

Health and medical device development for fundamental care: scoping review

ABSTRACT

BACKGROUND The use of technology and health and medical devices as a part of fundamental nursing care is increasing. Although involving users in the device development process is essential, the role of nurses in the process has not yet been discussed.

OBJECTIVES To examine and map what kind of health and medical devices have been developed specifically for fundamental nursing care and to examine the design and development of the devices, particularly focusing on the role of nurses in the process.

DESIGN Scoping review

DATA SOURCES The Medline, Cinahl, Web of Science, IEEE Explore and ACM DL databases

REVIEW METHODS The databases were searched to identify studies describing health and medical devices developed for fundamental nursing care published between the years 2008 and 2018 in English language. References of included articles were reviewed for additional eligible studies. Two research team members screened the abstracts and full articles against the predefined inclusion and exclusion criteria. The PRISMA-ScR-checklist was used.

RESULTS Of the 7223 reports identified, a total of 19 were chosen for the scoping review. Of these, five were further analyzed regarding the development process. Main focus areas of the included reports were patient monitoring, pressure ulcer prevention and patient transfer and mobility. Device development process, divided in three phases, was mainly driven by technological expertise and health care personnel were mainly involved in the evaluation phases.

CONCLUSIONS Health and medical devices are a crucial part of the healthcare today and nurses are increasingly involved with their use. Most of the devices have been developed mainly by using technological expertise although they are directly aimed at fundamental aspects of nursing care. The results of our review suggest that the expertise of the nurses as the end-users of the devices could be much more exploited.

Relevance to Clinical Practice

A combination of expertise of device development from both nursing professionals and technical experts is necessary to disentangle the requirements of increased quality in nursing care combined with the ever growing technological requirements.

What does this paper contribute to the wider global clinical community?

- There is a lack of scientific literature describing the health and medical device development process from the viewpoint of nurses, who often are the end-users of the devices.
- The expertise of nurses should be further exploited in the device development process as-to disentangle the requirements of increased quality in fundamental nursing care combined with the ever growing technological requirements.

Key words: Delivery of Health Care, Health Personnel, Medical Device, Nursing, Patient-Centered Nursing, Technology Development

INTRODUCTION

Improving the nurse's capacity to provide effective fundamental care has been a goal of many recent initiatives and guidelines (A Kitson, Conroy, Kuluski, Locock, & Lyons, 2013; NHS England, 2016). As the work of nurses today involves a growing amount of time spent with technical devices (West Health Institute, 2015) it is reasonable to expect that also those devices support the aim of delivering fundamental care. A recent review recognized the nuanced attitudes of nurses towards medical devices. Although the devices are mainly considered a positive addition to nursing, nurses found it hard to balance between the technically oriented device use and provision of fundamental care (Zhang, Barriball, & While, 2014).

Health and medical devices include a diverse range of equipment from simple wound care products to complex imaging techniques used in radiography. According to a recent survey, 43% of the nurses who answered, reported spending three hours or more managing various medical devices in their daily work (West Health Institute, 2015). As the amount of technological innovations is rapidly increasing in health care, it is important that nurses are engaged in the design and development of these devices (Castner, Sullivan, Titus, & Klingman, 2016; Zhang et al., 2014).

The development process of health and medical devices for hospital and other care environments is heavily regulated due to the high safety and efficacy requirements (Kramer, Xu, & Kesselheim, 2012). At the moment, device development is regulated in EU by the European Commission Medical Device Directive 93/42/EEC (European Commission, 2011) and after May 2020 by the European Union Medical Device Regulation (European parliament, 2017). In the US the development process is controlled by the Food and Drug Administration (FDA) regulations. Actions are also being taken to harmonize international medical device regulations and convergence (IMDRF, 2018). In the EU, the device approval is regulated by a graduated risk-based classification ranging from low-risk (Class 1) devices to medium- and

high risk devices (Classes IIA, IIB and III) (European Commission, 2010b). Streamlined, the development process mainly runs through pre-defined phases. At first, the need for the device is established and the preclinical research, including a review of the previously developed devices, is done (phase I). Thereafter the prototype of the device is built, tested for feasibility and the possible flaws corrected (phase II). At the last stage the validity of the device is assessed and pre-market evaluation done (phase III). As newly developed devices may also pose health risks to the patients, testing of safety and effectiveness, and clinical evaluation of the performance is needed as an ongoing process throughout the life cycle of a medical device (European Commission, 2010a; Kramer, Tan, Sato, & Kesselheim, 2014). Incorporating the experience, preferences and recommendations from nurses into the device development process might increase the effectiveness and safety of the devices.

Nurses are responsible for recognizing the fundamental physical and psychosocial needs of patients. Fundamental nursing includes the elements of care that are the most necessary and important also from the viewpoint of patients. These can be operationalized into care for: safety, prevention and medication, communication and education, respiration, eating and drinking, elimination, personal cleansing and dressing, temperature control, rest & sleep, comfort (including pain management), dignity, privacy, respecting choice, mobility and expressing sexuality (Alison Kitson, Conroy, Wengstrom, Profetto-McGrath, & Robertson-Malt, 2010). The Fundamentals of Care Framework (Alison Kitson, 2018) comprises these elements and may be used as a guiding tool for nurses' work. The framework is firstly built on the aspects related to nurse-patient relationship, such as trust, attention and focusing on the patient. The second dimension of the framework explores the integration of the patient's physical, psychological and relational needs along the continuum of care. The third dimension related to the context of care, identifies the contextual influences impacting on care delivery

and relationship development. (Feo, Kitson, & Conroy, 2018; Alison Kitson, Muntlin Athlin, & Conroy, 2014)

The health technology has improved rapidly over the past 10 years. At the same time, the demands to design more valuable innovations for healthcare have increased by bridging design processes, and health care needs and priorities through multidisciplinary collaboration (Lehoux, Williams-Jones, Miller, Urbach, & Tailliez, 2008). Medical device development is a multidisciplinary field, however, it is not clear to what extent the expertise of the nurses is exploited in the health and medical device development process currently. In a recent article (Castner et al., 2016), a model for strengthening the role of nurses in the process was proposed to encourage nurses and nurse researchers with their pragmatic experience and viewpoints to engage in medical device development more profoundly. As people using the device are the most complex part in determining the usability, safety and reliability of the medical devices, the user involvement in the design and development process of the devices has been proven reasonable (Branaghan, 2018).

AIMS

In this article, our objective is firstly to examine and map what medical devices have been developed specifically for fundamental nursing care. Secondly our objective is to examine the development process of the health and medical devices more profoundly and to examine the role of nurses' in the process.

METHODS

Literature search

We used the methodology of scoping review (Levac, Colquhoun, & O'Brien, 2010) and conducted a comprehensive search on the literature following the PRISMA guidelines

(PRISMA Extension for Scoping Reviews, PRISMA-ScR, (Supplementary File 1)) (Tricco et al., 2018). We chose to use this method in guiding our review as it has been found relevant to topics with emerging evidence with little primary research for conducting a systematic review (Levac et al., 2010). Scoping reviews have also been found useful in finding evidence to help in reporting and informing the practice in the field of nursing (The Joanna Briggs Institute, 2015). The protocol for this review has not been published.

We conducted a comprehensive literature search using PubMed, Scopus, Cinahl, Web of Science, IEEE Explore and ACM DL from 01 January 2008 to June 2018. The date restrictions were chosen partly due to the rapidly changing field of medical device development and partly due to the large number of references found in preliminary searches. Limiting the search to the past 10 years was chosen as it is a commonly used date limitation. In addition to the previously mentioned databases, we performed a manual search of the reference sections of included articles and hand-search of relevant journals (International Journal of Medical Informatics and International Journal of Nursing Studies) to identify additional records. The recent search was executed in August 2018.

Key search terms included terminology for health and medical devices (device OR equipment OR appliance), the development process (development OR validation OR feasibility OR testing OR manufacturing) and the context of fundamental nursing care (nursing OR basic care OR hospital). To avoid losing meaningful references we did not want to define the search terms too strictly and rather limited the results according to the inclusion and exclusion criteria when screening the titles and abstracts. Studies were considered to be eligible if they met the inclusion criteria described in Table 1. We limited the results to health and medical devices developed for aspects related to fundamental care and excluded devices developed for a specific health system or nursing procedure, or to nursing education.

Review process and data extraction

Two authors (H-M. M. and R.M.) reviewed independently the eligibility of the abstracts and full texts of the retrieved studies after the initial check of the titles performed by one author (H-M. M.). Disagreements between reviewers were resolved by consensus and third evaluator (S.S). As we used the scoping review methodology, we did not do a methodological appraisal of the quality of included studies (The Joanna Briggs Institute, 2015). One author extracted the data from included studies according to a data extraction plan and the second author checked the extracted data.

Data, including authors, year of publication and country and the context and focus areas of the device, were collected in table format. We also extracted the data on the expertise area of the first author of the report and whether the device was tested in laboratory or hospital settings. As the reports included did not follow any specific structure in reporting, only a narrative synthesis by identifying the key concepts and frequently arising themes is provided of the data describing the health and medical device development process and the role of nurses within the process.

RESULTS

An overview of the selected records

The procedure of the literature review and the numbers of studies included and excluded in different stages of the study are described in Figure 1. The database search identified 7223 records. Additional three references were found after screening the reference list of retrieved studies and hand searching the relevant journals. After the screening of titles we were left with 347 citations. When the duplicates were removed 310 remained. After the reviewing of abstracts we were left with 76 citations after which the full text of the remaining citations was examined in more detail. After the more detailed assessment of the full-texts, a total of 19

articles (Table 2) were included in the analysis describing the devices developed for fundamental care. Of the 19 articles, only five described the whole development process in more detail and were thus included in the more detailed analysis of the development process.

In addition to articles published in scientific peer-reviewed journals we also found proceedings from technological conferences describing devices developed for fundamental nursing care (n=17). However, we decided not to include the proceedings in this review as they only described the device itself focusing on its technological details without description of the development process and evaluation of the practice-relevant viewpoints in nursing care.

Generally, the included studies were of wide methodological variety. When examining the full-texts we found that vast majority of the reports did not include description and analysis of the full development process. Therefore we divided the data extraction and analysis in two phases. First phase was to examine all 19 articles to answer the research question 1: what kind of clinical devices have been developed for fundamental aspects of nursing care. In the second phase, we further analyzed the five articles that described the development process in more detail.

Five of the articles were authored by medical doctors (Balaguera et al., 2017; Bruyneel, Libert, & Ninane, 2011; Lewis, 2010; Weenk et al., 2017; Wirz, Conrad, Shtrichman, Schimo, & Hoffmann, 2017), three by nurse scientists (Hall & Clark, 2016; Hand et al., 2013; Hilbe, Schulc, Linder, & Them, 2010), ten by engineers (Charlon, Fourty, Bourennane, & Campo, 2013; Faudzi, Nasir, Fadzil, Mukri, & Satar, 2015; Iwamura, Yamaguchi, Tanaka, & Fujishima, 2017; Kim, Yeom, Kwon, Shin, & Shin, 2018; Kuroda et al., 2013; J. J. Liu et al., 2015; Y.-W. Liu, Hsu, & Chang, 2015; Otero, Apalkov, Fernandez, & Armada, 2014; Wai et al., 2008; Wolf, Hetzer, zu Schwabedissen, Wiese, & Marschollek, 2013) and one by expert in ergonomics (Nodooshan, Choobineh, Razeghi, & Khales, 2017). Included articles were mainly

published in technology oriented journals and authored by technological experts. Health care personnel were mainly involved in the evaluation phases.

Devices developed for fundamental care

Four of the included articles concerned devices developed for patient monitoring. These devices were focused on monitoring vital signs (Kim et al., 2018; Kuroda et al., 2013; Weenk et al., 2017) and respiratory function (J. J. Liu et al., 2015). Three devices focused on pressure ulcer prevention (Faudzi et al., 2015; Hall & Clark, 2016; Hand et al., 2013). Devices developed for patient transfer and mobility included devices aimed at preventing and detecting falls (Balaguera et al., 2017; Charlon et al., 2013; Hilbe et al., 2010; Wolf et al., 2013) and devices aimed at increasing patient and occupational safety in patient transfer (Iwamura et al., 2017; Nodooshan et al., 2017). The rest of the reports concerned devices developed for use in the domains of elimination (Otero et al., 2014; Wai et al., 2008), rest and sleep (Bruyneel et al., 2011; Y.-W. Liu et al., 2015) and medication (Lewis, 2010; Wirz et al., 2017).

Methodological considerations

A major source of heterogeneity in the reports included in this review was the reporting guidelines/practices/ between the fields of engineering sciences and medical/nursing sciences. Technologically oriented articles tended to focus on describing the technological characteristics of the prototype whereas scientific articles in the fields of medicine and nursing science included more profound analysis of the entire process and reported also the development process in more detail.

Development process of the devices

We identified five articles (Hilbe et al., 2010; Kuroda et al., 2013; Nodooshan et al., 2017; Wai et al., 2008; Wolf et al., 2013) which described and analyzed the device development process

in more detail and through three phases; defining the need, building a prototype and testing the device. The articles described devices developed for the prevention of falls (Hilbe et al., 2010), collection of vital signs (Kuroda et al., 2013), continence management (Wai et al., 2008), bed-exits (Wolf et al., 2013) and a mechanical aid for patient transfer (Nodooshan et al., 2017).

Phase I – Defining the need

The first and probably the most meaningful step of the device development process includes establishing and defining the need for the device. This was mostly done by reviewing the previous literature and work done in the area and examining the current practice. All five studies included a description of the previous work done on the field and devices previously developed for corresponding purpose. ~~More timely~~ Literature reviews were conducted and reported in two articles (Hilbe et al., 2010; Nodooshan et al., 2017). In the literature review, it was considered important also to analyze the limitations of other previously designed devices. Nodooshan and colleagues also reported conducting a field study during phase I including questionnaires and interviews of the healthcare workers. Two articles (Hilbe et al., 2010; Wolf et al., 2013) reported interviewing the hospital staff about their requirements and expectations concerning the proposed device. The included articles reported no other participation from nurses in the development process of the devices.

The requirements needed from the device are defined during the first phase. Factors related to the usability of the device, such as simple operations, minimum false-alarm rate and portability were focused on in all reports. Other requirements included factors related to hygiene, manufacturing and costs. Integration into current systems, such as nurse call systems and electronic patient records were also listed as requirements.

Phase II – Creating prototype

The second phase of the device development process is about the design and build of the prototype of the device. The technical design of the device was described in detail in all included articles. Two devices were first assessed as 3D prototypes (Nodooshan et al., 2017; Wolf et al., 2013). Often the 3D model or an initial prototype with partly commercial design was made, its pitfalls were analyzed and the required modifications were done thereafter. No participation from nurses in this phase of the device development was reported in the included articles.

Phase III – Testing and implementation

The third phase of the device development process includes the testing and possibly also the implementation of the device. Testing of the devices mainly took place in clinical settings either within voluntarily recruited subjects or patients. Two articles reported testing the device by comparing the traditional and new methods (Kuroda et al., 2013; Nodooshan et al., 2017) and evaluating also the nurses and patients viewpoints in addition to the technical features and functionality of the device. One article reported conducting a clinical trial to test the effectiveness of the device (Wolf et al., 2013). Overall, features mentioned in the evaluation process were usability, efficacy, safety feeling, stability, applicability and reliability and psychological resistance.

Reported challenges and limitations

The challenges and limitations reported in the reports mostly concerned the device itself, the nurses using the device and the research design. One challenge in device development was the fact that humans tend to rely too much on machines and nurses may neglect their role in confirming the output from the device. Sufficient training of the personnel as part of the safety management of the process is needed so that the nurses are able to handle the system. Device also needs to be designed so that the alarm-false alarm ratio is minimum and does not become

a burden for the nurses. A related challenge was proprietary designs which may limit the integration of the device into current systems. Further, costs were reported as one challenge in the medical device development process. The advantage of the proposed device needs to be proven also economically which may be challenging in health care settings. Privacy and ethical aspects need to be taken in account also throughout the development process.

DISCUSSION

Medical and health devices are a crucial part of healthcare today and nurses are increasingly involved with their use (West Health Institute, 2015). As the functioning and safety of the device depends also on the person using it, it is important that nurses engage more in device design and development. Our review on the current literature shows that the range of devices developed for fundamental nursing care is wide and ever growing. Most of the devices have been developed mainly by using technological expertise from engineers although they are directly aimed at fundamental nursing care. The results of our review suggest that the expertise of the nurses as the end-users of the devices could be much more exploited.

The quality of nursing care has been under debate during the recent decades as health care is facing tremendous changes when the nursing workforce is reducing at the same time with increasing demands for high quality of care (WHO, 2016). The challenge of meeting patients' fundamental care needs has been discussed simultaneously with the development and implementation of technology in the field. As the fundamentals of care framework (Alison Kitson, 2018) focuses on the quality of care by combining the physical, psychosocial and relational dimensions of care it could be also used within the process of implementing technology in the field as a guiding tool and reminder of taking the needs of the patient in account throughout the development process. The results of this review suggest that this has not yet been done.

Also past research has shown that the expertise of nurses as advocates of the patients and as end-users of medical devices is not exploited as well as it could be (Money et al., 2011). This was also observed in our review. Even though participatory design (Spinuzzi, 2005) and meeting the needs of the end-user are considered crucial in ensuring the development of functional and cost-effective medical devices, according to the results of this review these

approaches are not sufficiently used in medical device development for fundamental nursing care. Taking in account in addition to the physical needs of the patient, also the other crucial elements of fundamental care - psychosocial needs and the nurse-patient relationship, would probably increase the functionality of the devices further leading to higher acceptance (Kaye, 2017). By understanding the current care practices, work environment and work flow, nurses are able to ensure if the devices really enhance the work and promote patient safety. Figure 2 draws together the practical and theoretical viewpoints of the device development process within the framework for fundamental care.

Nurses have been reported to have mixed attitudes towards technical devices when forced to struggle between the fundamental nature of nursing and technical orientation (Zhang et al., 2014). We suggest that involving nurses in the design and development process, with their expertise on fundamental aspects of care, would not only improve the attitudes of nurses, but also increase the safety and efficacy of the devices. The framework for fundamental care not only acts as a reminder of taking in account the patient needs throughout the device development process but also helps the whole designer team to understand what nursing does for patients and how fundamental nursing influences also clinical outcomes (Alison Kitson, 2018).

The included reports covered several fields of nursing care from medication administration to pressure ulcer prevention and patient transfer. However, possibly guided by the availability of the current technological resources, patient monitoring and patient mobility and transfer were the most common fields. There are various aspects of nursing care, related for example to patient comfort, such as monitoring pain or agitation, that technology has not yet been able to successfully reach. Again, using the expertise of nurses and the fundamental care framework in the design phase could produce innovations that could ~~f. ex ease administrative efficiency~~ and increase patient satisfaction by focusing also on the psychosocial and relational needs of

the patient. According to the results of this review, it seems that currently devices are mainly aimed at the physical needs of the patient.

Although our initial search found a large number of citations, after reviewing the titles, abstracts and full-texts we were left with relatively low number of articles that met our pre-defined inclusion criteria. The other aim of our review was on describing the development process of the devices into which we were able to include only five articles. The first phase of the device development is about defining the need for the device. Often the process starts from finding or spotting a need for improvement in the practical field. Past research has identified the importance of involving users in all health care development practices, including medical device development (Bridgelal Ram, Grocott, & Weir, 2008). Phase I also involves gathering a multidisciplinary team to work on the subject. It is important to try to use the perspectives across multiple disciplines already in the design phase of the device when the aim is to design a device that is easy to use for both, the care giver and the patient, and at the same time comfortable, safe and efficient. Although this is considered time consuming and expensive according to many developers, it will also help in analyzing potential risks (Fearis & Petrie, 2017). Involving nurses in the development process already in the concept-stage could also be one factor that might improve the nurses nuanced attitudes towards the constantly increasing amount of medical devices introduced in their work reported by Zhang et al., 2014).

In the articles included in this review, the phase in which the participation of nurses was not reported during the device development process, was the second phase, perhaps as it includes mainly technical elements, such as prototype building. Castner and colleagues however suggested that being a part of this phase also may increase the awareness of the nurses about possible future requirements and barriers of the device developed (Castner et al., 2016). Bringing the fundamental care framework in this phase could also guide the design process to the level which takes the needs of the patient in account even more profoundly with the

viewpoints of patient experience and integration of care. Nurses, as the end users of the device, however are often included in the testing phase of the devices.

The articles included in the review did not report any challenges faced in the development process caused by the heavy regulation and control of the devices. However, costs were reported as one challenge faced during the process. The proposed device needs to be proven cost-effective already in the development phase. This may be challenging as the benefits, harms, and costs of the device need to be estimated and summed together to understand and prove its cost-effectiveness. (Owens, Qaseem, Chou, & Shekelle, 2011).

Strengths and limitations

We aimed at using precise and transparent review methods when performing this review. The search strategy included five databases. In addition, the reference lists of the included articles and all publications during the past ~~five~~ ten years of two journals were screened. The abstracts and full-texts were screened by two researchers independently.

Although we aimed at using as wide search terms as possible to be able to find all relevant articles, we still may have missed some important items. By limiting the included articles to those describing the development process of the device, and further excluding devices developed for a specific health system or nursing procedure, or to nursing education, we excluded many devices that might have been interesting regarding the involvement of nurses in the design process and within the fundamental care framework, such as robots developed for dementia care. We decided to limit the timeframe for the studies to past ten years. By doing this, we may have missed some articles. We included only articles published in English which may also be a limitation of this review. A limitation of this review is also the fact that we did not contact any experts on the field to find possible articles we may have missed in our search.

It needs to be taken in account that the medical device industry is large and ever-growing and not all the devices on the market include evidence published in scientific journals.

More research in the area of health and medical device development focused in fundamental nursing care is needed as the use of technology is likely to increase in nursing care in the near future. Internet of Things, big data and artificial intelligence are some of the key technologies in the future of health and medical device development and use. The development and application of such systems is crucial also when developing devices for nursing care with the enhanced safety, time-efficiency and managing of data they bring along. The fundamental care framework has been proposed to be developed and implemented so that it becomes routine in all healthcare encounters (Alison Kitson, 2018). In addition to capturing the essence of nursing practice, it focuses on the everyday physical, psychosocial and relational needs of the patients. As such, it could be also used in the development process of health and medical devices. Health and medical devices are a crucial part of the healthcare today and nurses are in growing amount involved with their use (West Health Institute, 2015). Most of the devices have been developed mainly by using technological expertise although they are directly aimed at several fields of nursing care.

CONCLUSION

The results of our review suggest that the expertise of the nurses as the end-users of the devices could be much more exploited so that the future technologies could answer the requirements for both, fundamental nursing and increased use of technology.

RELEVANCE TO CLINICAL PRACTICE

Based on the results of this review, a combination of expertise of device development from both nursing professionals and technical experts is necessary to disentangle the requirements

of increased quality in nursing care combined with the ever growing technological requirements.

REFERENCES

- Balaguera, H. U., Wise, D., Ng, C. Y., Tso, H.-W., Chiang, W.-L., Hutchinson, A. M., ... Wang, C. J. (2017). Using a Medical Intranet of Things System to Prevent Bed Falls in an Acute Care Hospital: A Pilot Study. *JOURNAL OF MEDICAL INTERNET RESEARCH*, 19(5). <https://doi.org/10.2196/jmir.7131>
- Branaghan, R. J. (2018). Human Factors in Medical Device Design: Methods, Principles, and Guidelines. *Critical Care Nursing Clinics of North America*, 30(2), 225–236. <https://doi.org/10.1016/J.CNC.2018.02.005>
- Bridgelal Ram, M., Grocott, P. R., & Weir, H. C. M. (2008). Issues and challenges of involving users in medical device development. *Health Expectations : An International Journal of Public Participation in Health Care and Health Policy*, 11(1), 63–71. <https://doi.org/10.1111/j.1369-7625.2007.00464.x>
- Bruyneel, M., Libert, W., & Ninane, V. (2011). Detection of bed-exit events using a new wireless bed monitoring assistance. *INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS*, 80(2), 127–132. <https://doi.org/10.1016/j.ijmedinf.2010.10.007>
- Castner, J., Sullivan, S. S., Titus, A. H., & Klingman, K. J. (2016). Strengthening the role of nurses in medical device development. *J Prof Nurs*, 32, 300–305. <https://doi.org/10.1016/j.profnurs.2016.01.002>
- Charlon, Y., Fourty, N., Bourennane, W., & Campo, E. (2013). Design and evaluation of a device worn for fall detection and localization: Application for the continuous monitoring of risks incurred by dependents in an Alzheimer's care unit. *EXPERT SYSTEMS WITH APPLICATIONS*, 40(18), 7316–7330. <https://doi.org/10.1016/j.eswa.2013.07.031>
- European Commission. Guidelines on Medical Devices Guidelines on Clinical Investigation : a Guide for Manufacturers and Notified. , Meddev 2.7/4 § (2010).
- European Commission. (2010b). *MEDICAL DEVICES: Guidance document - Classification of medical devices*. Retrieved from <http://ec.europa.eu/DocsRoom/documents/10337/attachments/1/translations>
- European Commission. *Council Directive 93/42/EEC concerning medical devices*. , (2011).
- European parliament. *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices*. , (2017).
- Faudzi, A. A. M., Nasir, H. M., Fadzil, M. M., Mukri, M. A.-R., & Satar, A. A. A. (2015). Structural Analysis of Portable Repositioning Equipment for Bedridden Patients. *JURNAL TEKNOLOGI*, 72(2, SI).
- Fearis, K., & Petrie, A. (2017). Best practices in early phase medical device development: Engineering, prototyping, and the beginnings of a quality management system. *Surgery*,

- 161(3), 571–575. <https://doi.org/10.1016/J.SURG.2016.08.052>
- Feo, R., Kitson, A., & Conroy, T. (2018). How fundamental aspects of nursing care are defined in the literature: A scoping review. *Journal of Clinical Nursing*, 27(11–12), 2189–2229. <https://doi.org/10.1111/jocn.14313>
- Hall, K. D., & Clark, R. C. (2016). A Prospective, Descriptive, Quality Improvement Study to Investigate the Impact of a Turn-and-Position Device on the Incidence of Hospital-acquired Sacral Pressure Ulcers and Nursing Staff Time Needed for Repositioning Patients. *OSTOMY WOUND MANAGEMENT*, 62(11), 40–44.
- Hand, M. C., Rose, M. A., Pokorny, M. E., Castles, R. T., Watkins, F., Kirkpatrick, M. K., ... Chen, K. (2013). Pilot testing the augmentech body position sensor on the morbidly obese patient. *Applied Nursing Research : ANR*, 26(2), 92–95. <https://doi.org/10.1016/j.apnr.2012.10.004> [doi]
- Hilbe, J., Schulc, E., Linder, B., & Them, C. (2010). Development and alarm threshold evaluation of a side rail integrated sensor technology for the prevention of falls. *International Journal of Medical Informatics*, 79(3), 173–180. <https://doi.org/10.1016/j.ijmedinf.2009.12.004> [doi]
- IMDRF. (2018). International Medical Device Regulators Forum. Retrieved August 6, 2018, from <http://www.imdrf.org/about/about.asp>
- Iwamura, M., Yamaguchi, Y., Tanaka, I., & Fujishima, H. (2017). Development of a telescopic boom lift for nursing care: design and optimization using a multibody dynamics approach. *MECHANICAL ENGINEERING JOURNAL*, 4(4, SI). <https://doi.org/10.1299/mej.17-00028>
- Kaye, S. P. (2017). Nurses' Attitudes Toward Meaningful Use Technologies: An Integrative Review. *Computers, Informatics, Nursing : CIN*, 35(5), 237–247. <https://doi.org/10.1097/CIN.0000000000000310>
- Kim, S., Yeom, S., Kwon, O. J., Shin, D., & Shin, D. (2018). Ubiquitous Healthcare System for Analysis of Chronic Patients' Biological and Lifelog Data. *IEEE Access*, 6, 8909–8915. <https://doi.org/10.1109/ACCESS.2018.2805304>
- Kitson, A, Conroy, T., Kuluski, K., Locock, L., & Lyons, R. (2013). Reclaiming and redefining the Fundamentals of Care: Nursing's response to meeting patients' basic human needs. In *Adelaide*. Retrieved from https://digital.library.adelaide.edu.au/dspace/bitstream/2440/75843/1/hdl_75843.pdf
- Kitson, Alison. (2018). The Fundamentals of Care Framework as a Point-of-Care Nursing Theory. *Nursing Research*, 67(2), 99–107. <https://doi.org/10.1097/NNR.0000000000000271>
- Kitson, Alison, Conroy, T., Wengstrom, Y., Profetto-McGrath, J., & Robertson-Malt, S. (2010). SCHOLARLY PAPER: Defining the fundamentals of care. *International Journal of Nursing Practice*, 16(4), 423–434. <https://doi.org/10.1111/j.1440-172X.2010.01861.x>
- Kitson, Alison, Muntlin Athlin, Å., & Conroy, T. (2014). Anything but Basic: Nursing's Challenge in Meeting Patients' Fundamental Care Needs. *Journal of Nursing*

- Scholarship*, 46(5), 331–339. <https://doi.org/10.1111/jnu.12081>
- Kramer, D. B., Tan, Y. T., Sato, C., & Kesselheim, A. S. (2014). Ensuring medical device effectiveness and safety: a cross-national comparison of approaches to regulation. *Food and Drug Law Journal*, 69(1), 1–23. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/24772683>
- Kramer, D. B., Xu, S., & Kesselheim, A. S. (2012). How does medical device regulation perform in the United States and the European union? A systematic review. *PLoS Medicine*, 9(7), e1001276. <https://doi.org/10.1371/journal.pmed.1001276>
- Kuroda, T., Noma, H., Naito, C., Tada, M., Yamanaka, H., Takemura, T., ... Yoshihara, H. (2013). Prototyping Sensor Network System for Automatic Vital Signs Collection Evaluation of a Location Based Automated Assignment of Measured Vital Signs to Patients. *METHODS OF INFORMATION IN MEDICINE*, 52(3), 239–249. <https://doi.org/10.3414/ME12-01-0096>
- Lehoux, P., Williams-Jones, B., Miller, F., Urbach, D., & Tailliez, S. (2008). What leads to better health care innovation? Arguments for an integrated policy-oriented research agenda. *Journal of Health Services Research & Policy*, 13(4), 251–254. <https://doi.org/10.1258/jhsrp.2008.007173>
- Levac, D., Colquhoun, H., & O'Brien, K. K. (2010). Scoping studies: advancing the methodology. *Implementation Science : IS*, 5(1), 69. <https://doi.org/10.1186/1748-5908-5-69>
- Lewis, E. (2010). A fresh approach to administering medication in the palliative care environment. *AUSTRALASIAN MEDICAL JOURNAL*, 3(9), 601–607. <https://doi.org/10.4066/AMJ.2010.390>
- Liu, J. J., Huang, M. C., Xu, W., Zhang, X., Stevens, L., Alshurafa, N., & Sarrafzadeh, M. (2015). BreathSens: A Continuous On-Bed Respiratory Monitoring System With Torso Localization Using an Unobtrusive Pressure Sensing Array. *IEEE Journal of Biomedical and Health Informatics*, 19(5), 1682–1688. <https://doi.org/10.1109/JBHI.2014.2344679> [doi]
- Liu, Y.-W., Hsu, Y.-L., & Chang, W.-Y. (2015). Development of a bed-centered telehealth system based on a motion-sensing mattress. *JOURNAL OF CLINICAL GERONTOLOGY & GERIATRICS*, 6(1), 1–8. <https://doi.org/10.1016/j.jcgg.2014.06.001>
- Money, A. G., Barnett, J., Kuljis, J., Craven, M. P., Martin, J. L., & Young, T. (2011). The role of the user within the medical device design and development process: medical device manufacturers' perspectives. *BMC Medical Informatics and Decision Making*, 11, 15. <https://doi.org/10.1186/1472-6947-11-15>
- NHS England. (2016). *Compassion in Practice Evidencing the impact*. Retrieved from <https://www.england.nhs.uk/publication/compassion-in-practice-evidencing-the-impact/>
- Nodooshan, H. S., Choobineh, A., Razeghi, M., & Khales, T. S. N. (2017). Designing, prototype making and evaluating a mechanical aid device for patient transfer between bed and stretcher. *INTERNATIONAL JOURNAL OF OCCUPATIONAL SAFETY AND ERGONOMICS*, 23(4), 491–500. <https://doi.org/10.1080/10803548.2016.1274161>

- Otero, A., Apalkov, A., Fernandez, R., & Armada, M. (2014). A New Device to Automate the Monitoring of Critical Patients' Urine Output. *BIOMED RESEARCH INTERNATIONAL*. <https://doi.org/10.1155/2014/587593>
- Owens, D. K., Qaseem, A., Chou, R., & Shekelle, P. (2011). High-value, cost-conscious health care: Concepts for clinicians to evaluate the benefits, harms, and costs of medical interventions. *Annals of Internal Medicine*, 154(3), 174–180. <https://doi.org/10.7326/0003-4819-154-3-201102010-00007>
- Spinuzzi, C. (2005). The Methodology of Participatory Design. *Technical Communication*, 52(2), 163–174. Retrieved from <https://repositories.lib.utexas.edu/bitstream/handle/2152/28277/SpinuzziTheMethodologyOfParticipatoryDesign.pdf?sequence=2>
- The Joanna Briggs Institute. (2015). *Joanna Briggs Institutes Reviewers' Manual: 2015 edition / Supplement*. Retrieved from www.joannabriggs.org
- Tricco, A. C., Lillie, E., Zarin, W., O'Brien, K. K., Colquhoun, H., Levac, D., ... Straus, S. E. (2018). PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Annals of Internal Medicine*, 169(7), 467. <https://doi.org/10.7326/M18-0850>
- Wai, A. A., Fook, V. F., Jayachandran, M., Biswas, J., Nugent, C., Mulvenna, M., ... Kiat, P. Y. (2008). Smart wireless continence management system for persons with dementia. *Telemedicine Journal and E-Health : The Official Journal of the American Telemedicine Association*, 14(8), 825–832. <https://doi.org/10.1089/tmj.2008.0084> [doi]
- Weenk, M., van Goor, H., Frietman, B., Engelen, L. J. L. P. G., van Laarhoven, C. J. H. M., Smit, J., ... van de Belt, T. H. (2017). Continuous Monitoring of Vital Signs Using Wearable Devices on the General Ward: Pilot Study. *JMIR MHEALTH AND UHEALTH*, 5(7). <https://doi.org/10.2196/mhealth.7208>
- West Health Institute. (2015). *Missed connections: A nurses survey on interoperability and improved patient care*. Retrieved from <http://www.westhealth.org/wp-content/uploads/2015/03/Nurses-Survey-Issue-Brief.pdf>
- WHO. (2016). Global strategic directions for strengthening nursing and midwifery 2016-2020. In *WHO*. Geneva, Switzerland: World Health Organization.
- Wirz, S., Conrad, S., Shtrichman, R., Schimo, K., & Hoffmann, E. (2017). Clinical Evaluation of a Novel Technology for Oral Patient-Controlled Analgesia, the PCoA® Acute Device, for Hospitalized Patients with Postoperative Pain, in Pilot Feasibility Study. *Pain Research and Management*, 2017. <https://doi.org/10.1155/2017/7962135>
- Wolf, K. H., Hetzer, K., zu Schwabedissen, H. M., Wiese, B., & Marschollek, M. (2013). Development and pilot study of a bed-exit alarm based on a body-worn accelerometer. *Zeitschrift Fur Gerontologie Und Geriatrie*, 46(8), 727–733. <https://doi.org/10.1007/s00391-013-0560-2> [doi]
- Zhang, W., Barriball, L. K., & While, A. E. (2014). Nurses' attitudes towards medical devices in health care delivery: a systematic review. *Journal of Clinical Nursing*, 23, 2725–2739.

Figure legends

Figure 1. Flowchart of the study selection process

Figure 2. Outline of the health and medical device development process within the context of fundamental nursing care

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
-scientific peer-reviewed articles	-conference proceedings
-study includes information on the development process of the device	-studies describing the use of mobile technology or telemedicine without a device
-clinical device is developed to help in the basic nursing care	developed for the purpose
-published between January 2008 and June 2018	-studies describing nursing education or more specialized fields of nursing
	-published before January 2008

Table 2. References included in the scoping review

Area	Author, Year, Publication	Focus	Country	1 st authors expertise	Development process described
Comfort	Hand et al. 2013. Applied Nursing Research	Pressure ulcer prevention	US	Nursing	
	Faudzi et al. 2015. Jurnal Teknologi	Pressure ulcer prevention	Malaysia	Engineering	
	Hall & Clark. 2016. Ostomy Wound Management	Pressure ulcer prevention	US	Nursing	
Elimination	Wai et al. 2008. Telemedicine and E-health.	Continence management	Singapore	Engineering	v
	Otero et al. 2014. Biomed research international.	Urine output monitoring	Spain	Engineering	
Mobility	Hilbe et al. 2010. Int J Medical Informatics.	Prevention of falls	Austria	Nursing	v
	Charlon et al. 2013. Expert systems and applications.	Fall detection and localization	France	Engineering	
	Iwamura et al. 2017. Mechanical engineering journal	Patient transfer	Japan	Engineering	
	Nodooshan et al. 2017. Int J Occupational safety and ergonomics	Patient transfer	US	Ergonomics	v
	Balaguera et al. 2017. J Medical Internet Research	Fall prevention	US	Medicine	
	Wolf et al. 2013. Zeitschrift Fur Gerontologie Und Geriatrie	Fall detection	Germany	Engineering	v
Rest & Sleep	Bruyneel et al. 2011. Int J Medical Informatics.	Detection of bed-exit events	Belgium	Medicine	
	Liu et al. 2015. J Clinical Gerontology & geriatrics	Monitoring movement in bed	Taiwan	Engineering	
Medication	Lewis E. 2010. Australasian Medical Journal	Medication administration	Australia	Medicine	
	Wirtz et al. 2017. S., W., S., C., R., S., K., S., & E., H. (2017). Pain Research and Management.	Medication administration	Germany	Medicine	
Patient monitoring	Kuroda et al. 2013. Methods of information in medicine.	Vital sign monitoring	Japan	Engineering	v
	Weenk et al. 2017. Jmir health and uhealth.	Vital sign monitoring	Netherlands	Medicine	
	Liu et al. 2015. IEEE Journal of Biomedical and Health Informatics.	Respiratory monitoring	US	Engineering	
	Kim et al. 2018. IEEE Access.	Vital sign monitoring	South Korea	Engineering	

