuries and illnesses is vital to improve athlete conditions. One participant even said that using electronic systems for collection and management of data is the future and the best way to investigate rates of injury and illnesses during athletics championships.
All (n=7) participants thought that it would shorten time to enter data compared to entering paper forms which was deemed very good because of the busy schedule they have during the events. The other reason was accessibility. It was explained that the paper forms are sometimes not available at the end of competition which can lead to extra work or even unreported injuries and illnesses. It was believed that if a report system is available through the web, then the team physicians can report the injury or illness in retrospect regardless which would make their task of reporting easier. Physicians (n=4) also had opinions about where the system could be available. It was perceived that if the EDC was available on a personal device i.e. tablet or smart phone, it would be adequate as they rarely carry around their computer.

Concerns about internet connectivity were communicated. It was pointed out that during championships, especially if it is outdoors, internet access is often limited. Many of the physicians (n=5) thought that if the access to the EDC report forms would be restricted due to limited internet access it could discourage reporting. Three of the physicians thought that this would be troublesome to handle and that the EDC report forms needed to be available offline to be usable during athletics championships.

Some of the physicians (n=4) explained that the system could also be useful for them if they could see and edit the injury or illness reports that they had submitted. It was explained that when reporting during events, sometimes mistakes in the reports are made. The current solution, recommended from Junge et al (2008), is that when a mistake is made in a submitted report then a new paper form should be submitted that corrects the mistakes and referencing to the incorrect report. This was however explained by the physicians to be troublesome and difficult and if they could edit reports in the system it would be an advantage.

None of the participants (n=7) had any worries about integrity or security when reporting athlete injuries or illnesses in an online system. They said that they trust the developers making sure it is safe.

**5.1.2 Assessments**

Many of the physicians (n=6) thought that the task was difficult and if inexperienced with the procedure it would be too difficult. The main issue that was reported was navigating through the steps. This resulted in confusion, hesitation and in many cases an inability to continue the task.
It is easy to fill in the forms, but it is difficult to navigate in the system. What is the next step and how do I get there? (Team physician)

I think it's pretty complicated. It doesn't very clearly show what the next step is. (Team physician)

It felt hard to know the next step. I would make the next step a little bit bigger or highlighted so it is easier to understand where to go next. (Team physician)

The above citations point at the main issue displayed from the physicians during task completion. It was pointed out by all except one physician that navigation was a problem and that the system did not have enough guidance on how to continue.

The physicians (n=7) did however display great proficiency in entering the data at each page and data entry was deemed easy and straightforward. It was thought to be similar to the systems they usually work with in their home country and therefore easy. All of them (n=7) did however have problem in using the date widget.

5.1.3 Usability defects
The procedure for completing the report form was to navigate through 4 pages, see appendix 1. Next, the difficulties recorded at each page will be presented.

Page 1
Four buttons are available in the system and the correct one to click is labelled “Save and assign study event”, see appendix 1. All participants (n=7) showed insecurity on what button to use. Two physicians clicked on “Save and exit” at the first step which directed them to the overview page for already reported athletes. Both physicians could not figure out how to get back to the report and had to start a new report. The result from this was a saved incomplete report form in the database and severely increased task duration for the physicians.

The main reason that was communicated from the physicians was that the labels of the buttons were hard to understand. Three of the physicians said that it might better if the “Save and assign study event” was named “Continue report” or “Continue”. This was thought to make it more apparent on how to continue.

Page 2
Providing an end date generated confusion for the physicians (n=6) as they pointed out that they could not know the end date of an injury or illness. It does say under
the entry field that they can ignore filling that in if not possible, but most participants did not acknowledge that.

Page 3

“Was I not supposed to enter data?” (Team Physician)

“Did I miss to enter the data?” (Team physician)

The citations above points at the confusions and difficulties generated at this step. In short, all physicians (n=7) got stuck wondering if they had missed something or if the task was finished. They often wondered why they had not entered any detailed information about the injury or illness.

Five physicians explained that because the button at step 2 was labelled “Proceed to enter data”, they assumed the next step would contain a form where they could enter detailed information about the injury or illness. This resulted in that two participants went back to step 2 to see if they had missed anything in the report.

Continuing from this step was also shown to be difficult. All participants (n=6) except one had to be guided on how to continue from this step. The problem, as in step 1, was to locate the correct button to continue the report. The location of this buttons is shown in figure 3.

The opinions of this step was mostly negative but it was pointed out that when you have the task procedure fresh in the memory it would be easier, but if you have not done the task before or for some time it was believed to be very difficult because of the lack of feedback and guidance in the system.
Figure 3: Step 3 caused a lot of confusion and the physicians were unable to continue from this step because they could not find the correct button (1).

Page 4
This did not generate any problems and physicians completed this step without any errors. The only problem occurring was interacting with the date widget which was a prominent issue on all steps.

However confusion was recorded when they had clicked “Save”. Physicians (n=5) asked if they had finished the report. Thus there was an uncertainty if they had completed the task and if the report had been submitted.

Date Widget
All physicians (n=7) had problems with the date widget in the system. This was an issue that caused delays and frustration. The problem was that OpenClinica only allows for one format of date to be entered. For example 27-Feb-2013 is accepted but 270213 is not. The first problem was that many team physicians tried to enter the date by typing which caused errors. Furthermore many of the team physicians had issues interacting with the date widget and many errors were made because of it causing frustration and delays.
5.2 EDC on pre-participation

5.2.1 Perceptions
The athletes perceived interaction in the system as easy and straightforward. They did point out that even if the web form was easy to use they might not complete it anyway. The main reason for this was that they are often asked to take part in studies and if they are not forced they will most likely ignore it. Another reason was that they could not see any gain for themselves in answering the report.

*It feels that the result from these studies usually does not help us athletes directly* (Athlete)

Many of the athletes (n=6) communicated that if they could see a direct benefit for themselves or that the trainers or someone official asked them to complete the form it could be a motivation. However two of the participants said that they would not fill in the web form unless they had to.

All athletes (n=8) said that if they would complete the form, they would want to do it after competition. None of them wanted to be forced to think about their injury or illnesses prior to the event as it was perceived that it could affect their focus negatively. The reason was that they almost always have some injuries or illnesses, and during competition they oppress that knowledge and just focus on performing their best. And it was believed that if they would be forced to recollect previous injuries or illnesses it would demotivate them to respond to the pre-participation form.

None of the athletes felt any worries about entering information about their injuries and illnesses in the web form. The main reason given for this was that they did not enter their name.

5.2.2 Assessments
The pre-participation questionnaire which was used as a template for the system provided problems for the athletes when reporting.

*“It is just no direct questions. The questions are not easy to answer and are not touching on something that the athletes are really aware of.”* (Athlete)

The above comment points at the general problem with the questions in the form. Most of the athletes (n=7) thought that the questions were difficult to answer because they did not ask about things they were aware of.
This problem regarded mainly two questions, these were “The mean time spent training during the last month?” and “How much fatigue have you experienced during the last month?”. It was explained that the latter could generate two different answers. On one side, the athlete could have experienced great physical fatigue but almost no mental fatigue and the reverse of that. They could try to create a mean of the two parameters, but this was thought of being prone to inaccurate answers.

The reason that answering mean time spent training was difficult was either that the athlete did not count training spent in weeks but in days which made the calculation of mean time more difficult. But even those who could account for hours per week had problems. The reason was differences in training hours per week. Some of the participants (n=4) said that it would be easier to just answer time spent for each week. The other problem was that the athletes did not understand was counted as training hours. One participant said that athletes basically train 24 hours a day which makes it more or less constant for them. It was also believed that if the web form also accounts for psychological illnesses then mental training should also be included in their answers. This was considered as confusing and the athletes thought that what is asked for needs to more apparent.

When the athletes were to enter health issues they communicated good knowledge about their current or previous health issues. However the terminology used in the web form caused problems. The majority of the athletes were of the opinion that the terminology needed to be simpler or that explanatory information was added.

5.2.3 Usability defects
All participants (n=8) were of the opinion that the web form felt easy and simple to interact with. The layout was thought of as clear and straightforward. Six of athletes did not have any interactive issues during data entry.

Two errors were however done when adding injuries and illnesses. The first was failing to identify that only one option between location and affected part could be chosen. This led to that the participant only filled in affected part. The other error was failing to click the button add health issue. This was not done by participants adding more than one injury or illness.
6 Implications for EDC on injury and illness

6.1 Data entry
Many of the physicians (n=6) pointed out the system did not provide much guidance to help them in completing the task and they displayed confusion about what to do and how to proceed. The main problem was navigating between the pages. These results are supported in the field of Human-Computer Interaction (HCI) where it has been determined that navigation between pages incurs cognitive cost (Sears and Jacko 2002). In conclusion, as determined previously, the data entry interface of an EDC used during athletics events might need to be self-evident and easy to use because of the limited possibility to instruct and guide the respondents in how to interact with the system.

6.1.1 Clear and correct labelling
The result suggests that there is a need for a more adequate terminology which suits the context of injury and illness reporting during athletics championships. The label “Save and assign study event” caused confusion and the physicians thought it could instead be labelled “Continue injury or illness report”. A button or indicator should be labelled so that it represents what it actually routes or guides the user to when interacted with (Rosenfeld 2006). The result indicates that this was a major problem for example the button “Proceed to enter data” which routes the user to step 3. Physicians seemed to believe that they would be routed to a page where they could enter the information about the injury or illness. Questions as “Was I not supposed to enter data?” and “Did I miss to enter data?” came up because of this showing that the button did not represent what the physicians thought would be the result when clicking it. The problem of incorrect representations was prominent for many of the buttons and labels making the physicians insecure if it would generate the correct result. This should be resolved so that buttons, through adequate labelling actually, represents the correct function and helps respondents interpret the functionality. In short the labels should be adjusted to the context of track and field events.

6.1.2 Indicate where to go
Physicians often had problems to continue the report. This was very apparent in step 3 where none of the physicians actually managed to find the button to continue. The result indicate that there is a need to make buttons for continuing to next step more evident so the team physicians can find them more easily.
Rosenfeld (2006) argues that in any web-design, features that have more importance to the task should be more prominent for the user. For each step there is a button for continuing, and there is only one button that is correct. Due to the importance of these buttons they should be more apparent in the interface so they are easier to find (Rosenfeld 2006, Tidwell 2011). An example might be to change the buttons to another colour that is unique to the rest of the page i.e. a colour only used for that button.

Highlighting the buttons to continue to next page might help physicians to find it. But it is also important that the buttons are explained with an adequate label so the physicians can interpret the result if clicking it.

### 6.1.3 Entering date

The difficulties with the date widget have been recorded in a study by Walther et al (2011) where *OpenClinica* were evaluated. It was determined that those who used the date-widget had significantly increased error rates in the date fields, whereas the error rates for other fields such as text or single select fields were not increased. In that study, dates were usually shifted one or two months or years forwards or backwards, which indicates that the interviewer missed the correct field, when choosing the date. Since the calendar function seemed to be associated with increased error rates, alternative methods such as separate fields for day, month and year, could be implemented. This was also the case in this study where many issues with entering date could be attributed to the date-widget. The recommendation that Walther et al (2011) does is to implement single select drop-down menus for the dates. Consequently, the date-widget should be improved and single-select dropdown menus might be an appropriate design choice

### 6.2 Implementation

The results show that the team physicians were very positive in using EDC for data collection. All of them thought (n=7) that using an EDC questionnaire would make their situation easier in reporting injury and illness data. This is an important insight about the physicians. Previous research has shown that perceived usefulness from practitioners is crucial to the success of implementations of electronic report systems (McGinn et al 2012). And if this perceived value is accurate it can help motivating the team physicians to contribute which is a known challenge during injury surveillance studies (Junge et al 2008). Consequently, this is a result that
points towards that the intention of using EDC during athletics championships might be adequate.

6.2.1 Accessibility

All physicians thought that using an EDC system would be an improvement as they then could report from any location. The lack of internet access was however a concern communicated from the physicians. And in previous EDC efforts during multi-sport events this has been a criteria (Derman et al 2013).

The result, supported by Derman et al (2013), indicate that an EDC effort that will support the perceived need from physicians and also be technically feasible needs to be implemented in an environment where internet access is guaranteed throughout the venue of the championships or that a sufficient solution can be implemented to support partial internet access.

The result also points towards that team medical staff wants a system accessible on several devices. Most of them (n=6) thought that it would be beneficial if they could create reports on smart phones or tablets as they move around a lot and rarely carry around their own computer. To support accessibility for most team medical staff, a solution on multiple devices might be necessary so they can report injuries or illnesses whenever able to.
7 Implications for EDC on pre-participation

7.1 Data entry
Most athletes had no problem with completing the form. Two errors where however recorded for the functionality of adding health issues. To avoid these errors in the future, it needs to be more apparent that only one option can be selected by showing the “OR” label more clearly or adding explanatory text.

The problem with athletes not adding health issues to the list can be managed by checking that they have added information to the health issue list when they submits the form. If the list is empty or health issues are marked but not added the athlete could be made aware of this problem and suggesting what the problem could be and how to correct it.

It is noteworthy that the single select drop-down menus worked as well as they did. This is supported by Walther et al (2011) who concludes that they are a good solution to minimize errors during data entry.

7.1.1 Queries
Some of the questions were not deemed adequate and the athletes had problems answering them. The results show that the questions “The mean time spent at training per week during the last month?” and “How much fatigue have you experienced during the last month?” generated most problems. The participants described that the calculation was difficult because the training hours differed a lot between weeks, especially before competition. This made it very tricky to estimate a mean of training hours. Many of the athletes (n=6) said that it would be a lot easier to report training hours for each week instead. This is supported by Clarsen et al (2013) where athletes were followed during a 13-week prospective study. In that study athletes were asked to report data on health and training status for the last week. Clarsen et al (2013) determined to have captured an accurate complete and nuanced picture of the burden of overuse injuries. Athletes seem to have a sufficient ability to provide weekly reports to provide high data quality and completeness (Clarsen 2013, Jacobsson 2013).
7.1.2 Terminology
The athletes also had problems understanding the medical terms used for the injury and illnesses lists (see figure 2). This could hinder the athletes to provide a complete report on pre-participation and by that lower the quality of data. This needs to be managed at some level in the EDC questionnaire design. Some of the athletes said that an explanation of each injury and illness term would be an improvement. Thus a solution where athletes can get further instruction on the terms used might be necessary.

7.1.3 Motivation
Many of the athletes (n=7) said that if they could see any gain for themselves in completing the form it would be more likely that they would do it. This is supported by results in psychology on motivation for behaviour.

Self-determination theory (SDT) maintains that an understanding of human motivation requires a consideration of innate psychological needs for competence, autonomy, and relatedness (Deci and Ryan 2000). Most contemporary theories of motivation assume that people initiate and persist at behaviours to the extent that they believe the behaviours will lead to desired outcomes or goals. SDT teaches us that motivation can be found where the individuals can identify a gain in personal health and well-being. This supports how the athletes perceived their reasons in not responding to the questionnaire i.e. they could not see any gain for themselves as athletes.

The other reason communicated was that if coaches or team medical staff encouraged them to answer the pre-participation forms they might do it. In other studies where the athletes have been asked to provide data for registration of overuse injuries in sports epidemiology (Clarsen 2013), the method have been to first approach team coaches and ask about interest in participating in the study. And if they consent, the athletes are asked about participation. That study had high response rate from athletes and maybe a similar approach is needed during track and field events.

Further investigations are needed to understand how the athletes can be motivated to complete the form so that data quality and completeness can be ensured. Both intrinsic and extrinsic motivation could be investigated to find a solution to this
challenge. The results indicate however that what should be avoided is to force response from the athletes prior to competing. All of the athletes said that this would not be desired and would be demotivating for them regarding responding to the pre-participation form.
8 General discussion

When including EDC systems for data collection in injury surveillance systems deployed during sports events the validation procedure have so far been on data quality and completeness obtained through the EDC system (Ranson et al 2011; Derman et al 2013). The investigation of EDC use during track and field events in this thesis instead focused on the respondents and the interface design. They are crucial for the injury surveillance studies as they provide the data, thus understanding how they can do it without much constraint seemed like a sensible approach.

The results points towards that team medical staff are positive in using an EDC solution which can further facilitate reporting from these individuals. The interface did not however provide an easy and self-evident solution as all physicians displayed difficulties in completing the task. Implications and recommendations to work towards a more sufficient design have been presented where guiding the respondents, through better navigational features, were emphasised. The result for the EDC system on pre-participation seems to be the opposite. The athletes did not display any difficulties in interaction and perceived it as easy and straight-forward. They did however communicate reluctance in actually responding to the pre-participation form. Recommendations provided, taken from psychology (Decy and Ryan 2000) and other epidemiological studies in athletics (Carsen et al 2013), is either to communicate gains for the athletes to generate a belief that response to the EDC forms can improve their health status in the future, or approaching coaches and team physicians to encourage response from the athletes. Both these can solution can of course be embraced simultaneously. An unexpected result also points towards that the pre-participation form needs to be improved to collect accurate data on risk factors.

Before ending with the conclusion a discussion about the approach and methodology in this thesis should be held.

8.1 Reporting injury and illness

The team physician’s task during a track and field event is not just to report data. They also have a responsibility to revise and complement reports already submitted. This can be for two reasons, either that they have made a mistake in the report or that further data on the injury or illness is available. The current recommendation from Junge et al (2008) is that if physicians make an incorrect response they are
instructed to create a new paper report referencing to the incorrect report. In situations when the diagnosis (or the duration of absence) is revised later as more information about the injury becomes available, the team physician should report the injury again (with the previous data and location of injury to indicate that this is a revised report) and state the corrected information.

Thus the system in this thesis also needs functionality to support these tasks for the physicians. *OpenClinica* have this feature but as shown in this thesis and other studies (Franklin et al 2011), the usability and ease of use needs to be investigated and most likely improved to allow the physicians to do editing in an easy manner.

### 8.2 Pre-participation forms
The EDC on pre-participation from athletes was developed as part of this thesis and the design seemed to provide a data entry solution that the athletes could report in without doing errors.

An unexpected result in this thesis was the perceived issues the athletes had with the questionnaire. The questions used in the system were taken directly from the paper form developed and validated for collection of pre-participation on risk factors during the 2013 International Athletics Championship in Gothenburg. The goal was to collect data on usability defects but instead most data concerned the formulation of questions and challenges in providing adequate and accurate response. Luckily the usability defects seemed to be minimal as the athletes did make very few errors. However the implications for this are that more work is needed to develop questionnaires to employ in the EDC system that the athletes easily can answer. Response rate can easily be affected by the difficulty of questions.

### 8.3 Supporting researchers
This study only examined the ease of use for reporting data, but an EDC can have other functionalities than that. As described previously, the goal with EDC systems is also to support the researchers conducting the injury and illness surveillance study. This is often achieved through a graphical interface where data can be overviewed and examined. Current study procedures (Junge 2008; Junge 2009; Alonso 2010; Engebretsen 2013) include the tasks of validating, checking for doubly entries, and analysing the reports submitted for the researchers.

Franklin et al (2011) revealed that *OpenClinica* has a steep learning curve and that users might be limited by all its functionalities. Thus further investigation on usability is needed to find a design that work in for injury surveillance during
athletics championships. For the EDC on pre-participation there is possible to overview the reported data but it is not done through a graphical interface. Thus if the system is going to be used live for injury surveillance, a graphical interface needs to be designed and implemented so it can provide the benefits of managing data during the study.

8.4 Aim

The limited design of OpenClinica to accommodate for the injury and illness questionnaire constrained the investigation. As displayed from the result for the novel EDC questionnaire design, it seems to be possible, and maybe even adequate to find a solution to the problem by the process of design (Faste and Faste 2012). As shown in this thesis, the task of creating an EDC questionnaire for the purpose to be easy and self-evident can be accomplished prior to evaluations. Thus because of the importance of successful data entry from team physicians is might be better to provide a novel design solution. And even though OpenClinica has established features in data security, it is still a greatly flawed design because of its purpose to be used in clinical trials where sufficient system introductions can be assumed.

The strength however for using a commercial EDC system is the established data security features. This is important for two reasons, first recording of athlete’s health is sensitive and a spread of this information to the public should be avoided. Therefore having a secure system is critical for the safety and privacy of the athletes. The second reason builds upon this fact. The IOC and IAAF are responsible for approving injury surveillance studies during athletics events. Thus they have a great interest in making sure that the athletes do not get exposed in a harmful way. Therefore these stakeholders might have a greater interest in using a system that have established and validated data security.

This potential constraint needs to loosened somewhere down the line if future investigation and development of EDC system for use in injury and illness surveillance during athletics championships is going to be a successful endeavour. Other studies have proved that developing a system (Derman et al 2013) or using a system based on the guidelines for injury surveillance in the given sport (Ranson et al 2013) can provide a solution that generate data quality and completeness. Adding to that, this study implicates that a partial EDC system can be designed to provide a solution that works in being self-evident and easy to use. Thus developing system
from the ground up seems to be the most appropriate approach if the knowledge and resources can suffice for that.

8.5 Limitations
This study has several limitations that need to be considered when interpreting the results. This study addressed usability issues, and does not provide complete information for the design of an EDC system for use during athletics championship. However, it points at issues important to consider prior to an EDC effort. The lack of motivation from athletes and the interaction issues displayed by physicians are two examples of this. However, it is also important to acknowledge that collecting data through an EDC system is just one step of a complex study workflow. Moreover, an assumption was made in the study design that the possibilities for personal on-site training in system use for athletes and team medical staff were limited, it is probable that individual training sessions in system use would have prevented several of the human-computer interaction issues observed in the evaluation data. Although a qualitative approach based on usability tests and interviews was used, with the purpose of eliciting rich accounts of the experience of athletes and medical staff, some important aspects and areas may still have been omitted in the data. However, the similarity of the accounts collected from the evaluations and interviews suggests that the findings can be regarded trustworthy.

9 Conclusion
In this study of factors critical for the usability of EDC systems for gathering of data on pre-participation risk factors and injury and illness in association to international athletics championships, we found that athletes’ motivation to enter data and the design of the human-computer interface for team medical staff were key issues. The EDC interface must harmonize with other fundamental surveillance elements such as the study protocol and data validation and analysis methods. Therefore, a successful implementation of EDC during athletics championships requires parallel adjustment of work processes and reallocation of resources. The results of this study can be used as a basis for implementation and evaluation of prototype systems for use in regular data collection.
10 Bibliography


11 Appendices

Appendix 1 – EDC on injury and illness data

Step 1
Step 2

Schedule Study Event for 126

Study Subject ID: 126
Study Event Definition: ILLNESS REPORT (Repeating)
Start Date/Time: 2012-04-15 15:00:00
End Date/Time: 

Schedule Another Event (optional)
Proceed to Enter Data  Cancel

Step 3

Enter or Validate Data for CRFs in INJURY REPORT

Study Subject ID: 125
Study Event: INJURY REPORT
Location: N/A
Subject ID: 125
Start Date: 27-Feb-2013
End Date/Time: 
Subject Event Status: data entry started
Last Updated by: Jowan (27-Feb-2013)

CRFs in this Study Event:

<table>
<thead>
<tr>
<th>CRF Name</th>
<th>Version</th>
<th>Status</th>
<th>Initial Data Entry</th>
<th>Double Data Entry</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>injury report</td>
<td>0.0.1</td>
<td>Jowan</td>
<td>n/a</td>
<td></td>
<td>View CRF</td>
</tr>
</tbody>
</table>

Workflow:

Study Event Overview → Data Entry → Mark Event CRF Complete
Step 4 (injury report)

Injury report Ver 0.93

Step 4 (illness report)

Illness report Ver 0.93
Appendix 2 – Pre-participation on risk factors, tutorial

**Pre-participation health questionnaire**

European Athletics Championships, Göteborg 2013

Injury & Illness Prevention Study

<table>
<thead>
<tr>
<th>Information about you:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender: ☐ Male Date of birth (YY/MM/DD):</td>
</tr>
<tr>
<td>Length (centimeters): Weight (kilogram):</td>
</tr>
</tbody>
</table>

Your primary event (e.g. high jump, shot put):

The mean time spent at training per week during the last month (hours):

<table>
<thead>
<tr>
<th>Information about your health:</th>
</tr>
</thead>
<tbody>
<tr>
<td>How much fatigue have you experienced during the last month?</td>
</tr>
</tbody>
</table>

(Please answer with an “X” on the horizontal line.)

---------------------------------------

No fatigue                                  Extreme
During the last month, have you had any difficulties participating in normal training and competition due to health problems?

☐ Full participation without health problems

☐ Full participation, but with health problems

☐ Reduced participation due to health problems

☐ Cannot participate due to health problems

If you have had health problems, could you please describe:

- the problem(s) (if there were more than one problem please describe all)?

☐ pain (without known exact diagnosis and/or cause)(codes in next page will help you):

- location or affected system:
- duration (days):

☐ injury (e.g. muscle strain, low back pain)(codes in next page will help you):
- location:
- type of injury diagnosis:
- duration (days):

☐ illness (e.g. cold, infection)(codes in next page will help you):
- affected system:
- main symptom(s)
- duration (days):

- to what extent the health problem(s) has(ve) affected your performance during training and/or competition?

☐ No reduction

☐ To a minor extent
To a moderate extent
☐
To a major extent
☐
Cannot participate at all
☐

Please return this document to the “I&I study office” in the warm up area (next to athletes enters).

Thank you for your participation!

European Athletics

Tutorial to describe the health problem

For pain and injury:

<table>
<thead>
<tr>
<th>Head and trunk</th>
<th>Upper extremity</th>
<th>Lower extremity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 face (incl. eye, ear, nose)</td>
<td>11 shoulder / clavicle</td>
<td>21 hip</td>
</tr>
<tr>
<td>2 head</td>
<td>12a/p upper arm (anterior/posterior)</td>
<td>22 groin</td>
</tr>
<tr>
<td>3 neck / cervical spine</td>
<td>13a/p elbow (anterior/posterior)</td>
<td>23a/p thigh (anterior/posterior)</td>
</tr>
<tr>
<td></td>
<td>13m/l elbow (medial/lateral)</td>
<td>24a/p knee (anterior/posterior)</td>
</tr>
<tr>
<td>4 thoracic spine / upper back</td>
<td>14a/p forearm (anterior/posterior)</td>
<td>24m/l knee (medial/lateral)</td>
</tr>
<tr>
<td>5 sternum / ribs</td>
<td>15a/p wrist (anterior/posterior)</td>
<td>25a/p lower leg (anterior/posterior)</td>
</tr>
<tr>
<td>6 lumbar spine / lower back</td>
<td>16a/p hand (anterior/posterior)</td>
<td>26 Achilles tendon</td>
</tr>
<tr>
<td>7 abdomen</td>
<td>17a/p finger (anterior/posterior)</td>
<td>27m/l ankle (medial/lateral)</td>
</tr>
<tr>
<td>8 pelvis / sacrum / buttock</td>
<td>18a/p thumb (anterior/posterior)</td>
<td>28a/p foot / toe (anterior/posterior)</td>
</tr>
<tr>
<td>Type of injury - Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>For pain and illness:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Affected system</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Upper respiratory tract (nose, sinuses, pharynx, larynx)</td>
<td>5 Uro-genital, gynecological or reproductive</td>
<td></td>
</tr>
<tr>
<td>2 Lower respiratory tract (trachea, bronchi, lungs)</td>
<td>6 Endocrine or metabolic</td>
<td></td>
</tr>
<tr>
<td>3 Gastro-intestinal</td>
<td>7 “Blood” (Hematologic or immune)</td>
<td></td>
</tr>
<tr>
<td>4 cardio-vascular</td>
<td>8 Neurologic, CNS</td>
<td></td>
</tr>
<tr>
<td><strong>Main symptom(s)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Pain, ache or soreness</td>
<td>6 Irregular heartbeat, palpitation, syncope, collapse or chest pain</td>
<td></td>
</tr>
<tr>
<td>2 Fever, excess sweating or chills</td>
<td>7 Congestion, hyper secretion</td>
<td></td>
</tr>
<tr>
<td>3 Nausea, vomiting or diarrhea</td>
<td>8 Cough, wheezing, dyspnea</td>
<td></td>
</tr>
<tr>
<td>4 Weight loss or dehydration</td>
<td>9 Dizziness or vertigo</td>
<td></td>
</tr>
<tr>
<td>or arterial hypotension</td>
<td>10 Rash, itch or eczema</td>
<td></td>
</tr>
<tr>
<td>5 Fatigue, lethargy</td>
<td>11 Numbness, weakness or tingling</td>
<td></td>
</tr>
<tr>
<td>or arterial hypotension</td>
<td>12 Mood/sleep disturbance, anxious</td>
<td></td>
</tr>
<tr>
<td>6 Fatigue, lethargy</td>
<td>13 other</td>
<td></td>
</tr>
<tr>
<td>7 Fatigue, lethargy</td>
<td>14 fasciitis / aponeurosis injury</td>
<td></td>
</tr>
<tr>
<td>8 Fatigue, lethargy</td>
<td>15 impingement</td>
<td></td>
</tr>
<tr>
<td>9 Fatigue, lethargy</td>
<td>16 laceration / abrasion / skin lesion</td>
<td></td>
</tr>
<tr>
<td>10 Fatigue, lethargy</td>
<td>17 dental injury / broken tooth</td>
<td></td>
</tr>
<tr>
<td>11 Fatigue, lethargy</td>
<td>18 nerve injury / spinal cord injury</td>
<td></td>
</tr>
<tr>
<td>12 Fatigue, lethargy</td>
<td>19 muscle cramps or spasm</td>
<td></td>
</tr>
<tr>
<td>13 Fatigue, lethargy</td>
<td>20 other</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 3 – EDC on pre-participation

A

European Athletics Indoor Championships, Göteborg 2013
Injury & Illness Prevention Study
- Information for athletes

Pre-participation health questionnaire

Information about you

Gender
Select Gender

Date of Birth
d m y

Country
Select Country

Length
Select length

Weight
Select Weight

Your primary event
Select primary event

The mean time spent at training per week during the last month
Select hours

Information about your health

How much fatigue have you experienced during the last month?
information about your health

How much fatigue have you experienced during the last month?

No fatigue [ ] Extreme fatigue [ ]

During the last month, have you had any difficulties participating in normal training and competition due to health problems?

☑ Full participation without health problems
☑ Full participation, but with health problems
☑ Reduced participation due to health problems
☑ Cannot participate due to health problems

If you have had a health problem during the last month, please describe:
If there were more than one problem, please describe all

Use buttons to add health problems

Pain   Injury   Illness
If you have had a health problem during the last month, please describe:
If there were more than one problem, please describe all

Use buttons to add health problems

<table>
<thead>
<tr>
<th>Select location</th>
<th>AND</th>
<th>Select diagnosis</th>
<th>AND</th>
<th>Select duration of health issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Face</td>
<td></td>
<td>Please select diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Head</td>
<td></td>
<td>1. Concussion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Neck</td>
<td></td>
<td>2. Fracture (traumatic)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Upper back</td>
<td></td>
<td>3. Stress fracture (overuse)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Sternum/ribs</td>
<td></td>
<td>4. Other bone injuries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Lower back</td>
<td></td>
<td>5. Dislocation, subluxation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Abdomen</td>
<td></td>
<td>6. Tendon rupture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Pelvis/acrum/buttock</td>
<td></td>
<td>7. Ligamentous rupture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Shoulder/clavicle</td>
<td></td>
<td>8. Sprain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Upper arm</td>
<td></td>
<td>9. Lesion of meniscus or cartilage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Elbow</td>
<td></td>
<td>10. Strain/muscle rupture / tear</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Forearm</td>
<td></td>
<td>11. Contusion/haematoma / bruise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Wrist</td>
<td></td>
<td>12. Tendinitis/tendinopathy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Finger</td>
<td></td>
<td>14. Fascitis/aponeurosis injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Thumb</td>
<td></td>
<td>15. Impingement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Hip</td>
<td></td>
<td>16. Laceration/abrasion / skin lesion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Groin</td>
<td></td>
<td>17. Dental injury/broken tooth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. Knee</td>
<td></td>
<td>19. Muscle cramps or spasm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. Lower leg</td>
<td></td>
<td>20. Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. Achilles tendon</td>
<td></td>
<td>2 Days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23. Ankle</td>
<td></td>
<td>[Add health issue]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Added health issues**
- Wrist: Sprain (injury of joint and/or ligaments) Duration: 9 days
- Ankle: Sprain (injury of joint and/or ligaments) Duration: 5 days
To what extent the health problem(s) has(ve) affected your performance during training and/or competition?

- No reduction
- To a minor extent
- To a moderate extent
- To a major extent
- Cannot participate at all

Submit Answers
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