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USABILITY OF THE MEDICAL DEVICE AMONG GENERAL PHYSICIANS AND SPECIALISTS - A STUDY IN CONTEXT TO INDIAN HEALTHCARE SCENARIO

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ABSTRACT

Usability engineering is a scientific discipline that studies how people interact with systems. Human factors engineers seek to optimize human performance by designing systems to match the cognitive and physical capabilities and limitations of users. Usability aspects of the medical device are crucial in ensuring efficacy of the medical care. For companies designing and manufacturing medical devices, poor usability is literally a matter of life or death. More than a third of medical device incidents involve usability issues and, on average, 195,000 people die in American hospitals annually because of medical errors. While not all of those cases are attributable to specific user interface design problems, increasingly complex user interfaces are unquestionably a part of the problem. This paper presents a case study of evaluating usability aspects of a medical device among general physicians and specialists.

KEYWORDS: Medical Device, Usability Engineering

INTRODUCTION

More than a third of medical device incidents involve usability issues and, on average, 195,000 people die in American hospitals annually because of medical errors. While not all of those cases are attributable to specific user interface design problems, increasingly complex user interfaces are unquestionably a part of the problem. We believe that it is of great importance to understand usability of the medical device among general physicians and specialists in context to Indian healthcare scenario.

Considering the vast Indian population, the disease patterns, ageing population, growing economy, emergence of technologies point to a need of custom specific design as well as services to create a healthcare platform which is hitherto unrealized.

Medical technology plays a vital role in the delivery of healthcare services in a country. When it is the question of India, the world's most populous democracy, which is fast becoming the hub for medical device design and medical tourism where people from other countries flock to get good quality, affordable medical treatment, medical technology is in a nascent state. However, the opportunities for innovation-led growth are immense. Medical professionals rely on medical technology for tests and investigations to aid their clinical decision-making. Innovation in medical technology can therefore be crucial for the Indian healthcare system to improve access, enhance quality and reduce costs.

The sector however does face significant challenges. Mahatma Gandhi had a dream that India would be a land of self-sustaining villages. 'The true India is to be found not in its few cities, but in its seven hundred thousand villages. If the villages perish, India will perish too', said Mahatma Gandhi. But here are some of the stark realities about the lives of

Indian rural population:

- 50% of all villagers have no access to healthcare providers.
- 37% are chronically starved
- 10% of all babies die before their first birthday
- 50% of all babies are likely to be permanently stunted due to lack of proper nutrition
- 33% people have no access to toilets, while 50% defecate in the open
- A mother dies every ten minutes in India
- Over 1.25 million children die annually in India.
- 48% of all children have stunted growth due to malnutrition.

One of the earliest and most critical steps early in the design process is to differentiate between the "customers" and "intended users." Clearly, balancing the needs and desires of both can be challenging, but it is a critical delineation to encourage the safest, most usable design. Considering the Indian scenario this is a vital point.

REVIEW OF LITERATURE

(Alexandra R. Lang, September 2013) Discusses that Adolescents are currently overlooked in many fields of healthcare research and as a result are often required to use medical devices that have been designed for use by either children or adults. This can lead to poor adherence and a reduction in health outcomes. This study examines the role of device design in the real-world effectiveness of a medical device used in the treatment of cystic fibrosis from the perspective of adolescent users. This study found that adolescent users of some of the devices do not use the device as regularly and correctly as is recommended by clinicians.

(Constance H. Fung, 2015) Suggests that medical equipment often fails to accommodate the needs of individuals with disabling conditions. Few studies have focused on the accessibility of home medical devices such as positive airway pressure (PAP), which is a type of home medical equipment prescribed for long-term therapy.

(Jasper van Kuijk, March 2015) Explored how usability was dealt with in four product development organizations active in different sectors: high-end automotive, professional printers and copiers, office coffee makers and fast moving consumer goods. The primary differentiators of the selected cases were whether they were targeting businesses or consumers and the degree of product complexity. The results indicate that differences in product–market combination lead to differences in organizational attitude towards usability. The prioritization of usability in an organization seems to be influenced by the degree of product complexity (complex products are more prone to suffer from usability issues) and whether developers think that usability is a purchase consideration for their clients. The product–market combination a company targets also affects the methods for user-centered design that a company can apply and that are relevant. What methods for user-centered design are used also seems to be influenced by the attitude towards usability: if usability is considered more important, methods that require more resources can be applied.

(Jorien van der Peijl, August 2012)**,** Jan Klein, Christian Grass, Adinda Freudenthal mention that the majority of medical device incident reports can primarily be attributed to use error. Greater attention to human factors and usability

during development of a medical device could improve this situation. However, recent studies have shown that companies do not find the application of a sound usability engineering process according to international standards a simple task. This collaborative research project between a medical device company, two universities and a university hospital was to study the practical application of the International Standard for Application of Usability Engineering to Medical Devices, IEC 62366, by means of a case study in industrial practice. This paper describes the user studies in the case and reveals the factors important to success. Also, the paper demonstrates how to apply an iterative usability engineering process within a linear product development process in industry. Management support and careful planning of resources and activities proved essential. To control use-related risks, the usability engineer should 'design for risk control' in a structured manner, while the risk manager should remain responsible for acceptable levels of residual risk. The paper concludes with recommendations for the improvement of IEC 62366 and ISO 14971, the standard for the risk management of medical devices.

(Liljegren, April 2006) discusses that the increased complexity of medical technology makes usability an important selection criterion when new equipment is purchased. However, this requires an understanding of what usability is in a medical technology context and what usability evaluation methods are suitable. The component 'difficult to make errors' was regarded as being 30% of overall usability. The components 'easy to learn', 'efficient to use', 'easy to remember' made up 20% each of overall usability. Satisfaction only made up 10% of overall usability. Four common methods, hierarchical task analysis, cognitive walkthrough, heuristic evaluation and usability tests were evaluated according to thoroughness, validity, reliability, cost effectiveness and clarity. Usability tests are recommended to be the primary method in usability evaluations at hospitals, as they fulfill the criteria and address the 'difficult to make errors' aspect of overall usability. Hierarchical task analysis and cognitive walkthrough fulfill some criteria. Cognitive walkthrough also addresses the 'difficult to make errors' aspect.

(Peter L. Kolominsky-Rabas, August 2015) aims to develop a platform targeting health care manufacturers and decision makers that facilitates the assessment of innovative health technologies prior to their launch. The simulation has been run for the first case study of Mobile Stroke Units (MSUs). Results of the simulation show that MSUs save up to 49 min of time between ambulance call and therapy decision.

(Constance H. Fung J. L., May 2015) made an interesting study that provides initial support for measuring PAP device usability as a growing number of positive airway pressure (PAP) device users will develop physical/sensory impairments such as arthritis. For these individuals, the usability of their PAP devices (eg, efficiency and satisfaction) may impact the frequency and safety of device usage.

Based on the literature review the following hypotheses were formed

Null ($H_{0\text{-}1}$): There is no difference for usability of the medical device among general physicians and specialists

Alternate ($H_{1\text{-}1}$): There is a significant difference for usability of the medical device among general physicians and specialists

Null ($H_{0\text{-}2}$): There is no difference for usability of the medical device among cardiac, critical care and diabetes specialists

Alternate ($H_{1\text{-}2}$): There is a significant difference for usability of the medical device among cardiac, critical care

and diabetes specialists

RESEARCH METHODOLOGY AND DESIGN

This section details out the research methodology for the present study. It explains the research objectives and a suitable methodology to achieve those objectives. The objectives of this study were to identify medical device market drivers for emerging markets in context to Indian Market.

Locale of the Study

This study is focusing on Indian market which is a microcosm of the emerging market. The present study was conducted in Indian medical device markets. For convenience, efficacies I have divide the regions in 5 different zones namely:

East (Kolkota)

West (Mumbai, Pune)

North (Dehradun)

South (Chennai, Bangalore)

NCT (Delhi, Gurgaon)

From each zone, equal numbers of samples were taken by collecting the list of doctors from the particular city and then selected the doctors based on their specialty.

Sample and its Selection

The total sample consisted of 300.

- 60 Cardiologists
- 60 Critical care
- 60 Diabetes specialists
- 60 general physicians

Research Tool

Keeping in mind the purpose of the study, types of sample and their specialties were decided to use questionnaires, schedule, interview, observation and case study method.

Based on the literature survey a questionnaire of 30 questions was made which was sent to a group of 10 doctors.

A final questionnaire consisting 25 questions open and closed (refer annexure 1 for details) was made based of the feedback from the above mentioned group of doctors.

Procedures of Data Collection

The study aimed to understand medical device market drivers for emerging markets in its total perspective with special focus and context to Indian market. For the data collection 300 samples were selected from the 5 zones:

- East (Kolkota)
- West (Mumbai, Pune)
- North (Dehradun)
- South (Chennai, Bangalore)
- NCT (Delhi, Gurgaon)

Each 60 of Cardio, diabetes, and critical care specialists were randomly selected from these cities. A total of 600 questionnaires were send by post, email, online survey and face to face interview.

Some of the respondents were very helpful while for many others emails and telephone were used extensively to make them understand the purpose of the research and assure them that the data provided will be used only for academic research and their identity will never be revealed.

Data was gathered through questionnaires and telephonic interviews were conducted to substantiate the integrity of the data received.

Only 340 filled questionnaires were received out of which 300 were found to be fully filled. The rest 40 were discarded since they were incomplete. Thus with the unconditional assistance of various associated. data was collected comfortably from the respondents within the scheduled time interval.

Hypothesis Test

The followings tests are conducted on the hypothesis for elicitation the relation.

When we found correlation between Usability and Low power design according to responses of my all respondents, general group, specialists group, all male respondents and all female respondents.

Below table indicates correlation between Usability and Low power design according to responses of my all respondents. Studies show that there is a correlation between Usability and Low power design, it means if low power consumption in devices then usability is better. We use this test for comparing the means of two samples, even if they have different numbers of replicate. In our study we use group t test.

Table 1: T Test between Groups

	Group2	N	Mean	Std. Deviation	Std. Error Mean
Usability	**Specialists**	180	18.28	1.547	.115
	General	120	18.09	1.420	.130

	T	df	Sig.	Decision
Usability	1.086	298	t is not significant.	H_{0-1} Null is accepted

DECISIONS

Null (H_{0-1}): There is no difference for usability of the medical device among general physicians and specialists

Alternate (H_{1-1}): There is a significant difference for usability of the medical device among general physicians and specialists

H_{0-1} Null is accepted

Table 2: ANOVA-1

ANOVA							
		Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**	**Decision**
Usability	**Between Groups**	28.378	3	9.459	4.356	.005**	H0-2Null is rejected
	Within Groups	642.808	296	2.172			
	Total	671.187	299				

** Significant at the 0.01 level.
* Significant at the 0.05 level.

In above table through t-test I checked different opinion of specialists and general groups about usability, telemedicine and low power design. I found about to usability specialists mean opinion is 18.28 and general people's 18.09, so opinion is same and t is not significant. About to telemedicine specialists mean opinion is 5.02 and general people's 5.12,so opinion is same and t is not significant but when i checked Low power designs specialists mean opinion is 4.64 and general people's 4.78,so opinion is not same and t is significant at the 0.01 level.

Null (H_{0-2}): There is no difference for usability of the medical device among cardiac, critical care and diabetes specialists

Alternate (H_{1-2}): There is a significant difference for usability of the medical device among cardiac, critical care and diabetes specialists

Alternate (H_{1-2}): **is accepted.**

In above table through ANOVA I calculate common views of groups-specialists and general group about to usability. Cardiac physician's view is 17.98, critical care specialist's view is 18.05, Diabetes specialist's view 18.82 and general group mean is 18.09.it shows all four groups have different opinion about it. Its F value 4.356 shows significance level is 0.01. Means all four groups have different view on the matter of usability. About to telemedicine cardiac physician's view is 4.93, critical care specialist's view is 5.12, Diabetes specialist's view 5.00 and general group mean is 5.12. its F value is 2.053 shows that there is no difference on the matter of telemedicine, and on low power design cardiac physician's view is 4.68,critical care specialists view is 4.57, Diabetes specialist's view 4.67 and general group mean is 4.78.,the F value 3.081 shows Significant at the 0.05 level.

CONCLUSIONS

This is an interesting point to note that

- There is no difference for usability of the medical device among general physicians and specialists
- There is a significant difference for usability of the medical device among cardiac, critical care and diabetes specialists

Second point crucial considering the fact that in India there is a shortage of doctors and specialists and medical devices. Sharing of the devices call for greater ad enhanced usability and this is the important take away for the medical device manufactures.

REFERENCES

1. (SGPGIMS), S. G. (n.d.). *SGPGIMS http://www.sgpgi.ac.in/.*
2. Abul Kashem, M. T. (March 2008). Managing Heart Failure Care Using an Internet-Based Telemedicine. 121-126.
3. Agtamel, A. V. (2007). *The Emerging Markets Century: How a New Breed of World-Class Companies Is Overtaking the World.* Free Press; annotated edition edition.
4. Alexandra R. Lang, J. L. (September 2013). The effect of design on the usability and real world effectiveness of medical devices: A case study with adolescent users. *Applied Ergonomics, Volume 44, Issue 5*, Pages 799-810.
5. Asikainen, K. (2012). *Barriers to Entry in a Regulated Industry: Tackling Barriers to Entry with Limited Resources - The Entrant Perspective.* Aalto University School of Business,.
6. Bernard Kamsu-Foguem, C. F. (December 2014). Telemedicine and mobile health with integrative medicine in developing countries. *Health Policy and Technology, Volume 3, Issue 4*, 264-271.
7. Biodesign, S. I. (2012). *Staford India biodesign.*
8. Cegedim. (2012). *Cegedim emerging larkets.*
9. Co, B. &. (2011). *Shan Zhai A Chinese Phenomenon.*
10. Constance H. Fung, J. L. (May 2015). Development of the Usability of Sleep Apnea Equipment – Positive Airway Pressure (USE-PAP. *Sleep Medicine, Volume 16, Issue 5*, 645-651.
11. Constance H. Fung, U. I. (2015). Human factors/usability barriers to home medical devices among individuals with disabling conditions: In-depth interviews with positive airway pressure device users. *Disability and Health Journal, Volume 8, Issue 1, January 2015*, Pages 86-92.
12. Consuting, I. (2013). Primer on the Indian Medical Technology,. InnAccel Consuting.
13. Deloitte. (2012). *Emerging Market Entry Keys Success.*
14. FICCI-Deloit. (2012). *Indian Medical Electronics Industry -Thought-paper-on-Medical-Electronics-.*
15. Govindarajan, V. (2012). *GE reports.* GE.
16. HCL. (2008). *Launching medical devices for emerging markets.* HCL.
17. *http://www.userfocus.co.uk/articles/ISO62366.html*. (n.d.).
18. IDF. (2012). *International Diabetes foundation IDF Study on Diabestes in India.* IDF.
19. IICA. (2012). *healthcare sector.* IICA.
20. Immelt, J. (2009). *1. Reverse Innovation: High end technology at a price affordable to consumers - case study by*

GE chairman. GE.

21. India, C. C. (2010). *Identification of competition issues in the healthcare sector in india.* Vasudha W, Competition Commission of India.
22. Insight. (2012). *Redefining the Emerging-i nsight report.* Boston Consulting Group.
23. Irene J. Petrick, S. (2010). *The rise of the rest: hotbeds of innovation in emerging markets.*
24. Jasper van Kuijk, L. v. (March 2015). Usability in product development practice; an exploratory case study comparing four markets. *Applied Ergonomics, Volume 47*, 308-323.
25. Jorien van der Peijl, J. K. (August 2012). Design for risk control: The role of usability engineering in the management of use-related risks. *Journal of Biomedical Informatics, Volume 45,,* 795-812.
26. Lampo, S. (2012). *National MEMS Technology Roadmap, Markets, Applications and Devices School 0f Electrical Engineering.*
27. Lancet. (2011). *India facts, in and India Development gateway.*
28. Liljegren, E. (April 2006). Usability in a medical technology context assessment of methods for usability evaluation of medical equipment. *International Journal of Industrial Ergonomics, Volume 36, Issue 4,,* 345-352.
29. Mark Sorgenfrey, L. M. (2009). *Strategies for market entry: fast moving consumer goods companies in emerging markets.* Aarhus School of Business.
30. MDDI. (2012). MDDI Report Medical Devices Challenges and Opportunities.
31. Medical, P. B. (2012). *India regulatory updates.* Pacific Bridge Medical.
32. Miles S. Ellenby, J. P. (April 2015). The Role of Telemedicine in Pediatric Critical Care. 275-290.
33. Naughton, B. (2007). *The Chinese Economy: Transitions and Growth. Cambridge: MIT Press.*
34. O'Neill, J. (2001). Building Better Global Economic BRICs. Jim O'Neill. 30th November 2001. Global Economics.
35. Peter L. Kolominsky-Rabas, A. D.-B. (August 2015). Technology foresight for medical device development through hybrid simulation. *Technological Forecasting and Social Change, Volume 97*, 105-114.
36. PWC. (2011). *10 minutes on medical Innovation.* PWC.
37. PWC. (2011). *PWC Study Enhancing access to healthcare through innovation- Medical technology in India.* Pricewatercooper.
38. report, U. (2011). *Medical Devices : The UK Industry and its Technology Development:.*
39. Ricafort, K. M. (2011). *Study of influencing factors that lead medical tourists to choose Thailand hospitals as medical tourism destination.* School of Business and Technology,Webster University.
40. Rumbaugh, T. &. (2004). *China: International Trade and WTO Accession. Washington.*
41. Sullivan, F. a. (2013). *Frost and Sullivan Report.* Frost and Sullivan.

42. times, E. (2012). Economic times. pp. 3-4.

43. Vimal Kumar, D. C. (2014). Cross Cultural design of medical device. *ISSN : 2277-419X vol 3. Sr.6*.

44. Wade, R. (2004). overning the Market, Economic Theory and the Role of Government in East Asian Industrialization.

45. WHO. (2011). *1. Addressing Health of the Urban Poor in South-East Asia Region: Challenges and Opportunities.*.

46. WHO. (2012). *WHO Study Local Production and Technology Transfer to Increase Access to Medical Devices.* WHO.

47. Widenmayer, B. L. (2012). *Reverse Innovation :Insights from Western Medical Equipment Manufacturers in China.*

48. Wilson, J. S. (2005). *Assessing the Benefits of Trade Facilitation.*

49. WTO. (2013). *Innovation in medical technologies.* WTO.

50. Young, E. &. (2011). *Ernst & Young - Doing Business in India- A Report.*

51. Zelkha, S. (2004). *Benchmarking of a medical device company's product development process.* Boston University.