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Published in:
Health Policy and Technology

DOI:
10.1016/j.hlpt.2016.07.008

2016

Document Version:
Peer reviewed version (aka post-print)

Link to publication

Citation for published version (APA):
Ivarsson, B., Wiinberg, S., & Svensson, M. (2016). Information and/or medical technology staff experience with regulations for medical information systems and medical devices. *Health Policy and Technology*, *5*(4), 383-388. https://doi.org/10.1016/j.hlpt.2016.07.008

Total number of authors:
3

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Information and/or medical technology staff experience with regulations for medical information systems and medical devices

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Funding: None

Keywords: Healthcare technology; Health information technology; Healthcare information security; Knowledge; Patient safety; Regulation; Staff attitudes

Running title: Regulation experiences for MT and IT systems

Highlights

- Recurrent training on medical technical regulation is needed to increase patient safety.
- Applying regulations in medical technology requires theoretical and clinical skills.
- Technology staff must educate healthcare professionals about these regulations.

Abstract

Objectives: Regulations heavily control medical technology (MT), which often includes information technology (IT), but staff experiences related to these regulations are unknown. The study aim was to assess Swedish IT/MT staff experiences regarding regulations for medical devices and medical information systems.

Methods: An anonymous, nine-item, self-report questionnaire was administered to IT and MT staff (N=228) who attended a 3-hour training course on IT and information security and MT regulations in 2014.

Results: Most of the 228 (86%) IT and MT staff who completed the survey strongly agreed that IT security and MT security are relevant to patient safety. One third of the IT staff reported feeling that their knowledge about regulations within MT was sufficient. Less than half of the respondents experienced that healthcare professionals generally had sufficient knowledge of IT or MT regulations (41% versus 46%, IT and MT regulations, respectively).

Conclusions: Although IT/MT staff felt that they had knowledge of regulations for medical devices and medical information systems, they reported that maintaining and increasing this knowledge is important and that there is a need for recurring training programs in IT and MT regulations. Improved knowledge in IT and MT regulation, and a better understanding of clinical healthcare, could lead to an increased quality in the daily operations and support to the healthcare professionals. Healthcare professionals may need education to develop their knowledge of IT or MT regulations, which in turn will ensure higher patient safety.

Introduction

Medical technology (MT) and devices and information technology (IT) serve an increasingly central role in clinical practice, improving patient health, safety, and quality of life. New applications for technology continuously arise in healthcare[1], including the information systems that often underlie the medical devices[2, 3]. There is also a constant need for efficiency, individualization, availability, and quality to create space for innovation[1]. IT allows for very complex and innovative solutions for use in healthcare, but this complexity at the same time is the biggest enemy of security[2]. Evidence suggests that medical devices also can cause substantial harm, and errors that underlie device-related injuries are often categorized into three groups: manufacturer-related errors, user errors, and use or design errors[4].

As in in other countries, Swedish healthcare staff is required to comply with directives for medical and IT systems. These directives are based on applicable laws, rules and regulations[5, 6]. Guillad[7] stated in a review that legal provisions probably can affect patient safety if education efforts target increasing the culture of compliance, given that staff in healthcare experience legal provisions as burdensome. Education and adaptation are needed to bring both organization and technology together to achieve the desired effect with the introduction of new technologies such as new information systems[8]. The aim of this study was to investigate Swedish IT/MT staff knowledge and experiences regarding regulations for medical devices and medical information systems.

Material and Methods

Design and setting

This prospective, descriptive design study was conducted in Skåne County, at Region Skåne, the authority for all public healthcare in Skåne[6]. The county, with a population of ~1.2 million inhabitants, covers both rural communities and cities. Region Skåne is responsible for medical services provided by various organizations within the county, which has 10 hospitals and more than 150 health centers. Region Skåne employs around 32,000 people, mostly in healthcare. In mid-2013, IT and MT were merged into a single organization with 277 employees, including staff with high-school or university education in IT or MT and some staff with an education in healthcare.

The questionnaire used in this work was developed for this study, inspired by Guidelines for MIDS (Medical Information Data Systems)[9]. It contains two sections: (1) demographics and (2) ten questions about the experiences with and attitudes toward IT, Information Security, and MT regulations. The questionnaire was tested for face validity and content validity by an expert panel of six people skilled in IT and MT. None of the

experts were working in the new IT/MT organization in Region Skåne. Some minor changes were made based on advice from the expert panel.

Data collection

The study was performed after a 3-hour training course on IT, Information Security, and MT regulations. In addition to creating understanding about and agreement with the new organization, the aim of the course was to give an update on the current laws and regulations, all to enhance employee skills. All attendees (N=259) of 13 courses with identical content were invited to anonymously participate in this study. Permission to carry out the study was obtained from the Chief Executive Medical Services at the Medical Services, Region Skåne. All attendees were informed of the aim and procedure of the study during a short oral presentation at the end of the courses. Informed consent of the respondents was implied by the completion of the questionnaire, and the investigation conformed to the principles outlined in the Declaration of Helsinki[10].

Data analysis

Descriptive statistics were used for the data provided from the questions. The frequencies in percent of each answer alternative were calculated. Data were analyzed using Pearson's Chi-square test, with significance assumed at $p<0.05$. Attitudinal data are presented as the mean Likert value. Statistical analyses were performed using SPSS version 22.

Result

The response rate was 88%, although not all respondents answered all of the questions. The reason for drop-out (disagreed to participate) was not stated (n=31). Respondents were mostly men (63%), and the respondents had a mean of 15 (median 16) years in the profession. Demographic data are shown in Table 1.

Of the respondents, 86% agreed in whole and the rest (14%) in part that IT security and MT security are a part of patient safety. No statistically significant differences were detected between women and men or when comparing age or years in the profession with one exception: Those with more than 15 years in the profession felt more than those with less than 15 years in the profession that they had sufficient knowledge of the MT regulations ($p=0.015$). Furthermore, 83% of the participant group also stated that they would like continuing training in IT and MT regulations.

Experiences regarding knowledge and practical application of laws and regulations in IT or MT are shown in Table 2. IT staff tended to a greater extent than the others to consider their knowledge of IT regulations adequate (p=0.051), but only one third felt their knowledge within MT regulations was sufficient. Compared to IT staff, significantly more MT staff and those who worked with both IT and MT felt that their knowledge of the MT regulations was adequate (p=0.000). Higher numbers of IT staff reported that regulations in IT and information security are in line with their practical experience in their daily work compared to the MT staff and those who worked with both IT and MT (p=0.004). In contrast, a higher number of MT staff reported that MT and information security are in line with their practical experiences in their daily work (p=.000). Compared to MT staff and those who worked with both IT and MT, a lower number of IT staff felt that applicable laws and other regulations in IT and information security generally correspond to the range that exists today in e-health (p=0.011).

Less than half of the respondents had experienced that healthcare professionals whom they encountered in their daily work generally had sufficient knowledge of IT or MT regulations (41% versus 46%, IT and MT regulations, respectively).

Discussion

This study investigated Swedish IT/MT staff experiences and attitudes toward regulations for medical devices and medical information systems and found important rationales for maintaining training and increasing knowledge about these areas to IT/MT staff but also to healthcare professionals. The Swedish Society for Medical Engineering and Medical Physics started a national project in 2005 regarding patient safety in healthcare for IT and MT. Based on questionnaires among their members, these groups identified a need for increased knowledge about IT and MT safety, rules, regulations, and risk analysis with a focus on patient safety[9]. Therefore, it is encouraging that this study showed that a majority (83%) find that recurrent training on these issues would have value. Also gratifying is that all respondents agreed to varying degrees that IT security and MT security are a part of patient safety. With respect to IT systems integrity, confidentiality, information security, and ownership[11] and MT device errors, inappropriate use, lack of training, and poor maintenance[12] have been seen as risks for patient safety. Modern medical care tends to involve not only hospital and primary care but also care in patients' homes, so that work related to patient safety is becoming more widespread and securing the information is no longer a matter only of securing the healthcare organization's own systems.

The present study confirms that overwhelmingly, respondents felt that they had knowledge of their fields' regulations and that the regulatory framework is consistent with their experiences in daily work. A Swedish survey of IT and MT staff indicated their interest in increasing their knowledge in IT and MT and vice versa[9], and this study shows that this desire can additionally apply to regulations.

Also important, however, is that the regulatory framework supports development and innovations in IT and MT, and the majority of the respondents agreed only reluctantly that the regulations live up to today's expectations within e-health, which is evolving rapidly. One result that stands out is that IT staff did not feel that their MT regulation knowledge was adequate. Today, more and more IT systems form a part of medical devices in healthcare, and it may be that IT staff need be integrated into clinical healthcare to a greater extent. In the last 10 years, IT systems used within healthcare have moved from being viewed as separate entities, to being full-fledged medical systems. This also puts requirements on the technical staff that installs and maintains these to have adequate knowledge in the governing legislation and requirements, which include both traditional MT and IT legislation. Thus, their own area of expertise must be considered to require knowledge from both IT and MT and additionally, it may be that IT staff need be integrated into clinical healthcare to a greater extent. Improved knowledge in MT regulation, and a better understanding of clinical healthcare, could lead to an increased quality in the daily operations and support to the healthcare professionals. Moreover, Li and Benton[13] have described that the benefits of technology in healthcare cannot be fully achieved unless healthcare professionals have the support of IT and MT staff in providing sufficient training and have an understanding of the technology, thus meeting the quality expectations that healthcare professionals have of IT systems and MT.

One surprising finding in this study was that the respondents experienced that more than 50% of healthcare professionals whom they encountered had insufficient knowledge of IT or MT regulations. How this result should be interpreted or explained is not clear, but perhaps it is related to the fact that achieving competence in technology takes time and that learning the basics is important for overcoming fear of new technologies[14]. Education and learning must be adapted to include IT and MT and the regulations that govern them. Healthcare professionals and IT and MT professionals must be encouraged to share their knowledge and get a better understanding of one another's challenges, and healthcare organizations must implement a strategy to support this aim. Further research should focus on regulatory compliance, which previously was found to be a neglected area[15].

Methodological considerations

This study was conducted in one county in Sweden. A strength of this study was that all staff in IT and MT healthcare organizations throughout the county were included. County-specific conditions and particular aspects of the Swedish healthcare system might have affected the results. Therefore, the findings of this study cannot be generalized, but we assume that they can inspire discussions around skills in IT and MT regulations. Furthermore, the questionnaires were answered after the course and therefore there is a risk that the results are affected because of changes in knowledge.

Conclusions

The feedback from the IT and MT staff from this study indicates a need for recurring training programs in IT and MT regulations. It can also be assumed that healthcare professionals need education to develop their knowledge of IT or MT regulations, which in turn will ensure improved patient safety.

Acknowledgments

Thanks to Anna Axmon for skillful help with the statistics.

Competing interests: None declared

Ethical approval: Not required

References

1. Abernethy AP, Wheeler JL, Bull J. Development of a health information technology-based data system in community-based hospice and palliative care. *Am J Prev Med* . 2011;40(5 Suppl 2):S217-224.

2. Mc Caffery F, Burton J, Richardson I. Risk management capability model for the development of medical device software. *Software Qual J.* 2010;18(1):81-107.

3. Tulasidas S, Mackay R, Craw P, Hudson C, Gkatzidou V, Balachandran W. Process of Designing Robust, Dependable, Safe and Secure Software for Medical Devices: Point of Care Testing Device as a Case Study. *Journal of Software Engineering and Applications.* 2013;Vol.06No.09:13.

4. Jha AK, Prasopa-Plaizier N, Larizgoitia I, Bates DW. Patient safety research: an overview of the global evidence.*Qual Health Care.* 2010;19(1):42-47.

5. Medical Products Agency. *Medical Information Systems – guidance for qualification and classification of standalone software with a medical purpose.* www.lakemedelsverket.se 2012.

6. Anell A, Glenngard AH, Merkur S. Sweden health system review.*Health Syst Transit* . 2012;14(5):1-159.

7. Guillod O. Medical error disclosure and patient safety: legal aspects. *J Public Health Res* . 2013;2(3):e31.

8. Fichman R, Kohli, R, Krishnan, R. Editorial Overview—The Role of Information Systems in Healthcare: Current Research and Future Trends. *Information Systems Research.* 2011;22(3):419-428.

9. MISD. *Guidelines for MIDS. Proposals for measures for collaboration between Biomedical Engineering and IT for improved patient safety.* : MTF:s Kansli, Karolinska Univercity Hospital. STOCKHOLM.; 2008.

10. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA.*2013;310(20):2191-2194.

11. DeCew JW. The Priority of Privacy for Medical Information. *Social Philosophy and Policy.* 2000;17(02):213-234.

12. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ.* 2001;322(7285):517-519.

13. Li L, Benton WC. Hospital technology and nurse staffing management decisions. *Journal of Operations Management.* 2006;24(5):676-691.

14. Gould KA. Technology: a gift for our patients. *Dimens Crit Care Nurs* 2014;33(3):105-107.

15. Appari A, Johnson ME. Information security and privacy in healthcare: current state of research.*Int J of Internet and Enterprise Management.* 2010;6(4):279-314.

Table 1. Staff demographics and other characteristics

	IT(n)	MT(n)	Both IT and MT(n)	No answer(n)	Total
	73	**80**	**68**	**7**	**228**
Age (years)					
<29	0	4	5	1	10
30–39	8	19	11	0	38
40–49	27	26	19	1	73
50-59	29	19	23	1	72
>60	7	9	9	2	27
No answer	2	3	1	2	8
Gender (n)					
Female	35	17	21	4	77
Male	36	61	47	1	145
No answer	2	2	0	2	6
Time in professions (years)					
<15	27	33	35	2	97
>15	43	42	31	4	120
No answer	3	5	2	1	11

Table 2 Experiences, knowledge and practical application of laws and regulations in IT or MT

	Strongly disagree (%)	Partly disagree (%)	Nearly Agree (%)	Strongly agree (%)	Mean*
In my opinion, IT security and MT security are both part of patient safety.					
IT (n=72)	1	0	13	86	3.8±0.5
MT (n=79)	0	0	16	84	3.8±0.4
Both IT/MT (n=68)	0	0	15	85	3.9±0.4
I would like to receive more continuing training in IT and MT regulations.					
IT (n=71)	1	11	46	41	3.3±0.7
MT (n=80)	0	0	16	84	2.9±0.8
Both IT/MT (n=68)	0	0	15	85	3.3±0.8
I consider that my knowledge about regulations within IT are sufficient.					
IT (n=72)	0	18	63	19	3.0±0.6
MT (n=79)	0	31	56	14	2.8±0.6
Both IT/MT (n=68)	4	16	62	18	2.9±0.7
I consider that my knowledge about regulations within MT are sufficient.					
IT (n=71)	17	52	27	4	2.1±0.7
MT (n=80)	0	9	58	34	3.3±0.6
Both IT/MT (n=68)	6	21	53	21	2.9±0.8

I experience that the current regulations within IT and information security are tied together with my practical experience during daily work i.e. there's a connection between theory and practice.					
IT (n=73)	3	1	60	36	3.3±0.6
MT (n=77)	1	14	70	14	3.0±0.6
Both IT/MT (n=68)	0	12	71	18	3.1±0.5
I experience that the current regulations within MT and information security are tied together with my practical experience during daily work i.e. there's a connection between theory and practice.					
IT (n=61)	7	34	52	7	2.6±0.7
MT (n=80)	3	1	54	14	3.4±0.6
Both IT/MT (n=65)	4	16	62	43	3.1±0.6
I consider that current laws and other regulations within IT and information security generally corresponds to the range that exists today within e-health, i.e. a wide application of information- and communication technology to achieve physical, mental and social wellness.					
IT (n=62)	5	34	56	5	2.6±0.7
MT (n=63)	0	16	76	8	3.4±0.6
Both IT/MT (n=60)	0	30	55	15	3.1±0.6

I consider that current laws and other regulations within medical technology generally corresponds to the range that exists today within e-health, i.e. a wide application of information- and communication technology to achieve physical, mental and social wellness.					
IT (n=60)	6	31	60	2	2.6±0.7
MT (n=44)	0	15	75	9	2.9±0.5
Both IT/MT (n=57)	2	22	69	7	2.9±0.7
In my experience, healthcare professionals (outside of the IT/MT organization) generally have sufficient knowledge of IT regulations.					
IT (n=72)	14	57	26	3	2.2±0.7
MT (n=78)	9	40	47	4	2.5±0.7
Both IT/MT (n=68)	8	52	34	6	2.4±0.7
In my experience, healthcare professionals (outside of the IT/MT organization) generally have sufficient knowledge of MT regulations					
T (n=59)	10	54	36	0	2.3±0.6
MT (n=75)	7	36	51	7	2.6±0.7
Both IT/MT (n=63)	2	51	40	8	2.5±0.6

*Likert scale data where 1 = strongly disagree and 4 = strongly agree.