TWO EXAMPLES OF IoT-RELATED HEALTHCARE WORKER'S HAND HYGIENE PRIVACY CODES

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Abstract

Purpose of the paper: To present two examples of healthcare worker's hand hygiene privacy codes (HWHHPCs), as well as the resources for fulfilment of one of those codes, illustrating an augmentation of an ISO 10001 system with ISO/IEC 27701.

Methodology: ISO/IEC 27701 requirements were mapped to the elements of the ISO 10001 HWHHPCs and the activities to develop the related resources were identified. A flowchart including the ISO 10001 requirements integrated with the ISO/IEC 27701 subsystem was drafted, which also depicted the activities and resources for preparing the HWHHPCs and the necessary resources to meet these codes.

Main Findings: Components of an ISO/IEC 27701 privacy system and definitions provided in ISO/IEC 29100 can be utilized to support the preparation of HWHHPCs and the related resources. A consent form can be used as a resource for the fulfilment of an HWHHPC.

Practical implications: This paper presents two HWHHPCs that healthcare organizations could establish to potentially improve healthcare workers' comfort with automated Hand Hygiene Monitoring Systems.

Originality/value: To our knowledge, this paper is the first to present examples of privacy-related customer satisfaction codes that illustrate the integration of ISO/IEC 20000-1:2018, ISO 10001:2018 and ISO/IEC 27701:2019.

Type of paper: Research paper.

Keywords

1. Introduction

Automated hand hygiene monitoring systems (HHMSs) are examples of Internet of Things (IoT) applications in healthcare (Boyce et al., 2019; Iversen et al., 2020). These systems have sensors that substitute human observers (McGuckin & Govednink, 2015) for monitoring whether healthcare workers perform hand hygiene at "*critical point[s] in care,*" defined as "*hand hygiene moment[s]*" in clause 3.11.11 of ISO 22886:2020. Although automated HHMSs have advantages in comparison to direct observation, such as the ability to provide immediate feedback (Benudis et al., 2019), HHMS users may have privacy-related concerns regarding these systems (Boscart et al., 2008; Ellingson et al., 2011; Dyson & Madeo, 2017; Tarantini et al., 2019)

One of the concerns expressed by healthcare workers regarding automated HHMSs is "*not having enough information*" about them (Ellingson et al., 2011). Potential users require knowledge of whom the recipients of the information gathered through the HHMSs would be (Boscart et al., 2008; Ellingson et al., 2011) and how this information would be utilized (Boscart et al., 2008; Ellingson et al., 2011) before using these systems.

Alraja et al. (2019) point out that the establishment of guarantees by suppliers of IoT applications in healthcare can cause users to perceive these applications as less risky and improve their opinion about the related use. ISO 10001:2018 offers guidelines for establishing customer satisfaction codes that include guarantees [called *"promises"*] and the related stipulations [called *"provisions"*] (ISO, 2018). Therefore, this standard could be used to guide the development of customer satisfaction codes that deal with the privacy-related concerns of IoT-based HHMSs users (Ortiz & Karapetrovic, 2020).

This paper presents two examples of Healthcare Workers' Hand Hygiene Privacy Codes (HWHHPCs) that follow the guidelines of ISO 10001:2018 augmented with elements of ISO/IEC 27701:2019. The resources needed to fulfill one of these HWHHPCs and the activities to develop them are also described, illustrating additional examples of augmentation of an ISO 10001 system with ISO/IEC 27701 to the ones presented in Ortiz & Karapetrovic (2020). The verification of the HWHHPCs' feasibility with personally identifiable information (PII) controllers (e.g., hospital managers) and PII processors (e.g., infection preventionists) and the evaluation of the importance of these codes for PII principals (i.e., healthcare workers) will be covered in the next stage of the related overall study.

2. Literature Review

IoT has multiple benefits for the healthcare context, including the ability to track humans and physical resources in real-time with fewer costs (Chacko & Hayajneh, 2018; De Michele & Furini, 2019). Automated hand hygiene monitoring systems are an example of an IoT application tracking the location of healthcare workers (Boyce et al., 2019; Iversen et al., 2020). These systems "*replace human observers with electronic sensors*" (McGuckin & Govednink, 2015), overcoming the limitations of direct observation, including the inability to provide real-time information (Benudis et al., 2019) and the tendency to be affected by biases (Conway, 2016; Kovacs-Litman et al., 2016) and "*human error*" (Benudis et al., 2019).

Despite the benefits of IoT in healthcare, users of various IoT applications in this context have reported concerns regarding the privacy and security of the collected data (Pal et al., 2018; Cohen et al., 2017; Auepanwiriyakul et al., 2020), including concerns about the potential adverse effects of "*information disclosure*" (Alaiad & Zhou, 2017), the "*lack of control over their data*" (Lowens et al., 2017) and about the purposes of gathering information (Boonstra et al., 2018).

Authors such as Boonstra et al. (2018) and Alraja et al. (2019) have suggested actions that IoT-based service providers in healthcare could take to mitigate these privacy concerns. Boonstra et al. (2018) point out that the consent process can play an essential role in reducing concerns about IoT data-collection purposes by incorporating a clear description of these purposes. Alraja et al. (2019) reported that "*guarantees offered through the IoT healthcare providers reduced the users' perception of the risks involved in the use of the IoT and therefore improved their attitude towards using the IoT*."

Previous examples of ISO 10001 customer satisfaction code systems integrated with other management systems in the healthcare context include:

- ISO 10001 – ISO 10002 (Khan and Karapetrovic, 2013 and 2015);
- ISO 10004 – ISO 10001 (Fernandez-Ruiz et al., 2017);
- ISO 10001 – ISO 10002 - ISO 10004 (Khan, 2016 and Khan et al., 2018).
- ISO/IEC 20000 – ISO 10001 – ISO 27701 (Ortiz & Karapetrovic, 2020), which presented a preliminary model for integrating management systems based on these three standards. Although an example of an HWHHPC was also introduced, this code only contained one of the five elements required in ISO 10001:2018 for customer satisfaction codes. While examples of integration between ISO 10001 and ISO/IEC 27701 were shown, none of those examples were related to the HWHHPC's preparation or the development of the required resources.

3. Research Methodology

This paper forms a part of a larger study on customer satisfaction standards and IoT in healthcare. The first component of the study consists of two stages:

a) the formulation of an initial model for integrative augmentation, and
b) the validation of this model in a Canadian hospital (i.e., a "case study hospital").

The present paper discusses three aspects of the first stage, namely:

(1) an extension of the HWHHPC presented in Ortiz & Karapetrovic (2020), hereinafter "HWHHPC1", by developing the four remaining elements required by ISO 10001:2018,
(2) a proposal of an additional HWHHPC (i.e., "HWHHPC2"), and
(3) the development of the resources needed for the fulfillment of HWHHPC1.

The methodology included six steps:

1) A promise was designed to address one of the privacy concerns of healthcare workers regarding automated HHMSs identified in the literature review conducted by Ortiz & Karapetrovic (2020). This promise constitutes one of the five elements of HWHHPC2.

2) The ISO/IEC 27701 standard, already identified as relevant for the augmentation of ISO 10001 privacy-related customer satisfaction codes in Ortiz & Karapetrovic (2020), was newly reviewed to determine requirements capable of augmenting the development of the four remaining elements of HWHHPC1 and HWHHPC2. The ISO/IEC 29100 standard was also consulted, and a definition was selected to support one of the elements of HWHHPC1.

3) Once the elements of the codes were formulated, resources needed for their fulfillment were determined.

4) The ISO/IEC 27701 was reviewed again to identify guidelines capable of supporting the development of the resources identified in step 3. ISO/IEC 27701 provisions were recognized as relevant for the development of resources needed for the fulfillment of HWHHPC1.

5) The ISO/ IEC 27701 system components following the guidelines selected in steps 2 and 4 were integrated into the ISO 10001 privacy-related system.

6) The section of the flowchart presented in Ortiz & Karapetrovic (2020) that describes the objectives, processes and resources needed for the provision of the automated HHMS was expanded by including the ISO 10001 requirements, already integrated with the ones from ISO/IEC 27701 in step 5.

4. Results

4.1. ISO/IEC 27701 augmenting the preparation of two ISO 10001 HWHHPCs

Two examples of HWHHPCs are presented in this section. The first customer satisfaction code (HWHHPC1, shown in Table 1) extends the promise presented in Ortiz & Karapetrovic (2020) by adding the four remaining elements required by ISO 10001:2018. The promise was also slightly modified by considering active voice instead of passive, replacing "*healthcare professional*" with "*healthcare worker,*" and changing the acronyms "*PII*" and "*HHMS*" to their complete forms (i.e., "*personally identifiable information*" and "*hand hygiene monitoring system,*" respectively). This promise addresses a common concern of healthcare workers about the purpose of collecting hand hygiene compliance data through automated HHMSs (Boscart et al., 2008; Ellingson et al., 2011). The proposed promise is in line with clause 7.2.1 of ISO/IEC 27701, which establishes that "*the organization should identify and document the specific purposes for which the PII will be processed.*"

A new customer satisfaction code (HWHHPC2) is proposed (see Table 1). This code addresses the concern of healthcare workers related to whom should have access to the data collected through the automated hand hygiene monitoring system (Boscart et al., 2008; Ellingson et al., 2011). This proposed promise follows a requirement from section 7.3.2 of ISO/IEC 27701, which states that "*the organization should determine and document the information to be provided to PII principals ... [including] information about recipients or categories of recipients of PII.*"

The four remaining elements of HWHHPC 1 and 2 were formulated according to the guidelines presented in ISO 10001, sub-clause 6.4. The second element of HWHHPCs (ISO 10001, 6.4.e) describes the healthcare organization's actions if these promises are not fulfilled. Once the codes are established, utilizing the PII collected through the automated HHMS for purposes different from the ones explained in the consent form and communicated to the PII principals or sharing the hand hygiene (HH) compliance rates with someone other than the healthcare worker will constitute "*information security incident[s]*" (ISO/IEC 27000, 3.31) involving PII. Therefore, the actions to be taken by the healthcare organization if these two promises are not met can follow the guidelines described in ISO/IEC 27701 for "*information security incidents response*" (sub-section 6.13.1.5). The guidelines presented in this sub-section were used as an input to formulate the second element of both customer satisfaction codes.

The third element of the HWHHPC is the scope and limitations of the customer satisfaction code (ISO 10001, 6.4.a). Since the collection of data related to hand hygiene compliance can also be conducted through direct observation, the scopes of these codes specify that both HWHHPCs will only apply to PII (and, therefore, hand hygiene compliance rates) collected through the IoT-based HHMS.

The fourth component of the HWHHPCs presents the definitions of the "*key terms*" used in these codes (ISO 10001, 6.4.c). For HWHHPC1, the explanation provided in clause 2.9 of ISO/IEC 29100 was used to define "*personally identifiable information.*" For HWHHPC2, the definition of the term "*hand hygiene compliance rates*" deployed by the healthcare organization that will be a case study for the validation stage was used.

The fifth element of the HWHHPCs indicates how healthcare workers can provide feedback on the code (ISO 10001, 6.4.d). For both HWHPPCs, they could give such feedback by sending an email. An email was selected here due to its convenience and efficiency. This method will be validated with healthcare workers through a survey and personal interviews in the next stage of the study.

A tabular approach, like the one used in Fernandez-Ruiz et al. (2017) and Ortiz & Karapetrovic (2020), was used to map the provisions of ISO/IEC 27701 against the elements of the HWHHPCs. Table 1 shows the outcomes of the mapping process. It presents the five elements of HWHHPC1 and HWHHPC2 in Columns 2 and 3, respectively, and the designators of relevant ISO/IEC 27701:2019, ISO/IEC 29100:2011, and ISO 10001:2018 sub-clauses, sections and sub-sections in italics in Columns 4, 5, and 6, respectively. Although ISO/IEC 29100 is used in Table 1 to support the preparation of HWHHPC1, the integration of management systems refers only to the components following the two management system standards (i.e., ISO 10001 and ISO/IEC 27701).

Table 1. ISO/IEC 27701 and ISO/IEC 29100 supporting the preparation of the HWHHPCs' elements

Element name	HWHHPC1 elements	HWHHPC2 elements	ISO/IEC 27701	ISO/IEC 29100	ISO 10001
Promise	*The hospital will only use the [personally identifiable information] collected from healthcare [workers] through the [automated hand hygiene monitoring system] for the purposes [that are both identified] on the consent form and communicated to the healthcare [worker]. (Ortiz & Karapetrovic, 2020)*		*7.2.1*		*6.4.b*
		The hand hygiene compliance rates of a healthcare worker recorded by the automated hand hygiene monitoring system will only be shared with the healthcare worker.	*7.3.2*		
Actions	*Otherwise, the hospital will record information about the incident and initiate a review to determine the "measures [...] to be taken".*		*6.13.1.5*		*6.4.e*
Scope and limitations	*This code applies to any personally identifiable information (PII) collected through the automated hand hygiene monitoring system.*	*This code applies to hand hygiene compliance rates recorded by the automated hand hygiene monitoring system.*			*6.4.a*
Terms	*"PII is any information that (a) can be used to identify the [healthcare worker] to whom such information relates, or (b) is or might be directly or indirectly linked to the [healthcare worker]."*			*2.9*	*6.4.c*
		"Hand hygiene compliance [rates are] calculated by dividing the number of compliant observations by the total number of compliant and non-compliant observations recorded by [the automated hand hygiene monitoring system]" (AHS, 2021)			
Feedback	*Healthcare workers can provide feedback about this code and its use by sending an email.*				*6.4.d*

4.2. ISO/IEC 27701 augmenting the development of resources required for HWHHPC1

Once the elements of HWHHPC1 were developed, the resources needed for its fulfillment were determined (ISO 10001, 6.8). Among these resources, two were deemed essential to fulfill this code, since the HWHHPC1's promise implies the existence of a consent form and the communication of these purposes to the healthcare workers using a method different from this consent form, namely:

1) Documentation: The case study hospital (CSH) would use a consent form that identifies the purposes of the collection of PII from healthcare workers through the automated HHMS.

2) Privacy awareness sessions: The CSH would run awareness sessions to explain its policies and procedures regarding the privacy of the data collected through the automated HHMSs. In these awareness sessions, the CSH could communicate the purposes for which the PII collected from healthcare workers through the automated HHMS will be used (e.g., to measure hand hygiene compliance and to evaluate healthcare worker's performance).

After having identified resources needed to fulfill the HWHHPC1, a tabular approach was applied to map the guidelines of ISO/IEC 27701:2019 against the ones from ISO 10001:2018 for the potential development of these resources. Table 2 shows the results of this mapping process. The first and second columns illustrate the designators (in italics) of relevant ISO/IEC 27701 sections and sub-sections, as well as the ISO 10001 sub-clauses, respectively, followed by a description of the development of the resource in the third column.

As shown in Table 2, the consent form is an essential resource for the fulfillment of the HWHHPC1 as it identifies the purposes for collecting PII. This function is different from the one specified in Ortiz & Karapetrovic (2020), where the consent form was only identified as a method used in the external communication plan since this form includes the HWHHPCs. For HWHHPC2, the consent form will only play the role described in Ortiz & Karapetrovic (2020).

Other documentation resources are identified in Table 2, including the "*Hand Hygiene Policy*" (AHS, 2021) and a Procedure for Automated Hand Hygiene Monitoring. The update of the "*Hand Hygiene Policy*" considering automated hand hygiene monitoring and the implementation of a Procedure for Automated Hand Hygiene Monitoring (PAHHM) would be in line with Boscart et al. (2008), where potential users pointed out the need to have "*clear and concise policies and procedures*" regarding the use of automated HHMSs.
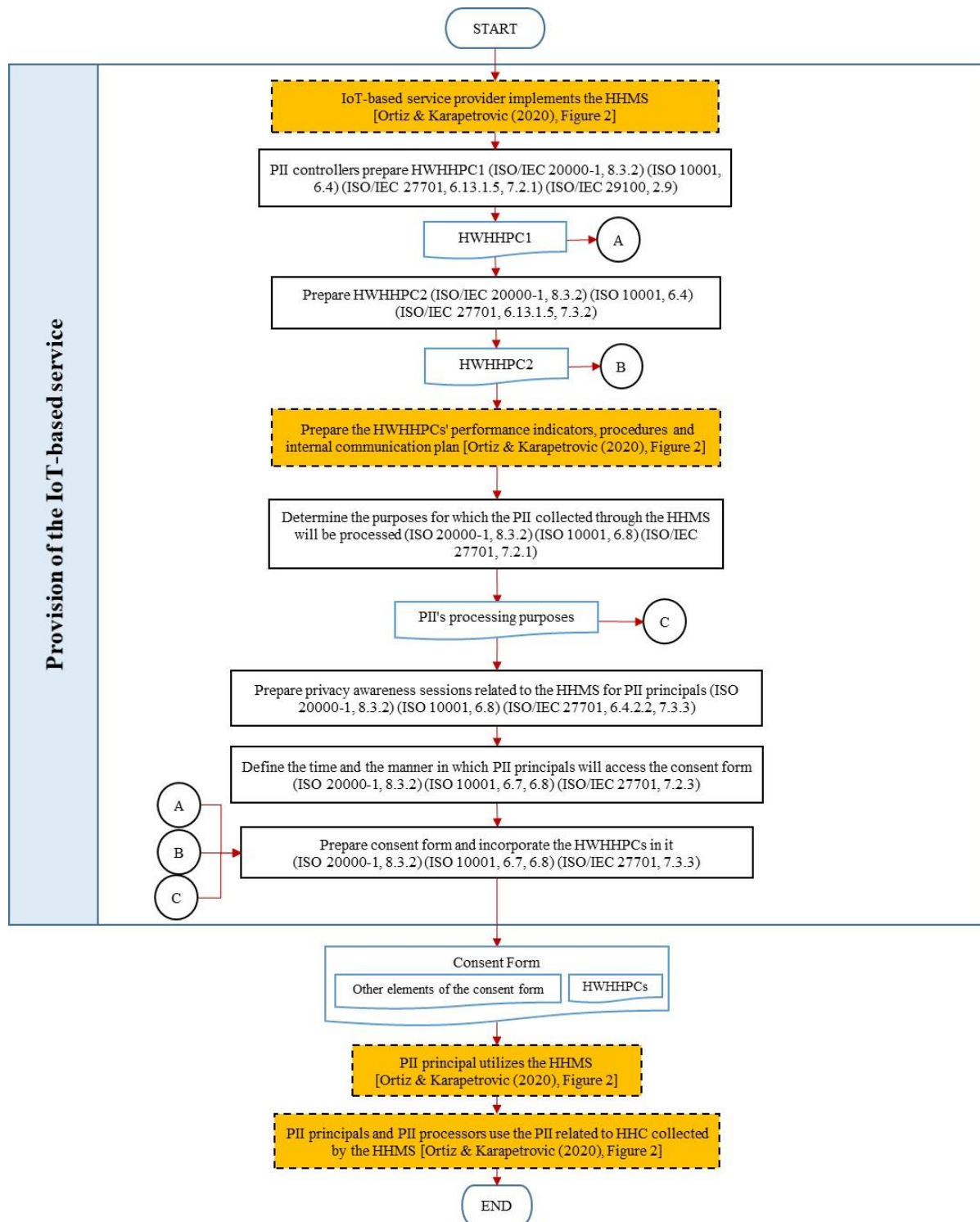
Table 2. ISO/IEC 27701 supporting the development of the required resources for HWHHPC1

ISO/IEC 27701:2019	ISO 10001:2018	Examples
7.2.1 7.2.3 7.3.2 7.3.3	6.8	• The CSH would identify the "*specific purposes for which the PII [*collected through the automated HHMS*] will be processed* [(e.g. to measure hand hygiene compliance, as an input for healthcare workers' performance evaluation)]" (ISO/IEC 27701, 7.2.1). The CSH would document these purposes in the *"Hand Hygiene Monitoring and Feedback"* section of its existing "*Hand Hygiene Policy*" (AHS, 2021) and in a new procedure regarding Automated Hand Hygiene Monitoring (e.g., see Boscart et al., 2008). • The CSH would identify other information to be supplied to PII principals, such as information about the "*recipients or categories of recipients of PII* [collected through the automated HHMS (e.g., unit managers, infection preventionists, and patients)]" (ISO/IEC 27701, 7.3.2). The CSH would also document this additional information in the "*Hand Hygiene Policy*" (AHS, 2021) and a PAHHM. • The information identified in the two previous bullet points would be an input for the development of the consent form. This information would be communicated to healthcare workers through the consent form (ISO/IEC 27701, 7.3.3) • The CSH would define when (e.g., when the healthcare worker is registered on the system or when they log into their system account for the first time) and how (e.g., manually or electronically) healthcare workers will access and sign the consent form (ISO/IEC 27701, 7.2.3).
6.4.2.2 7.3.3		• Healthcare workers being monitored by the HHMS would attend privacy awareness sessions. In these sessions, PII controllers (i.e., hospital managers) would explain the "*Hand Hygiene Policy*" (AHS, 2021) with an emphasis on the updated *"Hand Hygiene Monitoring and Feedback"* section and the PAHHM (ISO/IEC 27701, 6.4.2.2). The purposes for collecting PII through the automated HHMS would be presented to the healthcare workers when explaining this policy and procedure. • The purposes communicated in these awareness sessions would be the same as identified in the consent form. • A short video explaining the collection and use of PII gathered through the automated HHMS would be shown during the privacy awareness sessions (ISO/IEC 27701, 7.3.3). Screenshots of this video would be included in the PAHHM (ISO/IEC 27701, 7.3.3).

Figure 1 shows the activities involved in the planning, designing, and development of the HWHHPCs. This figure extends the first section ("*Provision of the IoT-based service*") of the flowchart presented in Figure 2 in Ortiz & Karapetrovic (2020). The extension focuses on the preparation of the HWHHPCs (ISO, 10001, 6.4) and the external communication plan (ISO 10001, 6.7), as well as the determination of the resources needed (ISO 10001, 6.8) by incorporating the guidelines of the ISO 10001 standard and the relevant ISO/IEC 27701 requirements for the augmentation of ISO 10001 presented in Tables 1 and 2.

The activities already illustrated in Figure 2 of Ortiz & Karapetrovic (2020) are presented in dashed orange boxes in Figure 1, including the implementation of the automated HHMS (first such box), the preparation of HWHHPC resources specified in sub-clauses 6.5-6.7 of ISO 10001:2018 (second box) and the activities related to the usage of the automated HHMS and the PII collected through it (third and fourth box, respectively). As shown in Figure 1, the consent form containing the HWHHPCs is an input for those latter activities.

Figure 1 – Augmentation of ISO 10001 with ISO 27701 for the preparation of HWHHPCs and resources

START

Provision of the IoT-based service

IoT-based service provider implements the HHMS
[Ortiz & Karapetrovic (2020), Figure 2]

PII controllers prepare HWHHPC1 (ISO/IEC 20000-1, 8.3.2) (ISO 10001, 6.4) (ISO/IEC 27701, 6.13.1.5, 7.2.1) (ISO/IEC 29100, 2.9)

HWHHPC1 → A

Prepare HWHHPC2 (ISO/IEC 20000-1, 8.3.2) (ISO 10001, 6.4) (ISO/IEC 27701, 6.13.1.5, 7.3.2)

HWHHPC2 → B

Prepare the HWHHPCs' performance indicators, procedures and internal communication plan [Ortiz & Karapetrovic (2020), Figure 2]

Determine the purposes for which the PII collected through the HHMS will be processed (ISO 20000-1, 8.3.2) (ISO 10001, 6.8) (ISO/IEC 27701, 7.2.1)

PII's processing purposes → C

Prepare privacy awareness sessions related to the HHMS for PII principals (ISO 20000-1, 8.3.2) (ISO 10001, 6.8) (ISO/IEC 27701, 6.4.2.2, 7.3.3)

Define the time and the manner in which PII principals will access the consent form (ISO 20000-1, 8.3.2) (ISO 10001, 6.7, 6.8) (ISO/IEC 27701, 7.2.3)

A
B → Prepare consent form and incorporate the HWHHPCs in it (ISO 20000-1, 8.3.2) (ISO 10001, 6.7, 6.8) (ISO/IEC 27701, 7.3.3)
C

Consent Form
Other elements of the consent form | HWHHPCs

PII principal utilizes the HHMS
[Ortiz & Karapetrovic (2020), Figure 2]

PII principals and PII processors use the PII related to HHC collected by the HHMS [Ortiz & Karapetrovic (2020), Figure 2]

END

LEGEND

PII (ISO/IEC 29100, clause 2.9): Personally identifiable information
PII controllers (ISO/IEC 29100, 2.10): People *"determin[ing] the purposes and means for processing PII"*, e.g., hospital managers.
PII principals (ISO/IEC 29100, 2.11): Healthcare workers tracked by the HHMS, e.g., nurses and doctors.
PII processors (ISO/IEC 29100, 2.12): People *"process[ing] PII"* related to HHC, e.g., infection preventionists.
IoT-based *"service provider"* (ISO/IEC 20000, 3.2.24): Group of people that *"manages and delivers"* the HHMS to users, e.g., technology specialists.
HHC: Hand Hygiene Compliance.
HHMS: Hand Hygiene Monitoring System.
HWHHPC: Healthcare Worker's Hand Hygiene Privacy Code.

5. Conclusions

Two examples of ISO 10001 customer satisfaction codes addressing the privacy-related concerns of healthcare workers regarding automated HHMSs were presented. The required resources for one of these codes and the activities to develop them were described. Examples of augmentation of an ISO 10001 system with components of an ISO/IEC 27701 subsystem related to the design of the HWHHPCs' elements and the associated resources are also detailed.

Requirements of the ISO/IEC 27701 standard and a definition presented in ISO/IEC 29100 were used to develop the elements of two HWHHPCs dealing with the concerns of healthcare workers regarding automated HHMS found in the literature (Boscart et al., 2008; Ellingson et al., 2011). A consent form would be a critical resource for the fulfillment of HWHHPC1. ISO/IEC 27701:2019 requirements can be used to guide the development of this consent form and other required resources. For example, its clauses 7.2.1 and 7.2.3 provide guidance on identifying and documenting the purposes for which PII is collected and other types of information to be supplied to PII principals, respectively. These guidelines would be helpful for hospitals when determining the specific information to be included in the consent form. The recommendations contained in clauses 6.4.2.2 and 7.3.3 can support the planning of privacy awareness sessions for PII principals. They provide guidance on privacy awareness, education, training, and considerations to have in mind when giving information to PII principals.

To our knowledge, the proposed satisfaction codes are the first to illustrate the augmentation of an ISO 10001 system with components of a management system based on the ISO/IEC 27701 augmenting standard for an IoT application in the healthcare context. These two codes are also the first to exemplify how an ISO 10001 system can be used to support the "*business relationship management*" component of an ISO/IEC 20000-1 Service Management System.

The establishment of the proposed HWHHPCs may increase healthcare workers' confidence in the automated HHMSs and cause a more positive attitude towards using these systems, as pointed out in Alraja et al. (2019).

This paper shows two examples of ISO 10001 HWHHPCs. The feasibility of these and other examples of HWHHPCs will be validated in the next stage of this study through a focus group with PII controllers (e.g., hospital managers) and PII processors (e.g., infection preventionists) in a Canadian hospital. The importance of these HWHHPCs for PII principals (i.e., healthcare workers) will also be evaluated using a survey and personal interviews conducted in the same case study organization.

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