Proving Experience Speeds Medical Device Time to Market

Lori E Lucke, *IEEE Member*, Anne Mickelson, David Anderson

Abstract—Experience is important for developing medical devices. This seems like a straightforward statement, yet it has been difficult to prove. In this paper, several medical device projects are compared to demonstrate how experience improves both overall development time and user interface design time. To prove that experience counts, actual data was assessed over a number of development projects. All projects were completed by a single organization. Data was collected over a period of several years. Time to market was measured along several dimensions including complexity, technological invention, and uniqueness of clinical application. Experience can improve time to market by as much as 50% whereas inexperience will slow development. This can be demonstrated even for a portion of the development. The user interface design times were studied in more detail and the effect of experience was similar to the overall product development time improvement.

I. INTRODUCTION

TRANSITIONING research from the lab to a new product is difficult. For medical device design, the development of new products requires interdisciplinary teams that understand the nature of the clinical application as well as the abilities of the technology. Successful development of complex electromechanical medical devices is complicated by the need to work within a regulated environment which requires well defined processes and significant testing to demonstrate the safety and efficacy of the device. In this paper the time it takes to develop a new medical device is studied. Actual data is used to demonstrate that an experienced development team can reduce development time. To further bolster this argument, a particular facet of development, user interface design, is studied in more detail. Again experience shows a reduction in development time for the user interface design.

A number of new product development techniques and metrics have been developed to assist with assessing and improving a particular product development effort. These include improving the communication of cross functional teams [1], using quality metrics to assist with product definition [2], and assessing performance during the development [3]. While these techniques have been shown to improve results for those who use them over those who do not, there is no data to show how the implementation of new processes improves success over time.

Development of new products for the medical field has

been studied in particular. The effects of project planning have been assessed [4] and a number of success factors have been tabulated [5]. The data used in such studies is typically compiled from several companies and provides a snapshot in time of the product development effort across several programs performed by different development teams. Only one or two projects are analyzed at each company. In [4], data was collected across 132 companies but only a single project was considered from each company. In [5], data was collected across 38 companies with at most two projects considered from a single company.

There has been little work done analyzing the effect of experience on the success of a medical device development project. This paper builds off the work from [6] to study the success of several projects completed by the same company. It analyzes the effects of experience on the overall development process and on the user interface design process. An experienced development team, well versed in the design and manufacturing of medical devices, can greatly enhance the success of a commercialization program. A study of actual programs shows how experience can reduce development times.

It is difficult to measure the effect of experience on the success of new product development. In this work, several medical device development programs were studied to determine the role experience plays in improving the time to market for medical devices. Time to market is measured along several dimensions including complexity, technological invention, and uniqueness of clinical application. All designs were completed by the same company. As time progressed, the time to market improved even for complex designs with new technology. Over a ten year period of time, ten significant medical device development projects were executed. All required development of complex electromechanical systems with moderate to high complexity and more than half of those developed were products for new clinical applications or utilized new technology. As the development group acquired experience, it was clear that the development times were improving. Over the 10 year period of this study, development times improved by almost 50% over the predicted development times.

Among the factors that contribute to this effect are the development of experts, the creation of design frameworks, and the optimization of processes which improve product development times while reducing project and regulatory

The authors are with Minnetronix, Inc, 1635 Energy Park Dr, St. Paul, MN 55108, (email lelucke@minnetronix.com, danderson@ minnetronix .com, afmickelson@minnetronix.com).

risk. Experts with specific experience in systems engineering, program management, electromagnetic compatibility, manufacturability, and usability along with expertise in electronics, mechanical and software design can significantly reduce design times. Design frameworks central to medical devices such as blood, fluid pumps, and sensor interfaces, are necessary for rapid development. Processes including project planning and tracking, requirements management, configuration management, risk analysis, and manufacturing design transfer are essential for streamlining development as well as ensuring support for regulatory submissions and audits.

In particular, this paper further delves into a specific part of the medical device development - the user-centered design process. The design of safe and usable medical devices is accomplished by following a structured process. Over a twelve year period, the user-centered design process is analyzed to show how continuous process improvements affect the time to complete the user interface design on eight separate projects. With experience, this subset of the development program shows equivalent time improvements to the overall product development effort. After ten years and with the reasonable assumption that usability constitutes 20% of the product development effort, there is clear evidence that the actual time to complete the user interface design is improving by 50% over the predicted completion time.

I. PREVIOUS WORK

In [5], several new medical device product development efforts across many companies were studied in an attempt to determine what makes a product development effort successful. Their results are summarized in Table 1.

Development Factors	More Success	Less Success	All Success
Technical Complexity	0.29	0.30	0.35
Customer Involvement	0.27	0.21	0.31
Financial Analysis	0.27	0.36	0.34
NPD Dissemination	0.39	0.46	0.32

Table 1: New medical device product development factors and their correlation with success [5].
.

It is clear from Table 1 that technical complexity, customer involvement, financial analysis tools, and communication (NPD dissemination) play an important part in any particular project development. Whether the development was more or less successful, or considering the overall success rate, in every case, these factors are strongly correlated with success. The data in this study was collected over a short period of time and across many companies with no more than two projects studied within any company. It provides a useful comparison of methods that can lead to success across many simultaneous product development projects.

There has been little work studying product development improvements over time. In [5], there is no mention of team experience as it applies to the success of a project. It is difficult to collect product development data over long time periods and within a single development group to show the effects of experience on product development. In this paper, data was collected over a period of several years to show the ability of experience to improve product development results.

II. ACTUAL DATA

It has been challenging to demonstrate the effect of experience on medical device development, which has been anecdotally known for some time, in a quantitative manner. Collecting data over time requires access to a number of projects over a number of years. In this study, a single organization was studied and a number of new product development efforts were analyzed. The study only considered medical device designs that contained electromechanical systems with embedded software. All of the devices were external; no implantable devices were included in this study. All of the devices were successfully released to production. A number of different clinical applications were included as well as different levels of technical complexity. The results of this study quantify the significant benefit of organizational experience in reducing time to market.

Clinic App	Yrs of Exp	Des Com	New Clin App	New Tech	Act Time	Exp Dev Time
Cardio	1	3	1	1.5	5	4.5
Blood Anal	2	2	1	1	2.5	2
Cardio	4	2	1.5	1	3	3
Drug Del	5	3	1	1	4	3
Cardio	6	3	1	1.5	5	4.5
Blood Anal	7	2	1	1	2	2
Cardio	9	3	1	1.5	4	4.5
Cardio	10	3	1	1	1.5	3
Arterial	11	2	1.5	1	1	3
Wound Care	11	1	1.5	1.5	1.5	2.25

Table 2: New product development data collected from a single company across a number of projects

The data collected across several projects is shown in Table 2. The projects were classified according to: the number of years of experience for the development organization, the design complexity, whether the device was a new clinical application, and whether significant new technology was implemented. The design complexity was ranked from 1-3 with 3 being the most complex. Clinical application was weighted such that a weight of 1.5 indicated a new clinical application. New technology was weighted similarly. To determine the effect of experience, the expected development time was calculated as follows.

$$\text{Expected Development Time} = \text{Design Complexity} \times \text{New Clinical Application} \times \text{New Technology}$$

In effect, the Expected Development Time was related to Design Complexity and increased by 50% if a new clinical application was developed or new technology was utilized during the development. The actual time to market was also recorded.
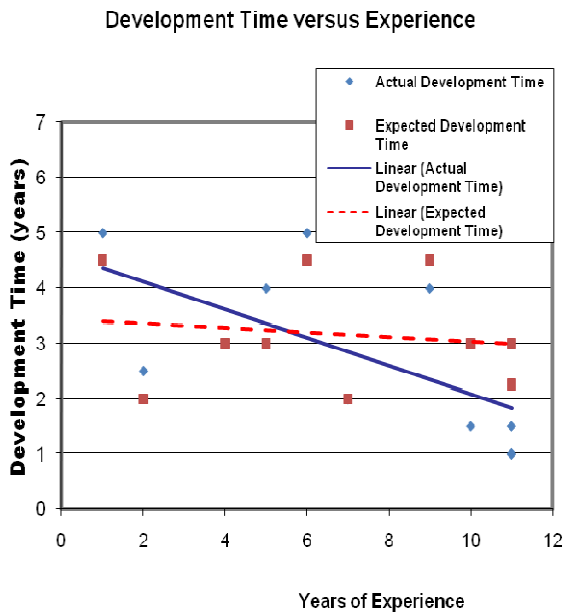

Figure 1: The effect of experience on medical device development times.

To demonstrate the effect of experience, the actual time to market was compared to the expected development time in Figure 1. It is clear from the figure that as experience increased, the actual development time improved. After about 5 years, the actual development times became better than the expected development times. This shows that experience does improve development times whereas inexperience can actually increase development times.

In Figure 2, the improvement in development time is even more apparent. Here the difference in the actual and expected development times are plotted versus experience. The correlation between experience and the difference in actual and expected development times is 0.82. Clearly experience plays an important role in development times.
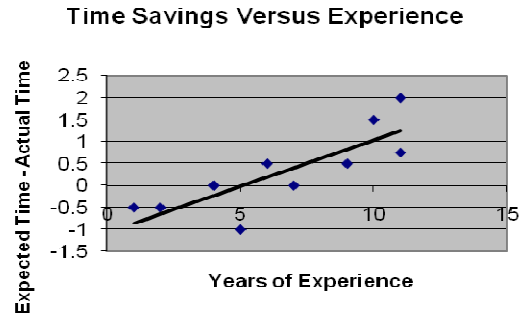

Figure 2: Development time savings in years compared to development team experience.

III. USABILITY AS AN EXAMPLE

Over time a mature development organization develops experts, design frameworks and efficient processes. These all contribute to the efficiency of the development team while reducing project and regulatory risk. As an example of how process improvements contribute to experience, one particular process was studied in more detail. Usability is essential to successful medical device design.
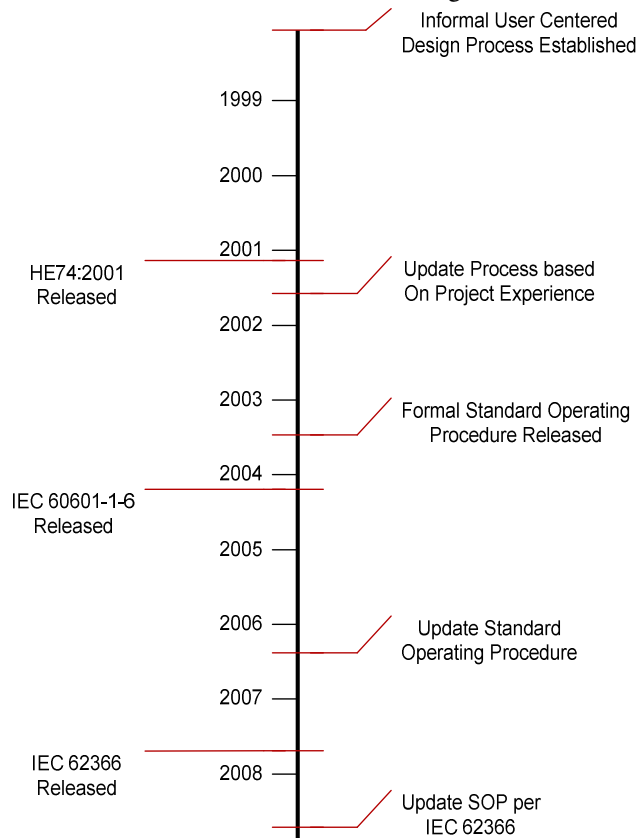

Figure 3. User-centered design process improvements over time

A young organization, even with experienced designers, will have immature processes. As time progresses the process of user interface design will mature. A timeline of the user-centered design process improvements, partially driven by improving standards, is shown in Figure 3. Here the standards are shown on the left while the process definition and improvements over time are shown on the right.

Collecting design time data across projects for the user-centered design portion of the project shows that the user interface design time also improved with experience. The data is shown in Table 3. The projects were classified according to: the number of years of experience for the development organization, the user interface complexity, whether the device was a new clinical application, and whether significant new technology was implemented. The user interface design complexity was ranked from 1-5 with 5 being the most complex. Clinical application was weighted such that a weight of 1.5 indicated a new clinical application. New technology was weighted similarly. To determine the effect of experience, the expected development time was calculated as follows.

Expected Development Time = User Interface Design Complexity x New Clinical Application x New Technology x 0.2

The user interface design time is expected to take from 10-25% of the total development time [7]. Here a factor of 20% was used.

Clinical Appl	Yrs of Exp	UI Comp	New Clin App	New Tech	Act UI Time	Exp UI Time
Blood Anal	1	2	1	1	0.4	0.4
Cardio	1	5	1	1.5	2.5	1.5
Cardio	5	4	1	1.5	0.6	1.2
Blood Anal	6	2	1	1	0.4	0.4
Neurol	7	1	1.5	1	0.3	0.3
Cardio	8	4	1	1.5	1.5	1.2
Cardio	10	4	1.5	1.5	1.0	1.8
Cancer	12	3	1	1.5	0.4	0.9

Table 3: User interface development data collected from a single company across a number of projects

The effect of experience even on a smaller portion of the design is quite clear. In Figure 4, the actual user interface design time improves with experience similarly to the overall project design time.

IV. CONCLUSION

It is difficult to measure the effect of experience on the success of new product development. In this work, several medical device development programs were studied to determine the role experience plays in improving the time to market for medical devices. As experience accumulated, the time to market improved even for complex designs with new technology. As a subset of the overall product development, the user interface design time also improved. Improvements of up to 50% were measured.

The ability of a development team to improve over time is an indication that experience is important. A more detailed analysis of those factors that affect experience would be beneficial as it could be used as a means to more quickly improve development teams. Although this paper anecdotally studied the process improvements for usability design, it is not yet clear how to apply these improvements to shorten the time it takes to improve a development team. Future study should focus on these factors.
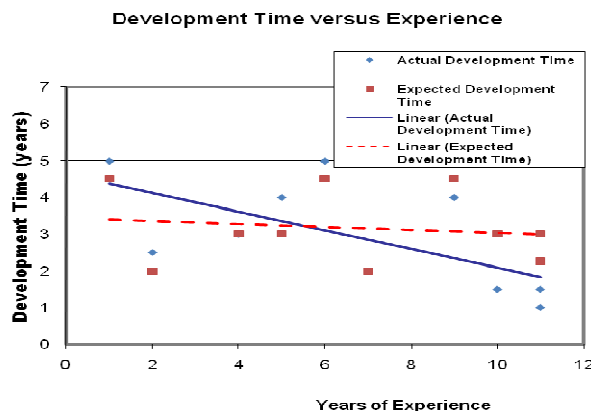

Figure 4: The effect of experience on user interface development times.

REFERENCES

[1] A, Donnellon, "Crossfunctional teams in product development: Accommodating the structure to theprocess" *Journal of Product Innovation Management*, Sept. 2003.

[2] K. Ashihara, et.al., "Application of quality function deployment for new business R&D strategy development", ASME IMECE, Nov. 2005

[3] M. Chiesa, et. al., "Measuring performance in new product development projects: A case study in the aerospace industry", *Project Management Journal*, Dec. 2007.

[4] S. Salomo, et.al., "NPD planning activities and innovation performance: The mediating role of process management and the moderating effect of product innovativeness", *Journal of Product Innovation Management*, July 2007.

[5] A, Brown, et.al.,"A survey of success factors in new product development in the medical devices industry", IEEE IEMC, June 2008.

[6] L.E. Lucke, David Anderson, Dirk Smith, "Harnessing experience for efficient medical device product development", *ASME Design of Medical Devices*, April 2009.

[7] Eric Schaffer, *Institutionalization of Usability: A Step-by-Step Guide*, Addison-Wesley, 2004.