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DESIGNING FOR VALUE, USING ANALYTICS OF MEDICAL DEVICE FIELD DATA

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1. Introduction

'Value' embodies the objectives of a process or system. During the design process, the desirability of forecasted decision outcomes are interpreted according to some model of Value. Often, Value models are communicated implicitly through dialogue with stakeholders during task clarification, and embedded within design specifications. However, the *explicit, quantitative* models of Value are of growing interest, and are being applied to the optimisation of many systems and processes, including the design process itself [Siyam 2012], [McManus 2005]. As a result of Value movements emerging in different fields, there is a growing demand for methods to forecast decision outcomes. This is certainly the case with medical device design, and the Healthcare Value movement.

In Healthcare, the recent focus on Value has been heralded as "the end of the quality movement" [Brook 2010]. This movement is driven by mounting pressures to better manage the complexity of healthcare systems, and distribute scarce resources between vastly diverse services. The emphasis is on aligning decisionmaking with the interests of the patient– similar to consideration of 'the voice of the customer' in quality function deployment. Developments in this area strive towards a better understanding of Healthcare Value and how it is achieved through various subsystems, including an organisation's 'Medical Technological Infrastructure' (MTI).

MTI consists of Medical devices, and those factors within the healthcare system, which have an impact on their performance throughout their life. It is a system of 'Value Entities' [Chase 2000] – that produce various outcomes. It is hypothesised that structured analyses of outcome field data, can yield new insights, that may be used to support design decisions. This paper outlines a framework which can be used to achieve this, by forecasting design impact, as it pertains to Value. A study of infusion devices is presented as an example. Data was provided by GSTFT (Guy's & St. Thomas' NHS Foundation Trust - London), where the second author leads the 'Medical Physics' Department.

2. Motivation and background

2.1 To improve forecasting and interpretation of design decision impact

The output of the engineering design process may be considered to be plans for product or system, delivered to the customer. However, the ultimate objective is the desired impact that the product or system delivers throughout its life, *after* this transaction. As discussed in this section, and proposed in section 3, the relative desirability of dimensions of impact (or 'Value attributes' [Chase 2000]) may be embodied in a Value model. If potential design activities can be mapped to an estimable impact using predictive models, then design decisions may be modelled to 'deliver' a net Value gain. In Healthcare Value, Value gains are estimated as a basis for productive competition between alternatives [Porter

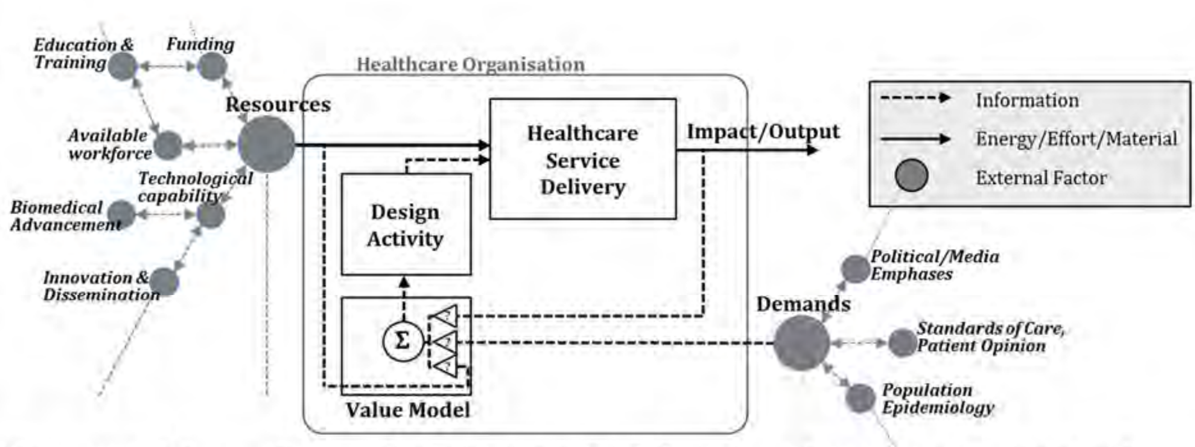
2006] - In the design process, competition between alternative solution concepts, proposals or parameter-levels benefit from this same treatment. Therefore it is attractive to pursue a more detailed understanding of what Healthcare Value is, and how a device may be modelled generate it throughout its life. This paper exemplifies how such a Value-based design support may be developed.

2.2 To represent the perspectives of stakeholders appropriately

Porter, a major contributor to the Healthcare Value movement, highlights the need to “align competition with the interests of the patient” [Porter 2006]. This is emphasised because of the overwhelming pressure exerted by financial drivers (e.g. in the US healthcare system, which is undergoing a costly transformation). Under Porter’s model, Value is defined as *patient outcomes/cost,* but in numerous health services internationally, efforts are being made to understand which ‘patient outcomes’ should be measured. For example, at KHP (‘King’s Health Partners’- an academic health science centre, which includes GSTFT) a series of workshops and discussions were held with 3 patient groups (Endocarditis, Hepatitis B and Stroke patients [KHP 2012]), in order to identify *which* outcomes matter to patients. Lists of outcomes only contribute to Value models at a ‘construct’ level (see section 3.2), but usefully, some of these outcomes relate to device performance – e.g. ‘*occurrence of infection’, ‘length of stay’* and *‘time to treatment’*. Therefore forecasts of how design produces such outcomes, could help us incorporate patient- (and similarly, other stakeholder-) perspectives in design decisions, alongside more obvious outcomes, which relate to functional performance.

2.3 To incorporate stakeholder perspectives with strategic, system-level considerations

Although the intended operational (i.e. physical, clinical, patient-facing) environment of a medical device is relatively static, circumstances at the system level are always in flux – this is illustrated in Figure 1. Design opportunities arise due to changing circumstances: for example, decreasing budgets can incentivise the reduction of medical device life cycle costs. The strategic importance of these factors must be considered in the context of how the system is currently coping with variations in need, (*e.g. due to an ageing population* [Takasaki 2012]*, or increased obesity rates*) which determine the design activity required. As illustrated below, information about these external actors can inform a Value Model. A rigorous treatment of Value, which is responsive to these factors has the potential to inform design activity on a more strategic level.



This conceptual diagram illustrates how design activity (including a range of processes: e.g. organisational decision-making and device design) is driven by design opportunities, which should ideally factor considerations of healthcare demand, the resources and capabilities of the healthcare system, and some evaluation of the current level of output. Each of these factors may be incorporated into a model of Value. Therefore Value may be used to integrate design and systems thinking.

Figure 1. The integration of external factors, in healthcare system design

2.4 Value as a means of aligning the interests of device designers and MTI designers

Although design is both a powerful and controllable factor in determining the Value derived from a medical device, the successful deployment of the device and its features depends on a whole host of factors. When the manufactured product arrives with the purchasing Healthcare organisation, it is incorporated into the MTI. Other than devices themselves, MTI consists of quality systems, allocation and access systems, transport arrangements, repair and maintenance procedures, user-training processes, user engagement etc. All of these things exist to deploy a device's core functionality, and ultimately to deliver Value to the patient. This infrastructure includes users, technicians, auxiliary devices, and often central EM ('Equipment Management', or 'Clinical Engineering') functions. Some aspects of MTI are receiving more and more attention from the design community– e.g. the performance of the device and operator in combination is the subject of human-factors research. However, there is potential to expose more design improvement opportunities, by facilitating engagement with the other, less well understood mechanisms of device impact.

It is proposed that the medical device design process may benefit from increased information flows between device designers and EM functions within the MTI. Other industries, such as the aerospace [Flager 2007] enjoy a relatively free flow of information between design and deployment functions, mainly because of the degree of vertical integration within firms in these industries. In these fields, the potential for collaborative innovation has been noted [Sharma 2005] and is being exploited, to track the performance of existing designs in the field [Rouse 2002]. Unfortunately, in many aspects of medical device design there is a chasm between the Designer/Manufacturer and EM functions. Rakitin and others, for example, have concluded that, in order to improve collaborations, "device manufacturers need to share more information about design validation," and staff need to "share specific knowledge they have… about how medical devices are used" [Rakitin 2009]. For this to be achieved, it is important to address the need to 'create a common language and then collaborate and share information'. It is proposed that Value frameworks can fulfil this role, and align the design activities of both the device designer and EM (i.e. MTI Designers), with the interests of the patient and healthcare organisation as a whole. This is particularly timely, given the movement towards the estimation and pursuit of Value in Healthcare [Brook 2010]. For the designer, the advantages of this level of collaboration include the enhanced design feedback and the ability to demonstrate Value propositions on more levels. This is reflected in Figure 1, where those 'Design activities' shown as internal to the healthcare system include both device- and MTI- designers.

The main objective of this paper, is to present a framework for forecasting the impact of design decisions on outcomes delivered by a medical device throughout its operational life, and for interpreting this impact in terms of Value. A specific example is given in 4.2, which demonstrates the capability to forecast performance based on medical device field data. It is hoped that the principles demonstrated will be developed in further work, and eventually provide more design information.

3. Value delivered by a medical device in MTI

3.1 Overview of framework for Value-based decision making

The Value framework proposed here (see Figure 2) adopts terms from Chase's work on Value in product development, where he describes a framework for the 'Dimensions of Value' [Chase 2000]. Within this framework, the 'analysis levels' of Value are said to be *per-spective, entity*, and *attribute*. Value perspective is the dimension that describes to whom Value is delivered (e.g. the individual/ organisation/ population etc). Under Chase's framework, the Value entity is anything that can be modelled to produce Value- that is, a system, process or information. The Value entities considered in this paper, is the Medical device design features. Value attributes are those outcomes that embody the impact of the entity. These might, for example, include cost, failure rate and performance. The conceptual framework in Figure 2, which incorporates these concepts, illustrates how Value metrics may be developed, and used in design and decision-making. Challenges in Value based analysis and decision making can be described with reference to this diagram.

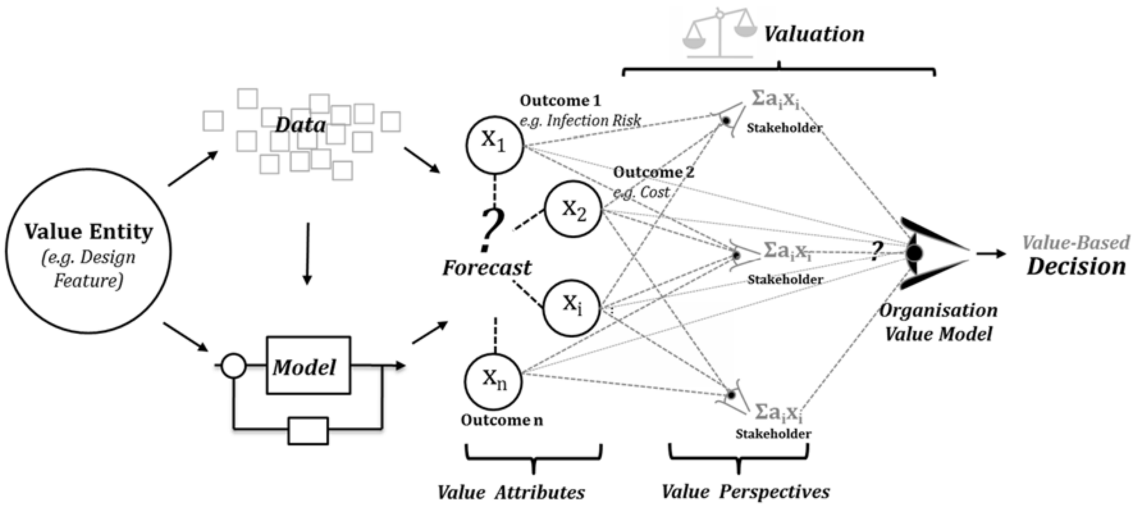


Figure 2. Proposed conceptual framework for Value analytics

The impact of a design decision may be forecasted, based on an understanding of the Value entity's behaviour (in this case, a medical device design feature), which is embodied in a model. Practically, models are imperfect; built heuristically and held informally. Nonethless they encapsulate what we know about the Value entity. Models may be informed by observations - that is, the data surrounding the Value entity. The combination of models and data, can enable forecasts of the likely design decision outcomes (e.g. through predictive analytics – see 4.1), in terms of Value attributes and their associated metrics. Therefore forecasts are approximations to *objective* knowledge of the behaviour of the Value entity. Everything that follows forecasting in the process is *subjective*. The multiple criteria (or Value attributes), may then each be subject to valuation by multiple objectives. Depending on the method for consensus, a unitary leader, or a number of Value perspectives may be used to determine a Value interpretation. Subsequent sections explore how Value from MTI may be defined and analysed.

3.2 Defining Value

The definition of value is not trivial, and it can have a profund impact on the design activities that the framework in Figure 2 is applied to. Semantically, Value is generally defined as some measure of worth or 'goodness', but the nature of this measure may be considered on several levels, that vary in their level of abstraction, from the most abstract 'Value concept' level definition, to the application-specific 'Value construct' level definition, and finally to the system/process-specific 'Value model' level definition. The concept of Value and its significance, is the subject of theory in the field of Axiology, which seek to understand/propose respectively, which things are good, and how good they are. As the concept is applied to a context (in this case, device design and MTI), the definition of Value becomes a matter of which *attributes* might constitute Value; thus the *construct* of Value is defined. Finally the relative importance/'goodness' of attributes in the Value construct may be defined in a quantitative Value *model* which can be used with the framework in Figure 1, to inform decisions.
In much of the literature on existing decision-support frameworks, definitions of Value (or analogs) are assumed, or not made explicit - even in lean applications, which are fundamentally rooted in the concept of Value. As with quality-based literature, lean methodologies are mostly applied to specific processes and it has been found that, in healthcare "while lean theory emphasises a holistic view, most cases report narrower technical applications with limited organisational reach" [Mazzocato 2010]. Similarly Porter et al. [2006], argue that the 'Value criteria' used are often inappropriate for healthcare- partly because of their inability to capture patient outcomes. In order to develop a construct-level Value definition for MTI, Value attributes expressed implicitly or explicitly in EM literature were collated. Further consultation with EM staff at the collaborating organisation (GSTFT), was used to determine other Value attributes. The resulting Value construct is represented as a hierarchy. The top levels of this hierarchy are included in Table 1, along with examples of EM literature, which indicates how various events and processes in a devices life, impact these attributes.

With a Value construct defined, the next logical step is to define Value at the model level, by assigning weightings to each Value attribute in the hierarchy in Table 1. As shown in Figure 2, this process is not trivial, and potentially involves the combination of multiple Value perspectives. Various methodologies exist to derive quantitative measures of Value perspectives, by 'commensurating' (quantifying the trade-offs between-) Value attributes. The 'Commensuration Method' of each methodology, describes how Value weightings are actually assigned. Many of these methodologies ultimately involve the direct assignment of weightings to attributes (or to the magnitude of preference curves). Therefore these are subject to various forms of response bias. Alternatively the ranking of value attributes ranking is more repeatable, but cannot be easily or adequately related to relative attribute weightings. Some methodologies, however, exploit the repeatability of rankings, and derive weightings from them – such was the methos used by [Zhang 2011]. The AHP ('analytic hierarchy process') is a promising Value perspective survey. The premise of AHP is that "direct comparisons are necessary to establish measurements for intangible properties that have no scales of measurement" [Saaty 1980]: Thus series' of pairwise comparisons are converted into numerical Value weightings.
The investigation of how Value persepctives are surveyed using methodologies like AHP, and how these perspectives may be used (or not used, if a 'leadership' model is adopted) to define an organisational-level Value perspective, is being expanded on in concurrent work. The purpose of this paper is to introduce the Value framework – as such, in this paper, Value definition in MTI is not investigated in depth, beyond the construct level in Table 1. Even this relatively coarse Value definition is instructive in focusing enquiry on the next question – *how does a medical device deliver each of these Value attributes throughout its life?*

3.3 Modelling Value delivered throughout the operational life of a medical device

The impact of a medical device can be said to be defined by events throughout its life; interactions between the device and users, patients, and its operational environment. The Value that the device delivers in its life, is the cumulative impact of events/processes in its life, evaluated according to the attributes in Table 1. The events of a device's service life are shown in Figure 3. Table 1 shows examples of some of the literature that indicates how each of these events delivers Value.

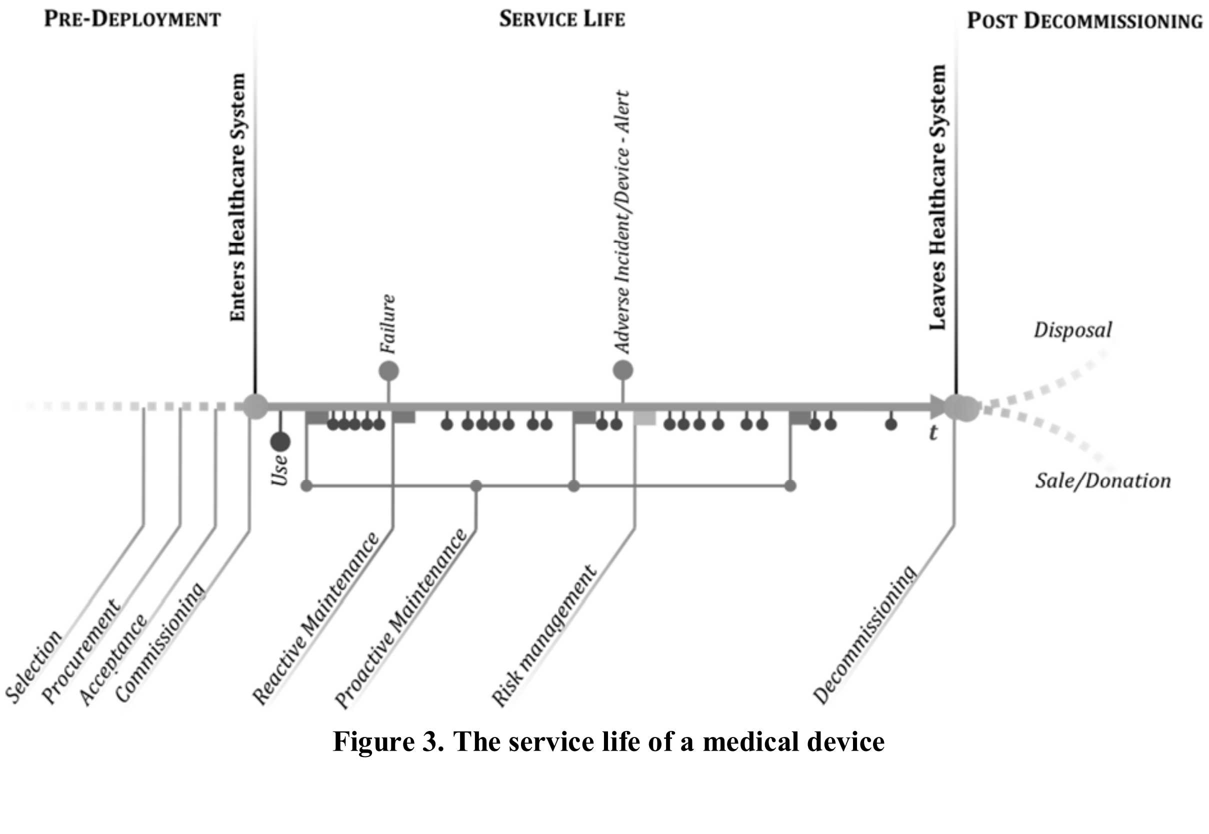


Figure 3. The service life of a medical device

It is important to note that Table 1 only shows which events processes deliver Value *directly*. It does not embody interactions between these events. For example, proactive maintenance does not deliver benefit to a patient directly - but it is intended to reduce the frequency of adverse incidents, and therefore increase ‘benefit’ in the form of device-uptime and availability. Similarly, design output has no direct impact on Value, yet it is the single most powerful factor in determining the Value delivered by all subsequent events. The network of relationships between these events and processes is the subject of ‘predictive analytics’. For a device designer, it is important to forecast: *how would each of the available design options affect the delivery of Value throughout the device’s life?* As demonstrated in Table 1, goes beyond the focus of medical device regulations (Medical device directive [EC 1993]) on ‘essential performance’ (sufficient Value through functional benefit) and ‘basic safety’ (sufficient Value through reduced harm), and can result in better informed, optimised design decisions.

Table 1. Direct impact of device service life-events on Value attribute delivery

Life Event/Process	*Examples from literature, showing direct impact on Value attributes…*					
	VALUE					
	BENEFIT +		HARM -		COST -	
	FUNCTIONAL (outcomes)	AESTHETIC (comfort)	TO PATIENT	TO USER/EM	FINANCIAL	TIME
PRE-DEPLOYMENT						
Needs identification & Procurement					[Ventola 2008]	[Ventola 2008]
Acceptance *(verification testing, labelling etc.)*					[Rocha 2004]	[Rocha 2004]
SERVICE LIFE						
Use	[EC 1993]	[Pezzin 2004]			[Luce 1990]	[Luce 1990]
Observation *(Monitoring/Checking)*					[Rocha 2004]	[Rocha 2004]
Adverse Incident *(MTI Failure)*	[Ward 2004]	[Clarkson 2004]	[Clarkson 2004]	[Clarkson 2004]	[Ward 2004]	[Ward 2004]
Reactive Maintenance					[Rocha 2004]	[Rocha 2004]
Proactive Maintenance					[Rocha 2004]	[Rocha 2004]
Decommissioning					[Gatrad 2007]	[Gatrad 2007]
POST DECOMMISSIONING						
Re-purposing *(Transfer, sale)*					[Gatrad 2007]	[Gatrad 2007]
Disposal					[Ongondo 2011]	[Ongondo2011]

3.4 The network effect of MTI factors

In order to analyse the network of relationships that exist within MTI, and ultimately produce Value, it is necessary to describe the factors involved. The row headings in Table 1 give an overview of the events/processes in a device’s life, but it is *attributes* of these processes that interact as factors. For example, rather than considering ‘proactive maintenance’ as a factor in itself, it may be further described in terms of variables that characterise factors: i.e. *frequency/interval, type*, etc. Therefore a significantly more complex network of factors, may be described.

This paper describes the framework that underlies a wider programme of work, exploring the extent to which predictive analytics may be used to understand how MTI produces Value. The scope of *this* paper does not extend to consider all factors involved. The relationship explored in the case study in 4.2, is between device design (design features were not resolved as individual basis, but ‘whole products’ were evaluated) and device failure rate. This simple relationship was selected based on an assessment of the ‘controllability’ and ‘observability’ of the factors involved. By analogy with systems theory [Kalman 1963], the most attractive relationships for analysis, are those which are sensitive to a control input (i.e. design) and generate enough data that the Value produced can be observed.

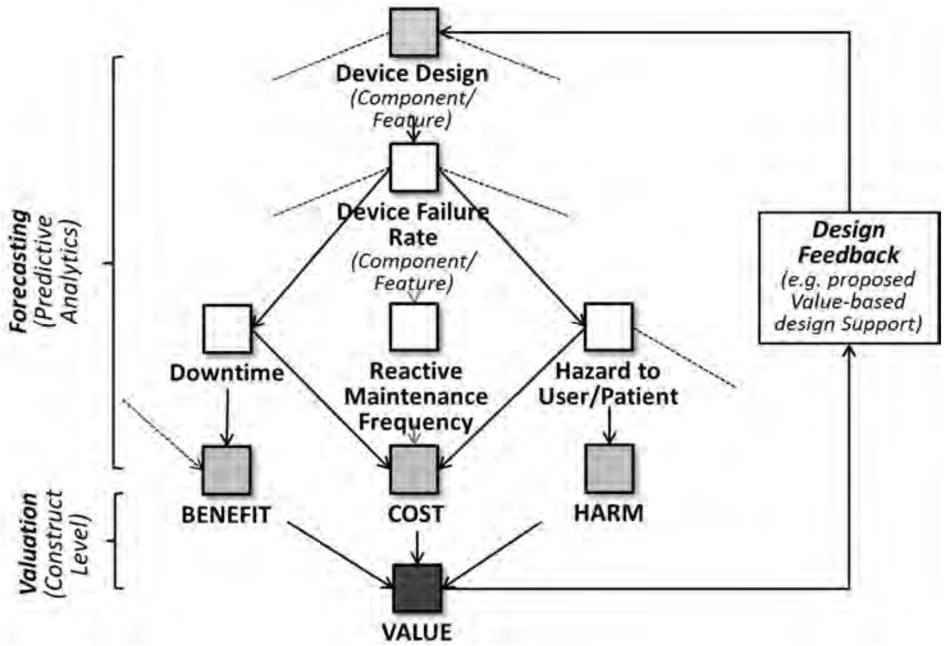


Figure 4. Selected MTI factors involved in case study: *"Design for Value: through Reliability"*

4. How can the Value delivered by a device be estimated? Forecasting Value

As illustrated in Figure 2, data and models surrounding MTI factors are the basis for forecasting design or decision impact. Often in practice, these models are often built heuristically and held informally. However, the Value implications of the decisions that these models inform, and the complexity and volume of relationships to consider, mean that there is a motivation to make models explicit and analytical. While this motivation increases, the abundance of data surrounding MTI and other healthcare subsystems creates a corresponding opportunity. This opportunity is further increased, by the growing body of methods available from the field of 'Predictive Analytics' [Koh 2011].

4.1 Predictive analytics of MTI

'Predictive Analytics' is a blanket term, used to describe the growing body of tools and techniques, which may be used to carry out *experience based forecasting*, through the quantitative analysis of historical data. These techniques may be used to exploit (sometimes vast amounts of) data, to generate models, which may be descriptive (e.g. in assessing past performance of devices), predictive (e.g. in forecasting device performance), or decision models, which apply predictive models with respect to changes in control variables. The proposed Value framework (Figure 2) requires decision models, to forecast the Value of the *marginal* impact of design alternatives. Our ability to forecast, is of course limited by the abundance and reliability of data, but if appropriate analysis methods are used, the best possible forecasts, and therefore the best possible decisions can be made. Since we can define MTI Value to an extent, (on a coarse, construct level – Table 1) some attributes of interest have already been determined. As indicated in Figure 4, these have been further narrowed down, through the identification of a relationship of interest for a case study; *Design for Value, though Reliability*.

4.2 Case study: Design for Value, through Reliability

As described in 3.4, this subject was chosen on the basis of the observability and controllability of the factors involved – a strong factor in this decision was the relative accessibility of over 150,000 work records for analysis (Kindly provided by GSTFT) at the time of writing this paper, which could be analysed to estimate device reliability. This simple case study, demonstrates how predictive analytics methods may be used to describe design performance in terms of reliability. The subject of this case study is the infusion device referred to as 'Pump A', which has been specifically marketed for reliability. Survival data for this and two other device models were analysed and presented below.

NB/. These models were selected for analysis because of similarities in the way they are used (which means, for example, that in the absence of harm data at this time, the forecasted 'harm' induced by each failure could be considered to be similar). Unfortunately data was not available, to compare the performance of sucessive design iterations within ranges of models.

4.2.1 Overview of method and results

165528 work records were extracted from GSTFT's medical devices database, where job histories (both performed by an in-house team, and by external service providers) are listed against individual assets, which may be categorised by product model etc. Each job record contains a cost summary and downtime measurement, as well as a code to describe the job type, and various other fields, including a free text field describing the actions carried our within the job. In a data mining process, a sequence of filters were used to restructure the data according to variables of interest. For example a Boolean variable '*Device Failure Indicated'* would be inferred based on a look up table, applied to the *job codes* field: this variable would be set to 'true' for a work record if the job code was 'repair'; 'false' if the job code indicated so ('Acceptance', or 'Upgrade', for example); Where the job code was ambiguous – e.g. 'Check/Service', successively less reliable fields would be used (e.g. *job request*, which is completed by a non-specialist requestor). Where no reasonable inference could be made, *Device Failure Indicated* would be left as 'Unknown'. The data mining algorithm used will be developed further, and applied to data from other oganisations, and so it is yet to be validated in its entirety. Nonetheless it can be used in its current form for this simple case study.

In order to analyse the re-structured data to give an indication of device reliability, weibull survival curves were generated for a selection of infusion device models. The goodness of fit of the assumption that variation device failure-rate over time, could be modelled using the Weibull distribution, was checked, according to reccommendations by [Taghipour 2010]. Notably, dependency on *time-since-last-maintainted* is represented in Figure 5: Subsequent iterations will include device age as a variable. Later iterations of this study will also employ a Bayesian learning approach similar to that described by [Abramovici 2011], as a means of quantifying and handling model uncertainty.

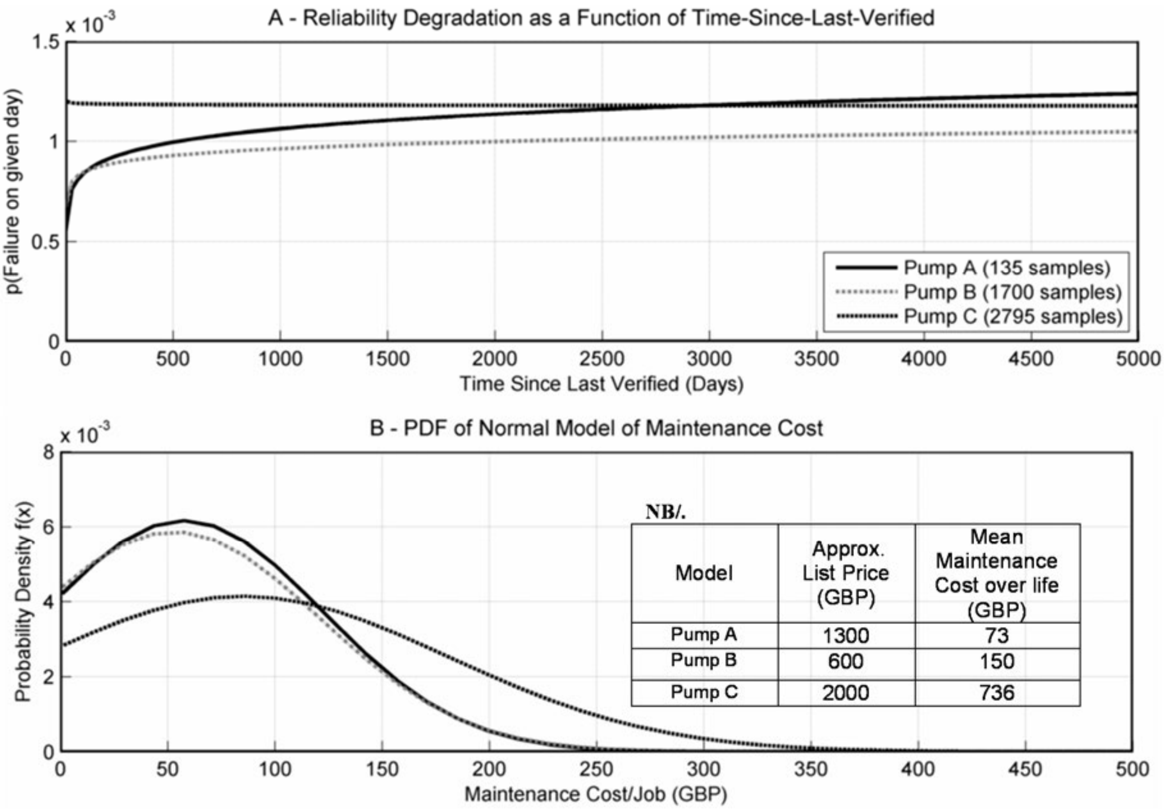


Figure 5. Results of field data analysis

4.2.2 Discussion and evaluation

Based on survival curves in Figure 5a, the Pump A's reliability is greater than the other models during the first few weeks after it is released by EM, but as indicated by the gradient of pump A's survival curve, this model's likelihood of of failure increases more rapidly, once it is in the field, compared to the other models. This indicates a relatively low robustness, contrary to marketing claims. Although this indication is surprising at first, it is interesting to note that some months after this analysis was performed, pump A had it's CE mark removed, on grounds of unreliability. Even though the forecasts above, might be distorted by differing usage patterns at GSTFT, of the device models considered (this case analysis did not normalise for usage patterns).

In terms of Value implications; one thing is very clear. From model to model, the cost implications of maintenance vary vastly. Figure 5b gives some indication of which model tends to cost more in maintenance; Pumps A and B have similar cost distributions. However, Pump A has a significantly lower average life cost than the other models. Again, there are other factors at play in this relationship – namely the differing prices of service contracts associated with each of the models above.

Despite the shortcomings described above, and using a coarse, construct-level Value definition , this simple preliminary study shows the potential of MTI predictive analytics to generate forecasting models that can drive decision-making. Further work in this predictive analytics framework will include, the parameterisation of device age in failure forecasts, the generation of downtime predictions and other metrics, and the categorisation of failures according to failure mode. It is also thought that, with the imminent availability of clinical coding data, usage rates can be factored into these analytics.

5. Conclusions and prognosis

The Value framework described in this paper has many applications that relate to decision-making in MTI. By considering medical device design alongside MTI activities, there is potential for providing useful design feedback. Although the simple case study described here is an early embodiment of MTI analytics that are being developed as part of a wider programme of work, it demonstrates how predictive analytics might be used, to forecast the delivery of Value through MTI and device design. As a more complete picture of MTI relationships is built up, through the accumulation of more data from GSTFT and beyond, and as the predictive analytics methods employed are developed, this methodology will be more effective in exposing design opportunities. These design opportunities may, for example, be identified by strategically examining Value delivery by device designs within and across markets, and identifying key areas in which to increase Value gains, or minimise Value losses. As further research is conducted into Healthcare Value and how it is delivered, it will be possible to integrate the knowledge that it embodies, within the design processes. For example, the combination of this Value framework with 'the house of quality' from quality function deployment, may better represent relationships between design parameters and healthcare Value.

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