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Publication date
2017

Document Version
Final published version

Published in
Tijdschrift voor Human Factors

Citation (APA)
Meeuwsen, F., Guédon, A. C. P., van der Elst, M., & van den Dobbelsteen, J. (2017). Living labs: The Smooth Operator. *Tijdschrift voor Human Factors*, *42*(2), 5-8.

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Living labs: The Smooth Operator

More and more medical technology is finding its way to the operating room, which is a great benefit for efficiency and patient safety. However, it may also cause disturbances in the workflow. Living labs and Test Beds such as a Research Operating Room can provide a real-life setting in which safe implementation/ research in the field of work processes and protocols can be studied. In this paper, we discuss the added value of such a Living Lab, illustrated by two cases.

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The perioperative process is a complex, high-risk core activity within a hospital in which the activities of many professionals of different disciplines should be managed and aligned to ensure a safe environment for the patient. The potential of new technology to improve the quality, efficiency and safety of healthcare delivery is undisputed. However, introducing novel medical technology may inflict unexpected changes in the workflow and could introduce unforeseen risks and dangers for the patient; even the smallest disruptions of the normal workflow may induce delays or deviations from protocol, thereby reducing patient safety and efficiency in the entire care pathway (Arora et al., 2010; Wiegmann, ElBardissi, Dearani, Daly, & Sundt, 2007). Moreover, not all medical devices undergo clinical trials prior to introduction. In fact, many novel medical technologies are in conflict with the request for efficient treatment processes, which in the end results in increased costs and unviable products (Kumar, 2011).

A major challenge for safe introduction of novel medical technology is the management of proper work processes and protocols that go along with the application of the technology. This includes the availability of properly trained clinical staff, device compatibility with other necessary medical equipment and materials, all of which have to be joined at a defined point of time and at a specified location. However, the limited saliency of small disruptions of the workflow in daily routine will not stimulate active reorganisations of the working processes and severe disruptions that impose major risks might only happen once in several years. Ideally, there should be continuous surveillance and monitoring based on methods that are sufficiently sensitive to detect problems, however small they may be.

Living Labs and Test Beds

Active seeking and defining the best methods of organizing healthcare delivery is crucial to detect problems with new and existing technologies and to maintain patient safety. An essential feature of this approach is the validation of the service or the product in an (small scale) implementation setting. Validation in a real-life setting can be achieved in so-called Living Labs (LL) or Test Beds (TB). These facilities provide an environment with actual end-users in which both new work processes and validation of new products and services (Living Labs) or just validation of new products and services (Test Beds) can be performed. To illustrate the benefits and potential of such facilities for both the development of novel technologies and the evaluation of the safety or safe use of existing technology we discuss in this paper two cases that were studied in such a real-life setting; the Research Operating Room (OR) that was established in the Reinier de Graaf hospital (RDGG) in Delft, The Netherlands. The RDGG is a Top clinical training hospital providing a range and format of accessible healthcare facilities and resources.

The RDGG Research OR is equipped with monitoring technology (e.g. RFID tags and cameras) for automated recording of critical steps during surgical procedures. Thereby, objective data can be gathered on the impact of novel technology on changes in the OR resource management and on safety aspects. While the availability control of medical staff and medical devices could be achieved with for instance clinical information systems, the management and automated monitoring of other resources is in normal OR settings limited or not possible at all. Within the RDGG Research OR, an appropriate assistance system for validation of new

Figure 1. Electrosurgical device and current sensor (encircled).

technologies and protocols is already in place (i.e. a Digital Operating Room Assistant (Guedon et al., 2014)), which allows assessing the impact of events in advance to the actual implementation of the proposed technology.

In the following we will discuss two cases that were studied in the Research OR. Case 1 focuses on the validation of the application of pattern recognition methods for automatic phase detection in surgical procedures. The developed system automatically informs the OR staff about the optimal timing to start preparing the next patient (Guedon et al., 2016). Case 2 targets detailed registration of the application of a common but high-risk technology, electrosurgery (Meeuwsen et al., 2017). Electrosurgery is used in 80% of surgical procedures and allows surgeons to skilfully dissect tissue and achieve rapid hemostasis.

Case 1. Phase detection in surgical procedures

The usage of devices and instruments can provide essential information about the progress of a procedure (Blum, Padoy, Feussner, & Navab, 2008b). Patterns in the usage of devices and instruments can be detected for various types of procedures. These patterns can then be used to detect the actual phase of a surgical procedure. Several pattern recognition approaches explored in previous studies have presented the potential of automatic recognition of the phase of procedures (Blum, Padoy, Feussner, & Navab, 2008a).

During a laparoscopic cholecystectomy, electrosurgery is activated during the removal of the gallbladder from the liver, which matches a certain stage of the procedure. Therefore, the activation of the electrosurgical device is suited to monitor for pattern recognition purposes. Activations of the electrosurgical device were detected by measuring the current delivered to the device at a frequency of approximately 10 times per second. Each peak in the amount of current corresponds to an activation of the device. The current sensor we used is shown in Figure 1.

Predicting end-time

During 57 laparoscopic cholecystectomies, the activation pattern of the electrosurgical device was measured to train an algoritm suitable for automated monitoring of surgical progress. The main goal of the experiment was to study the feasibility to use these activation patterns as input for predicting the end-time of the procedure, which in turn can be used to streamline the scheduling of procedures in the OR. A real-time prediction system was developed which was used to communicate the predicted end-time of the procedure to the OR staff.

The reliability and usability of the system's predictions were tested during 21 subsequentially performed laparoscopic cholecystectomies. The mean absolute error was smaller for the prediction system (14 min) than for the OR staff predicting the end-time (19 min). The results show that the system's predictions were more reliable for procedures with average or long duration than for the ones with short duration. For procedures longer than 40 min, the mean absolute error was 9 min and therefore within the margins of reliable predictions. For these procedures, the system's predictions outperformed the OR staff's predictions, which presented a mean absolute error of 29 min. The predicted end-time was used to estimate the optimal time to prepare the next patient for surgery. To receive feedback we asked the OR staff (i.e. nurse anesthetist) to validate this prediction via a software interface presented on a tablet (see Figure 2).

The timing to start preparing the next patient was predicted slightly later than optimal by the system and mostly earlier than optimal by the OR staff. Nevertheless, the main benefit lays in the enhanced access to information on the progress of the procedure from outside the OR. This information can be used by the OR schedulers without having to interrupt the surgical process. Additionally, information on the progress of the procedure is valuable for the nursing staff, who can anticipate the preparation and transport of patients from and to the nursing department (Guedon et al., 2015). It can also reduce the efforts of the nursing staff to update the patients and the persons accompanying patients about their progress.

Case 2. Application electrosurgery

In this study, current measurement technology was used to get insight in the actual application of electrosurgery devices. This study was motivated by recently published reports by the Dutch Healthcare Institutions (Dutch association of hospitals (NVZ) and Dutch association of university hospitals (NFU), 2011; Dutch Healthcare Inspectorate (IGZ), 2014). These reports express concerns about the rapid increase of medical technology, its related risks to patient safety and the lack of structured certification systems to assess necessary competences in using medical equipment. Crucial for such a certification program is to have proper and frequent assessments for each type of medical technology. Therefore, it is necessary to understand how devices are used in real-life.

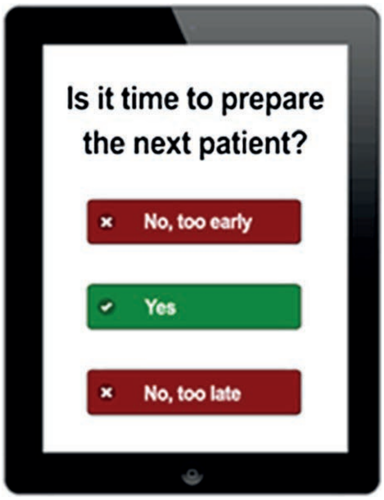

Figure 2. Interface used to validate real-time monitoring of OR processes.

For this study we obtained a detailed registration of 91 laparoscopic cholecystectomies performed by five experienced surgeons and 11 surgical residents. The main objective was to examine potential differences in handling techniques between operators and to determine whether experience plays a major role in the way electrosurgery is applied.

Our main findings show that different approaches in application technique can be distinguished among the operators; typically, a higher number of activations goes along with a short activation time and vice versa. Figure 3 left shows the pattern of an expert surgeon, whereas Figure 3 right shows the performance of a surgical resident. Also, differences between individual surgeons and residents were found.

All residents use a higher number of activations with a shorter activation time, while various surgeons seem to choose for the opposite approach. The latter is remarkable as the guidelines suggest using brief intermittent activations. Such insights are valuable information when setting up a certification system according to the earlier mentioned reports.

Discussion

Evaluating the safety of medical technology in Living Labs allows assessing its impact in advance of the actual implementation. The need for such facilities is further strengthened by the guidelines formulated in the 'Dutch Convenant safe use of medical equipment' that prescribes hospitals to ensure that a competence assessment and certification system is in place (Dutch association of hospitals (NVZ) and Dutch association of university hospitals (NFU), 2011). Living labs and Test Beds, such as the Research OR, offer the real-life setting in which necessary protocols and training programs for using the technology can be designed and validated.

The two cases on measurement of activation patterns of electrosurgical devices show the potential of non-obtrusive monitoring of surgical handling. Systematic and continuous recording of detailed use of medical equipment may provide insight in many aspects of the surgical workflow. Table 1 lists the key features that should be part of any working protocol; that is, all resources that are part of the clinical procedure such as devices, instruments and personnel. Therefore, well-designed protocols are not only relevant for dealing with new technology, but it also touches upon the performance of the involved staff and the smooth flow of essential resources.

In short, Living Labs allow us to introduce new technology with minimum waste and maximum benefit for the healthcare system.

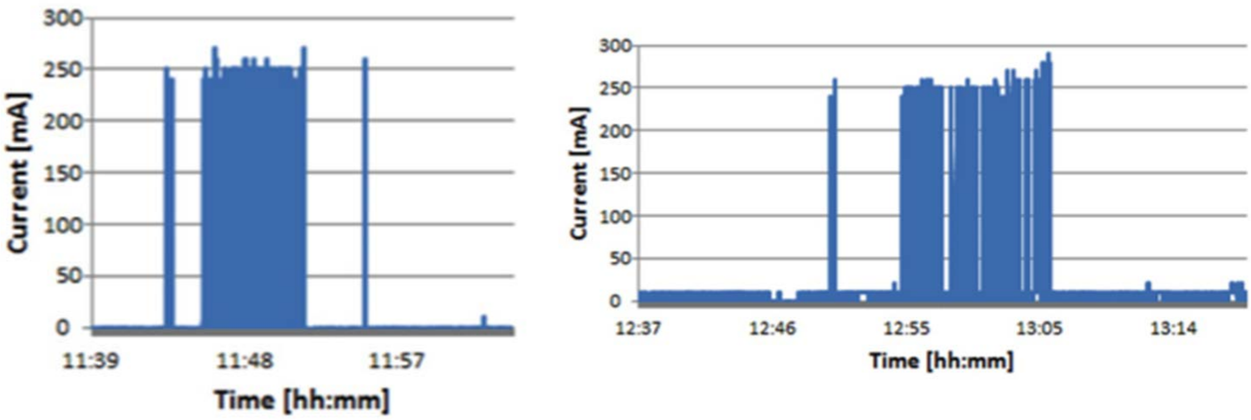

Figure 3. Application of electrosurgery by an expert surgeon (left) and a surgical resident (right).

Table 1. Most important aspects of the Research OR protocol.

	Domains Research-OR		
	1. Devices	**2. Instruments**	**3. Personnel**
Development goals 3 year	**Devices monitoring:** • Link with planning • Integration in time out procedure • Maintenance and reports of defects	**Just in time delivery:** • Supporting supply management at sterilisation department • Visualisation of problems in processes by automatic check of delivery (tracking, RFID, barcodes) • Digital communication system, IT support	**Safe use of medical devices:** • Development of measurements for competences • Link to training modules • A complete competent & certified system for electrosurgery
Products	• Device status and safety monitoring systems • Support systems preoperative and dynamic OR planning • Support systems for maintenance devices	• Track & trace system for OR instruments • Support systems for resource planning and supply management • Monitoring systems for safe cleaning instruments	• Automatic registration system for safe and certified use of high-risk medical devices • Training programs for high-risk medical devices

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