MATEC Web of Conferences **135**, 00020 (2017) DOI: 10.1051/matecconf/201713500020
ICME'17

Review on Design for Medical Device

Naqibah Azman[1], *Nik Hisyamudin* Muhd Nor[1], *Mohd Fahrul* Hassan[1], *Saifulnizan* Jamian[1], *Muhammad Hanif* Abd Rashid[1], *Badrul* Omar[1], *Siti Zarina* Mohd Muji[2], *Fariza* Mohamad[2], *Mohd Fauzi* Ahmad[3], *Faiz* Mohd Turan[4], *Elmi* Abu Bakar[5]

[1]Department of Design and Material Engineering, Faculty of Mechanical Engineering and Manufacturing, Universiti Tun Hussein Onn Malaysia (UTHM), Batu Pahat, Johor, Malaysia.
[2]Faculty of Electric and Electronic Engineering, Universiti Tun Hussein Onn Malaysia (UTHM), Batu Pahat, Johor, Malaysia.
[3]Faculty of Technology Management and Business, Universiti Tun Hussein Onn Malaysia (UTHM), Batu Pahat, Johor, Malaysia.
[4]Faculty of Manufacturing Engineering, Universiti Malaysia Pahang, Pekan, Pahang, Malaysia.
[5]School of Aerospace Engineering, Universiti Sains Malaysia, Nibong Tebal, Seberang Perai Selatan, Pulau Pinang Malaysia.

Abstract. Medical devices are one of the uprising star in product development due to high demand among users. Developing safe, effective and usable design is indeed a challenging work which faced by designer nowadays. There are comparative methods in designing medical device to achieve desired outcome. Weather designing a "User-friendly", "Safe to use" or "Eco-friendly" product requires an exclusive method. This review paper might illuminate some light to the designers and researchers who choose to integrate those aspect in their design work in healthcare sector. A review on current method used on user-friendly approach, ensuring safety, regulations on safety of medical device and suggested standards to ensure safety in less complicated way. Thus, there is no solid method or standard yet to establish on safety for medical device.

1 Introduction

Reported by the Department of Health United Kingdom, in an article "An Organization with a Memory" which record repeated cases which occur not only in medical sector but also in industry and research area. However, the patient safety is not generally secured in this particular aspect [1]. Reported by The National Patient Safety Agency's (NPSA), 24,207 patient safety incident was reported which involve medical device since April 2006 until March 2007 which equivalent to 3% of overall incident that been reported in the time period [2]. From these reported incident in 2008, 303 incidents were classified as a result of fatal or severe harm to patient [3]. Investigations shows that such incident experience a classic system failure thus amenable for prevention [4][5]. Record have found weakness at every stage process which include poor labeling, confusing procedure, lack of standardization across units and other cause [6]. Further analysis have been made throughout the year have found that medical device design was one of the issue.

*Corresponding author: hd160039@uthm.edu.my, nhisyam@uthm.edu.my

For example, incorrect connection, identification issue and lack of feedback from user have led to patient safety incident. The awareness of the role played by the user in recognizing user error by the staffs and manufacturer have contributes in improving procurement decisions, scopes and selecting well-designed device. Thus, suggested by NPSA was to demonstrate safe design philosophies and guidelines for a more standardized device which suits user requirements, usage context and potential usage environment need to be taken into measures [7].

Table 1 shows the classification of incident according to their groups that is reported by NPSA in 2008. The collected data have shown that incident cause by medical device is in the top-five causes of incident reported although the safety of medical device is often neglected [8].

Table 1. Classification of incident that is reported in 2008 by NPSA [8]

	Number in group in incident reports	**Number remaining in initial group after reclassification**	**Percent remaining in initial group after reclassification, %**	**Number in group reallocated by investigators**
Access admission, transfer and discharge	362	312	86	1032
Clinical assessment	266	217	82	49
Consent, communication, confidentiality	232	172	74	549
Documentation	247	227	92	552
Implementation of care	412	336	82	1047
Infection control	174	161	93	257
Infrastructure, staff	814	714	88	1289
Medical device／equipment	647	586	91	1003
Medication	1145	1096	91	1450
Patient accident	330	273	83	286
Treatment procedure	786	366	43	576
Other	200	57	23	365
Total	5615	4517	80	8905

Reported by the European Pressure Sore Advisory Panel grades that 119 cases of pressure sore are associated with medical device. In 87 cases of pressure sore which are often associated with medical device are being presented on admission, suggested that implementation of care and regular monitoring should be implemented [9][10][11]. There is no 'accurate' or 'safe' number of patient safety to be considered as safe however a 'low'

reporting rate can be interpreted as 'safe' and a 'high' report rate can be describe as 'unsafe' which represent culture of greater openness [12].

2 Medical Device

2.1 What Is Medical Device?

Primarily define by Medical Device Authority of Malaysia, medical device is any instrument, apparatus, implement, machine, appliance, implant , calibrator or in vitro reagent , material or software produce by the manufacturer to be used alone or combined for humans in various purpose [13]. Generally explained by Top Market report in 2016 produce by the US government, a medical device also defined as any piece of equipment or apparatus used to treat or diagnose diesease and involves direct contact with patients. US medical device companies have highly respected ranks due to their innovations and high-tech product. In recent years, the investment in medical device research and development have ben doubled than previous years [14]. The medical device universe, largely encompasses specifically emitting special technological innovation, which includes hundreds of different technologies and thousands of types of products. Six major technology themes were identified and elaborated as highly to prefigure medical device innovation over the next decade: (1) electronics technology; (2) detection, diagnosis, and monitoring technologies; (3) decentralized care technologies; (4) minimally invasive technologies; (5) synthetic organs, tissues, and combination device/biological and device/drug technologies; and (6) demographically oriented technologies [15]. More than billions patients across the globe depend on medical device and its technologies. Most of them are used in diagnosis, prevention and disease treatment. Medical technologies such as wheelchairs, contact lenses and pregnancy test are frequently used by humans [16].

2.2 User-Centered Design Approach

User-Centered approach are the most common approach that been used in designing medical device aside from data driven design due to organized and more reliable in designing process [17]. It also adds to customer satisfaction when using the product because it fits the needs of user.

2.2.1 Medical Devices and User-Centered Design

In previous years, the focus on designing medical device have increased due to high demand in such area. In relation of a user-device design embodiment, most designers have focus more on device design, human error, usability and patient safety in their conceptual design. The aim of improving such aspect, a numbers of initiative have been organized. The role of medical device in patient safety incident have been investigated in 2007 by the United Kingdom's National Patient Safety Agency. Looking at all death and severe incidents reported by them, the cause of the incident is mainly the design of the medical device that is not safe to be used [18]. In addition, the incident includes developer who does not solely understood the context of the device and do not predicted hazard scenario. They also do not consider user practicality first before manufacturing resulting the device did not reached customer's satisfaction [19][20][21]. Ergonomic or widely known as human factor have contribute significantly in medical device safety have highlighted contribution which will improving safety in health care discipline especially on design [7][22][23][24].

Reported by the Institute of Medicine , that medical error report have significantly increased awareness on the magnitude, frequency, complexity and seriousness of error. Top eight leading cause of death in US is motor vehicle accidents, breast cancer, or AIDS, and medical error [25]. There are technologies such as Health Information Technology (HIT) which reduced the risk on getting a serious injury for hospitalized patients [26]. Therefore, it proves validates that the usage of technology itself can saves life. A study was conducted in the field of shoulder surgery where "A brief fatigue inventory of shoulder health developed by QFD technique". The usage of QFD techniques is to develop an instrument to diagnose the severity of symptoms on neck and shoulder thus trace the cause of the symptoms [27].

Previous research made by Kianfar have used QFD methodology to Reliability-Centered Maintenance (RCM) to improve RCM capability in preserving the functions of the plants. Their objective is mainly to preserve the function of plant with least resource. By adding such method to the RCM have regain more efficiency [28]. Self-management initiatives increasingly rely on the use of technologies to facilitate the process of care in the home. These technologies range from medical devices such as glucose monitors to comprehensive computer-mediated telemedicine systems that provide interactive support as well as World Wide Web access. Although such devices are required to meet certain standards, very little is known about their usability [25].

3 Medical Device Safety Assurance Method

3.1 Review on method in ensuring safety of medical device

Table 2 shows review on previous researchers in order to ensuring the safety of medical device and method chosen to cater certain case study.

Table 2. Review on method in ensuring safety of medical device.

No	Case Study / Medical device	Objective	Methodology	Reference
1	General	✓ Meeting design requirement ✓ Reduce medication error ✓ Ergonomic methods	a. System based user control approach b. Mapping workshop c. Designers workshop ✓ Ideas for solution ✓ Design concept ✓ Improve design ✓ Patient-centred	[29] [30]
2	General	✓ Reduce medication error ✓ Increase safety ✓ Reorganized design system	✓ User centred design ✓ Standardization ✓ Information sharing ✓ Effective monitoring ✓ Risk management ✓ Action plan	[31] [32]

3	Laparoendoscopic single-site (LESS)	✓ Evaluate new medical device usability ✓ User-centred ✓ Improving ergonomic posture	✓ Clinical simulation lab ✓ ETI training ✓ EMG sensor and DataLINK™ software	[33]
4	General	✓ Reduce device related errors ✓ Increase efficiency ✓ Functionality ✓ Performance ✓ Increase safety	✓ Human machine interface ✓ Use machine ✓ User training	[34][35] [24] [36]
5	Patient-controlled analgesia	✓ Decrease patient injuries ✓ Increase safety ✓ Introduce to new interface ✓ Decrease human error ✓ Faster performance	✓ Continuous of representative during design ✓ Field observation ✓ Task analysis (bottle neck) ✓ Technology compatibility with human limitations ✓ Iterative design process ✓ Experiment evaluation ✓ Market study ✓ Programming sequence	[2], [18], [20], [26], [34], [35]
6	Infusion pumps	✓ Identify risk ✓ More usable by end users	✓ Heuristic analysis ✓ Nielsen-Schneiderman ✓ Rules	[11] [37]
7	Glucose meter	✓ Framework that introduces concentric layers to dicot	✓ DiCoT-CL	[38]

4 Medical Device and Regulations

The medical device industry has undergone significant changes in recent years due to the passing of the Affordable Care Act (ACA) and the expansion of government regulations, including the adoption of Unique Device Identification (UDI) [39]. The regulatory procedures for medical devices will vary according to their class. In general, higher-risk

devices will require more regulations and a more stringent conformity assessment process. The regulatory procedure for medical devices varies according to their class [40].

Nowadays, medical device regulations differ across the globe which makes the compliance gets complex and difficult process. The main scope of these medical device regulations around the world is mainly on risk management to ensure that the device do not compromised with either clinical condition or safety of patient and its users. Medical device developers need to eliminate nor reduce as much as possible the risk associate with the device [7]. Taking decrease in non-renewable resource into measures, manufacturing sustainability is indeed a crucial issue. Stricter regulation is needed on environment and occupational safety as customer preference for more eco-friendly product [41].

4.1 Review on existing standardized medical device

There are a few methods that have already achieved certain standard fixed by ISO. Table 3 shows review on method used to standardized current medical device according to regulations.

Table 3. Review on method use to standardized medical device

IS0/IEC	Case study	Method	Reference
ISO 14117	Electromagnetic Interference (EMI)	Risk-based analysis : Computational Human Phantom (CHP)	[42]
ISO 9241-11	General	User-centred design in development	[43]
ISO 13407	Laparoendoscopic Single-Site (LESS)	User-centered design	[33]
ISO 13485:2003	General	Design for Reliability : S&E assessment	[44]
ISO 14971	Fault Injection	FMEA	[45]

4.2 Preference standard for medical device developer

One of most crucial issue when it comes to designing or development of medical device is safety. There are no certain standards put to every medical device in ensuring safety. Therefore, IEC 60601 covers mainly in electrical medical device which more safety measures need to be taken.

4.2.1 IEC 60601-1

One standard that commonly used by medical device developers are likely to encounter is IEC 60601-1 (2004): general requirements for safety of electrical medical equipment. This standard is identical to the equivalent European standard (EN) and the British standard (BS) [7]. IEC 60601-1 originally have represent a major issue on medical electrical equipment

on its safety standard in 1977 [46] [47]. Initially the scope was not covered on a few important devices such as automatic external defibrillator (AED) which is used commonly in airports and other handling issue. IEC 60601-1 only covers basic safety standards that contribute to basic safety and performance of a device. After IEC 60601-1 have been revised in 2006, the general requirements involved basic safety and essential performance with collateral standard in general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. The manufacturer company need to have ISO 14971 certificate for risk management process in order to obtain the standard that is required by IEC 60601-1 [46][48]–[50]. As suggested by J. Martin, the best approach in achieving IEC 60601-1 is by using user-centred design approach because this method has specific aims of improving medical device usability in order to reduce medical error [18]. Usability and other user-centred issues are covered in the collateral standard: 60601-1-6, which specifies the usability requirements for safety of electrical medical devices. This collateral standard requires developers to adopt a usability engineering process to ensure medical electrical equipment safety and function accordingly [7]. Usability engineering should begin early and continue through the equipment design and development life cycle [51].

5 Conclusion

This review paper has confirmed that there is no solid standard procedure in designing medical device to ensure the safety inclusively. There are comparative methods suggested by other researcher in achieving safety in design for several type of medical device which cause arguments among designers. This review is mainly highlighted the procedure and design method used currently in designing medical device. Medical device industries have put abundance of effort in ensuring safety of the product in line with the increasing demand in this area. For further research, standardized procedure and design method on ensuring safety both need to be performed before the product is released to the market so the safety of its user is guaranteed, thus decrease number of incident in healthcare sector. Therefore this paper suggested the implementation of IEC 60601-1 in medical device might be the holy grail of endless arguments among researchers by looking at its simple yet effective method in ensuring safety in a universal range of electronic medical device.

Acknowledgement

The authors would like to thank the financial support from Centre for Graduates Studies and Research Management Centre, Universiti Tun Hussein Onn Malaysia (UTHM).

References

1. Department of Health London (2000). "An organisation with a memory - Report of an expert group on learning from adverse events in the NHS," Clin. Med., vol. 2, no. 5, pp. 452–457.
2. Patient Safety Observatory (2007). "Safety in doses: medication safety incidents in the NHS," pp. 9–12.
3. National Patient Safety Agency (2008) "Device-related incidents : reports of serious harm," vol. 9, no. 9, pp. 2007–2009.
4. B. Toft (2001) "External inquiry into the adverse incident that occurred at queen's medical centre, Nottingham, 4th January 2001," Inquiry, no. January, p. 76.
5. S. I. Panel (2007) "Report on a Medication Incident of Intrathecal Administration of Vincristine in Prince of Wales Hospital," no. August.

6. B. D. Franklin, S. S. Panesar, C. Vincent, and L. J. Donaldson (2014). "Identifying systems failures in the pathway to a catastrophic event: An analysis of national incident report data relating to vinca alkaloids," BMJ Qual. Saf., vol. 23, no. 9, pp. 765–772.
7. J. L. Martin, B. J. Norris, E. Murphy, and J. a. Crowe (2008). "Medical device development: The challenge for ergonomics," Appl. Ergon., vol. 39, no. 3, pp. 271–283.
8. A. N. Thomas, U. Panchagnula, and R. J. Taylor (2009). "Review of patient safety incidents submitted from Critical Care Units in England & Wales to the UK National Patient Safety Agency," Anaesthesia, vol. 64, no. 11, pp. 1178–1185.
9. A. N. Thomas and B. A. McGrath (2009). "Patient safety incidents associated with airway devices in critical care: A review of reports to the UK National Patient Safety Agency," Anaesthesia, vol. 64, no. 4, pp. 358–365.
10. A. N. Thomas and U. Panchagnula (2008) "Medication-related patient safety incidents in critical care: A review of reports to the UK National Patient Safety Agency," Anaesthesia, vol. 63, no. 7, pp. 726–733, 2008.
11. A. N. Thomas and I. Galvin (2008). "Patient safety incidents associated with equipment in critical care: A review of reports to the UK National Patient Safety Agency," Anaesthesia, vol. 63, no. 11, pp. 1193–1197.
12. National Patient Safety Agency (2016). "Guidance notes on National Reporting and Learning System quarterly data summary publications," no. September.
13. European Commission and D. G. Health (2001). "Medical Devices : Guidance document medical device software," no. July 2001, pp. 1–21.
14. T. M. Report (2016). "2016 Top Markets Report Medical Devices Overview and Key Findings," pp. 1–9.
15. W. a. Herman and G. B. Devey (2007). "Future Trends in Medical Device Technologies," FDA Natl. Sci. Found.
16. J. Cunningham, B. Dolan, D. Kelly, and C. Young (2015). "Medical Device Sectoral Overview," Galw. City Cty. Econ. Ind. Baseline Study.
17. O. M. F. De Troyer and C. J. Leune (1998). "WSDM: a user centered design method for Web sites," Comput. Networks ISDN Syst., vol. 30, no. 1–7, pp. 85–94.
18. J. L. Martin, D. J. Clark, S. P. Morgan, J. A. Crowe, and E. Murphy (2012) "A user-centred approach to requirements elicitation in medical device development: A case study from an industry perspective," Appl. Ergon., vol. 43, no. 1, pp. 184–190.
19. D. R. Kaufman, V. L. Patel, C. Hilliman, P. C. Morin, J. Pevzner, R. S. Weinstock, R. Goland, S. Shea, and J. Starren (2003). "Usability in the real world: Assessing medical information technologies in patients' homes," J. Biomed. Inform., vol. 36, no. 1–2, pp. 45–60.
20. J. N. Amoore (2014). "A Structured Approach for Investigating the Causes of Medical Device Adverse Events," vol. 2014, no. Table 1.
21. M. Aljazzazi, M. Rawashdeh, T. Alshawaheen, and A. Malkawi (2013). "A User - Requirements Approach in Medical Devices Maintenance System Development : A Case Study from an Industry Perspective," World Acad. Sci. Eng. Technol., vol. 75, no. 3, pp. 780–790.
22. O. Safety (2000). "Ergonomics : The Study of Work," vol. 2000.
23. N. Moray (2000) "Culture, politics and ergonomics.," Ergonomics, vol. 43, no. 7, pp. 858–868.
24. L. Fennigkoh and H. Diego (2009). "Human Factors and the Control of Medical Devi|Freescale," pp. 39–43.
25. J. Zhang, T. R. Johnson, V. L. Patel, D. L. Paige, and T. Kubose (2003). "Using usability heuristics to evaluate patient safety of medical devices," J. Biomed. Inform., vol. 36, no. 1–2, pp. 23–30.

26. J. Horsky, J. Zhang, and V. L. Patel (2005). "To err is not entirely human:Complex technology and user cognition," J. Biomed. Inform., vol. 38, no. 4, pp. 264–266.
27. S. F. Liu, Y. Lee, and Y. Huang (2009). "A brief fatigue inventory of shoulder health developed by quality function deployment technique," J. Shoulder Elb. Surg., vol. 18, no. 3, pp. 418–423.
28. A. Kianfar and F. Kianfar (2010) "Plant function deployment via RCM and QFD," J. Qual. Maint. Eng., vol. 16, no. 4, pp. 354–366.
29. P. Buckle, P. J. Clarkson, R. Coleman, J. Bound, J. Ward, and J. Brown (2010) "Systems mapping workshops and their role in understanding medication errors in healthcare," Appl. Ergon., vol. 41, no. 5, pp. 645–656.
30. P. Buckle, P. J. Clarkson, R. Coleman, J. Ward, and J. Anderson (2006). "Patient safety, systems design and ergonomics," Appl. Ergon., vol. 37, no. 4 SPEC. ISS., pp. 491–500.
31. N. Khambete and A. Murray (2012). "National efforts to improve healthcare technology management and medical device safety in india," pp. 1–5,.
32. Department of Health (2003). "A System-wide Design-led Approach (Design for Patient Safety)," Design, p. 45.
33. de Laveaga and Adam E. (2012) "An Investigation Of Medical Device Design And Physical Ergonomics In Healthcare," Industrial and Management Systems Engineering - Dissertations and Student Research., Paper 32.
34. P. Carayon and K. E. Wood (2010). "Patient safety: The role of human factors and systems engineering," Stud. Health Technol. Inform., vol. 153, pp. 23–46.
35. L. Lin, K. J. Vicente, and D. J. J. Doyle (2001). "Patient Safety, Potential Adverse Drug Events, and Medical Device Design: A Human Factors Engineering Approach," J. Biomed. Inform., vol. 34, no. 4, pp. 274–84.
36. A. Çetin (2004). "Applying Product Design Methods to Medical Device Design With a Case Study on Home Care Devices," Strategy.
37. L. Duque-Muñoz, C. A. Aguirre-Echeverry, and G. Castellanos- Domínguez (2014). "EEG rhythm analysis using stochastic relevance," IFMBE Proc., vol. 41, pp. 658–661.
38. H. Care (2012). "2012 Symposium on Human Factors and Ergonomics,".
39. The Association for Packaging and Processing Technologies (2016). "Pharmaceutical & Medical Devices: Trends and Opportunities in Packaging Operations,".
40. N. Radhadevi, V. Balamuralidhara, T. M. P. Kumar, and V. Ravi (2012). "Regulatory guidelines for medical devices in India: An overview," Asian J. Pharm., vol. 6, no. 1, pp. 10–17.
41. M. Mutingi, P. Dube, and C. Mbohwa (2017) "A Modular Product Design Approach for Sustainable Manufacturing in A Fuzzy Environment," Procedia Manuf., vol. 8, no. October 2016, pp. 471–478.
42. J. E. Brown, R. Qiang, P. J. Stadnik, S. Member, L. J. Stotts, S. Member, and J. A. Von Arx (2016)."MR Conditional Safety Assessment of Implanted Medical Devices : Advantages of Computational Human Phantoms," pp. 6465–6468.
43. National Patient Safety Agency (2010). "Design for Patient Safety User testing in the development of medical devices," Patient Safety, 2nd Ed., p. 68.
44. S. Weininger and D. Ph (2009). "and Its Relationship to Safety and Effectiveness," Pace Pacing Clin. Electrophysiol..
45. J. Park, C. Yi, K. Kwon, and J. W. Jeon (2014). "Method Of Fault Injection for Medical Device Based on ISO 26262," pp. 1–2.
46. L. Eisner (2006) "Iec 60601-1 – the Third Edition," Regulation, pp. 8–17,.
47. Taylor A. (2013) "Standards : Medical Devices," pp. 1–3.
48. Mitch Gaudyn (2012). "The third edition of IEC 60601-1-A manufacturer's perspective," no. February.

49. J. O. Hare (2006) "Today's Moves Towards Eco-innovation in the Medical Electronics Sector," pp. 1–10.
50. P. G. Rajendra K. Songara, Ganesh N. Sharma, Vipul K. Gupta (2010). "Need For Harmonization Of Labeling Of Medical Devices: A Review," J. Adv. Pharm. Teachnology, vol. 1, no. 2, pp. 1–36.
51. Rigel Medical (2007). "A Practical Guide to IEC 60601-1,".