Automated Life Cycle Processing for Complex Medical Imaging Devices

Rafael B. Fricks, Duke University
Kishor S. Trivedi, PhD, Duke University

Key Words: R&M applications in health care, life data analysis, mean cumulative function, non-parametric methods

SUMMARY & CONCLUSIONS

Medical imaging systems from major modalities such as Magnetic Resonance Imaging or X-Ray Computed Tomography are complex devices subject to various types of maintenance. Medical device companies that develop these systems often monitor and maintain systems sold throughout their potentially decades-long design lives, recording a variety of maintenance operations that occur in practice. In order to interpret such massive repair record volumes collected over hundreds of distinct product lines, we present a data processing method developed for compiling maintenance histories of MRI and CT scanners. We then use the outputs of this program to compute a common non-parametric estimate, the mean cumulative function. Results are presented from active in vivo imaging product lines with identifying information omitted. Finally, key insights from the produced MCFs preface a discussion on the methods as well as future directions.

1 INTRODUCTION

Modern medical scanners for diagnostic imaging are complex devices [1] with intricate maintenance histories. A typical system may have thousands of parts subject to regular radiation, heat stress, high electrical current, or mechanical wear. To maintain image quality up to physician standards, several types of reactive service, preventative maintenance, and scheduled maintenance are interweaved and provided both proactively and reactively. Often these actions occur concurrently as major manufacturers balance support-on-demand versus minimizing site visits. Consequently, the observed time until replacement often differs from theoretical lifetime estimates or stated maintenance schedules. Real systems are also subject to imperfect maintenance and process or production changes with impacts on component lifetimes [2]. Supporting the devices through decades-long product life cycles generates significant quantities of data. The vast data collected contains observations on component lifetimes that may deviate from design expectations due to a combination of the various above factors. In contrast, classical presentations of reliability and maintainability studies based on empirical evidence often show system lifetimes as time-series plots with few distinguishable events, coarse-grain system statuses, and measured lifetime intervals [2-5]. Lifetimes are often estimated for individual components, or a limited test sample which may not represent the variety of use conditions [5]. In practice a single major company may collect data on thousands of units in operation, generating thousands of records each, with various fields of information attributed to each repair report. The growing size of readily collected information on devices in service is not unique to the medical industry. Scaling to data on products in use and the variety of use factors present an insurmountable challenge to manually processing system histories as may be feasible under volume-limited testing conditions or in classic examples.

We present a program produced to automate system history compilation tasks such as interval calculations requiring the cross-referencing of many large data sets. Additionally, our automated method includes provisions for retaining multiple fields and classes of data, or selective omission, without necessitating a loss of information. The composed system histories are stored as distinct objects with several attributes and events in our programming paradigm, opening many avenues for subsequent analysis relevant to improving maintainability.

The methods are demonstrated with examples from two available product lines, in two major imaging modalities. For confidentiality purposes the exact models or precise size of install base and associated repair reports are not specified. The product lines demonstrated are examples of specific 1.5T Magnetic Resonance and single-source X-Ray Computed Tomography models. Both lines have had more than 300 units in operation for more than 3 years in the U.S., and are in use internationally. We demonstrate the use of this program in computing a variant of non-parametric estimates of the mean cumulative function (MCF) for repairable medical imaging systems in these product lines. MCF imposes few assumptions in analyzing recurrent repair events [5], ideal for automation when complex device histories may violate common assumptions imposed by other models. This approach to analyzing medical devices has often been used at the system level [6-8]. We decompose the system histories on a component basis, and we introduce a method for ranking component contributions to mean system cost based on MCF. The MCF estimates are finally used to examine system- or component-level insight into maintenance trends and

978-1-5090-5284-4/17/$31.00 ©2017 IEEE

economic considerations for these devices.

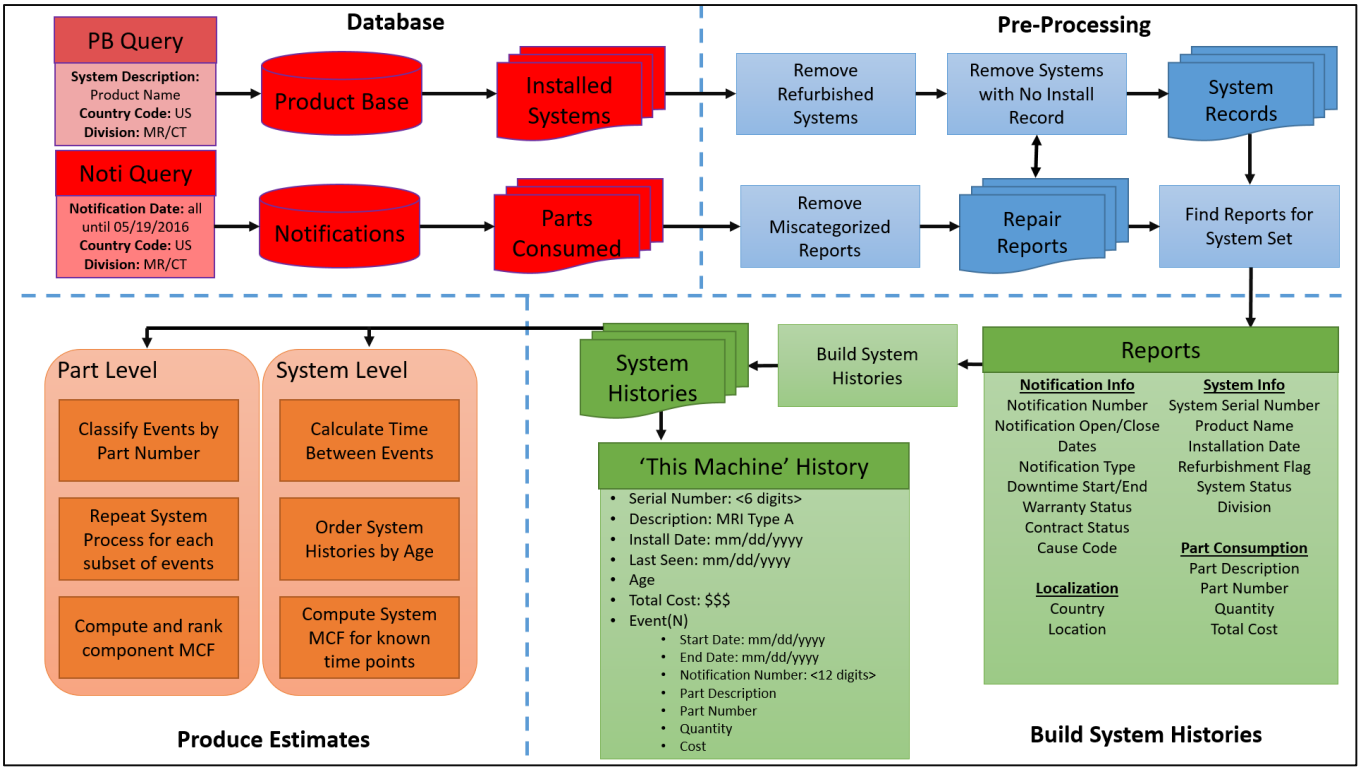

Figure 1: Automated system and maintenance records processing program flow

2 METHOD DESCRIPTION

Critical features of our data processing flow are illustrated in Figure 1. The approach is presented in general form for adaptation to other complex systems and industries. This diagram illustrates major features of the pre-processing chain we employ in practice. The central feature however is the production of indexed 'system history' data structures that retain several relevant fields from initially millions of tabulated reports. We now detail considerations for each segment.

Database: Two databases (Product Base and Notifications) are maintained internally, capable of providing finite size queries with limited modifiers. Due to size limits queries are performed in batches by consecutive calendar periods and annealed. Due to limits on filtering logic, results are primarily filtered in subsequent steps where results can be verified during runtime. The Product Base (PB) database contains records of most systems operated by this company with fields for country and location of operation. Entries are also classified according to product divisions, which generally correspond to modalities such as Magnetic Resonance (MR) or Computed Tomography (CT). Division portfolios may be broader, such as X-Ray Products (XP); the examples here are drawn from one product line in MR and one in CT. Minimal filters are provided at this stage to draw the most complete record possible. Specifically, we supply a product line name (for size limits on query response), a country code (required input), and a division. Division is necessary as installed systems are assigned a unique serial number which is only unique within the division; i.e. a CT system and MRI system may have the same six-digit system serial number, but two systems within the same division will not share serial numbers. The Notifications (Noti) database contains tabulated records of notification events. A notification event is an internal record generated each time a customer contacts the device company in regards to a system, or when a repair is logged. Each notification is assigned a unique 12-digit number. Our queries are performed on the subset of notifications that record a part consumption. No date boundaries are specified in the query for notifications, records predating the introduction of the product line are queried, and filtered in subsequent steps.

Pre-Processing: At this phase the algorithm screens for known imperfections in the records, before consolidating reports. For PB results, we begin by eliminating refurbished systems for the purposes of this analysis. Since refurbished systems are reassigned a serial number, we cannot readily determine the age or state of components in these systems. For the remaining systems, we confirm that each serial number is associated with a single, unique installation date. For product base records that do not have a listed installation date, the PB records cross-reference the repair reports to find potential repair events listed as installation occurrences, and use the date for those repairs instead. In limited cases where no installation date is found, that system is excluded from subsequent steps. Similarly, the Noti results are filtered for various miscategorized results. Entry error examples include

entries with assigned notification numbers that are not within the country code, as these numbers have characteristic sequences encoding their country of origin. Similarly, repair events that are attributed to a system prior to any installation window may indicate recycling of a serial number, and the resulting part consumption logs are discarded. To ensure finally that systems with potential interval censoring are omitted, we exclude reports of systems where no repair contract or warranty is recorded. Pre-processing completes by producing a merged set of reports. The reports are a set of unique, valid serial numbers for the input product line, as well as all associated part consumption records. In practice less than 5% of records for any given product line are rejected based on entry imperfection, with records typically representing hundreds of systems. Omitted systems reduce the sample size negligibly.

Build System Histories: Once the pre-processed reports are tabulated, we construct an array of system history data structures, with data fields as shown in Figure 1. Each indexed structure associates system-level properties such as serial number, install date, and product description with a sub-indexed array of the recorded repair events. A single system has N system-specific events, where N is discretely valued and positive or zero. System properties such as the last seen date and total cost are inferred from the associated reports. The system histories allow for analysis by aggregating individual notifications associated to each system.

Produce Estimates: We use the compiled system histories here to compute a variant on the mean cumulative function non-parametric estimate, detailed extensively in [5], which has been employed in maintainability studies for medical devices [5, 6, 8]. Our rendition is a slight reinterpretation for discretely sampled time points, where a formulation based on the algorithmic description in [5] is provided in Equation (1):

$$M^*[k] = \frac{1}{n[k]} \sum_{\forall \phi[k]} Q_i[k] \qquad (1)$$

where the MCF estimate ($M^*[k]$) is defined for the discrete time point k as the accumulated number or cost of repairs for system i by point k ($Q_i[k]$). We sum across ϕ[k], the set of all systems i observed at point k, and normalize by the number of systems observed at point k ($n[k]$). The index k is the number of days that system has been in operation, and is relative to each install date. Similarly we use Nelson's confidence limits [5], interpreted here for the discrete case as Equation (2):

$$M^*[k] \pm N_C \left(\frac{s^2[k]}{n[k]}\right)^{\frac{1}{2}} = M^*[k] \pm N_C \{var[M^*[k]]\}^{\frac{1}{2}} \qquad (2)$$

N_C is the $\frac{1}{2}(100 + C)$ standard normal percentile, and $s[k]$ is the sample standard deviation at time point k. In our implementation, we assume that a finite MCF exists at each time point k, which is sampled daily. By construction we have omitted systems where the installation date is ambiguous, and assume that due to the nature of use and monitoring inherent with the contracted systems considered that no interval censoring occurs. This approach reduces sample size slightly but removes ambiguity in the sampled system histories. Critically, we interpret systems where the kth day has no associated repairs as an observation on day k where $Q_i[k] = Q_i[k-1]$. This distinguishes our computation from the method in [5], but produces numerically equivalent results at all defined time points. Finally, our analysis distinguishes between a system level MCF $M^*[k]$ and the contribution to the system level MCF by each part type j, which we denote $M_j^*[k]$. We compute $M_j^*[k]$ identically, using the recorded system installation date as $k = 0$ and the last seen date as a right-hand censoring point, however the contributions to $Q_{i,j}[k]$ are explicitly the cost or number of repairs of part type j in system i. For the set of all parts J we can then define a ranking system that orders the contribution to accumulated repairs by time point k as Equation (3):

$$M_1^*[k] \geq M_2^*[k] \geq M_3^*[k] \geq \cdots \geq M_{J-1}^*[k] \geq M_J^*[k] \qquad (3)$$

where

$$M^*[k] = \sum_{j=1}^{J} M_j^*[k] \qquad (4)$$

Doing so this technique is able to quantify the relative importance of part type j to the overall burden of maintaining the studied class of systems, where burden is either the accumulated cost or quantity of repairs due to part j at point k.

3 RESULTS

Figure 2 illustrates an interim step in processing, showing $Q_i[k]$ for five randomly selected MR systems. Here we are plotting the accumulated costs incurred by these systems for all parts over their observed history, on a relative cost axis. By construction only right-hand censoring is considered; the subset of systems sampled have well-defined installation dates and have contracted repairs recorded during the operating interval. The latest observed age of the system therefore dictates the right-censoring point.

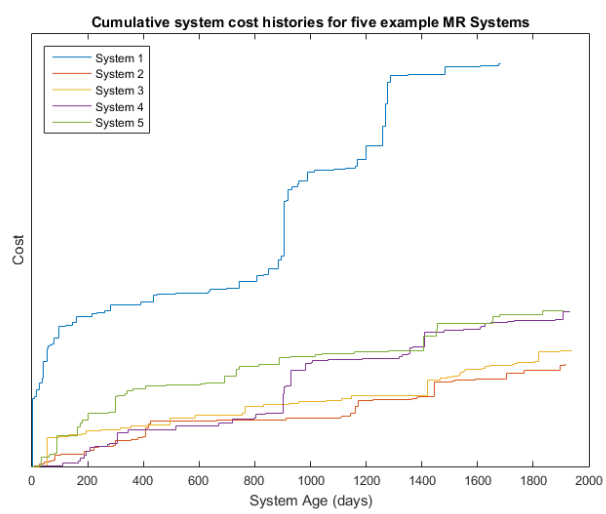

Figure 2: Cumulative repair costs for five sample magnetic systems, relative cost scale

Figure 3 shows the endpoint of computing the indicated estimates, as well as ranking based on cost contribution at 3 years' time (1095 days' system age). For clarity, in all MCF figures a 95% confidence interval is shown only for the system MCF. Also, part decomposition results are super positioned in reverse rank order for visibility, such that for example the second curve from the bottom is equal to $M_1^*[k] + M_2^*[k]$. Figure 3 estimates the mean cost of operating a MR system from this product line over the first three years, as well as which parts contribute to this operating cost in order of the expected accumulated cost at k = 1095. The top twenty parts (out of approximately 1200 unique parts) contributing to cost are shown, with descriptions in rank order in the legend.

Figure 4 shows the associated costs for a CT system. Whereas the MR product line MCF exhibited a relatively constant slope, the raising curvature in Figure 4 indicates an increasing cost rate. This trend, often associated with wear-out processes, is conceivable in CT systems that operate under heavy mechanical and radiation stresses. Compared to MR systems that use no ionizing radiation and have comparatively non-moving parts, we expect more predictable slopes (referred to as recurrence rates in MCF [5]) in MR systems.

The reaction to CT operating stresses is seen in Figure 5. For the same CT line, Figure 5 shows accumulated maintenance quantities and the top contributors. Comparing the legend entries in Figure 4 to Figure 5, it is apparent that the largest contributors to expected operating cost are not typically the frequently repaired parts. Adherence to a maintenance schedule is thought to minimize the need for more frequent expensive repairs, and is evidenced in the parts contributing to Figure 4 versus Figure 5. The distinct staircase pattern is due to maintenance for the filter components. Only some parts are regularly replaced during periodic maintenance visits, the appearance of periodicity in many of the component MCFs is an artifact of the super positioned plotting.

4 DISCUSSION

For maintenance, it is often useful to consider repairs of a system as a point process. Various authors have employed the mean cumulative function for analyzing the point repair process as it imposes minimal assumptions for the estimate to be valid [3-5]. MCF is consequently a useful first-pass in automated approaches, as it is applicable under broad conditions and may be sufficient for the answers sought [5]. Automation becomes necessary in practice, as a company may produce several complex product lines with optional items and thousands of unique parts. The approach presented here imparts reproducibility to product line analysis, and can be easily shifted from one product line to another as maintenance priorities shift.

One consideration in employing MCF estimates as done here are the quality of repair records. As noted, in preprocessing we erred on the side of caution in excluding systems with potential censoring points in repair records. While adjustments exist for well-characterized censoring [5], gaps in repair histories would lead to underestimation of the cumulative number of repairs, especially if undocumented repairs are frequent. This could occur if for instance third-party repairs were performed. Restricting our sample to systems under repair contract reduces the sample size, but ensures that complete system repairs are documented in the reports used.

As for maintenance priorities, the method described here provides a quantifiable means of reproducibly ranking maintenance priorities. The method demonstrated here strives for improved objectivity. In addition, the results align with the Pareto Principle [9], where generally 80% of problems in a design are attributable to 20% of components.

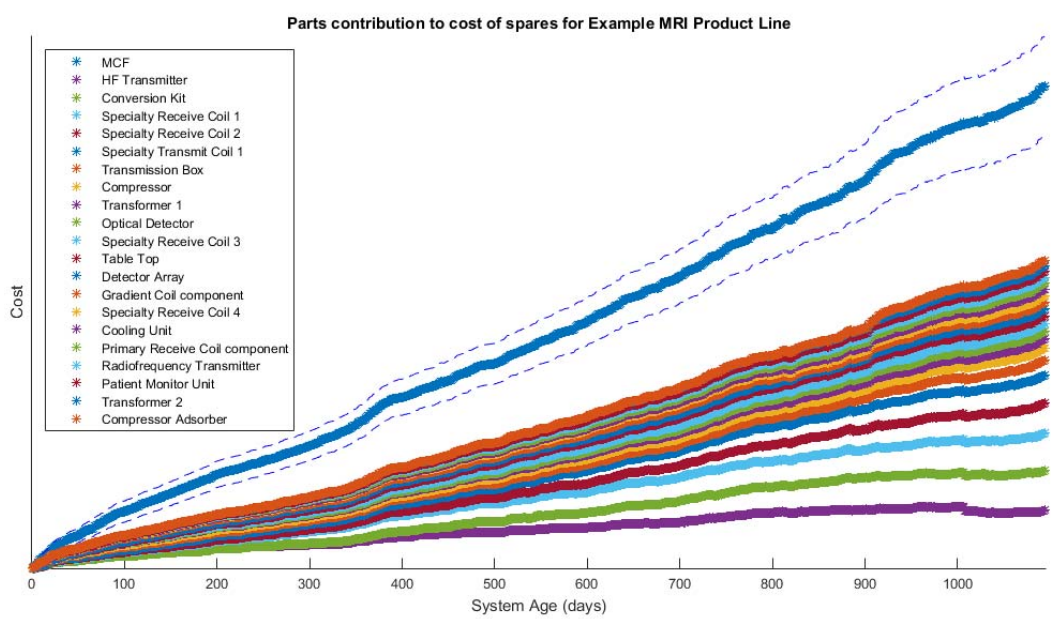

Figure 3: Magnetic Resonance repair cost MCF estimate, showing top twenty contributing parts on relative cost scale

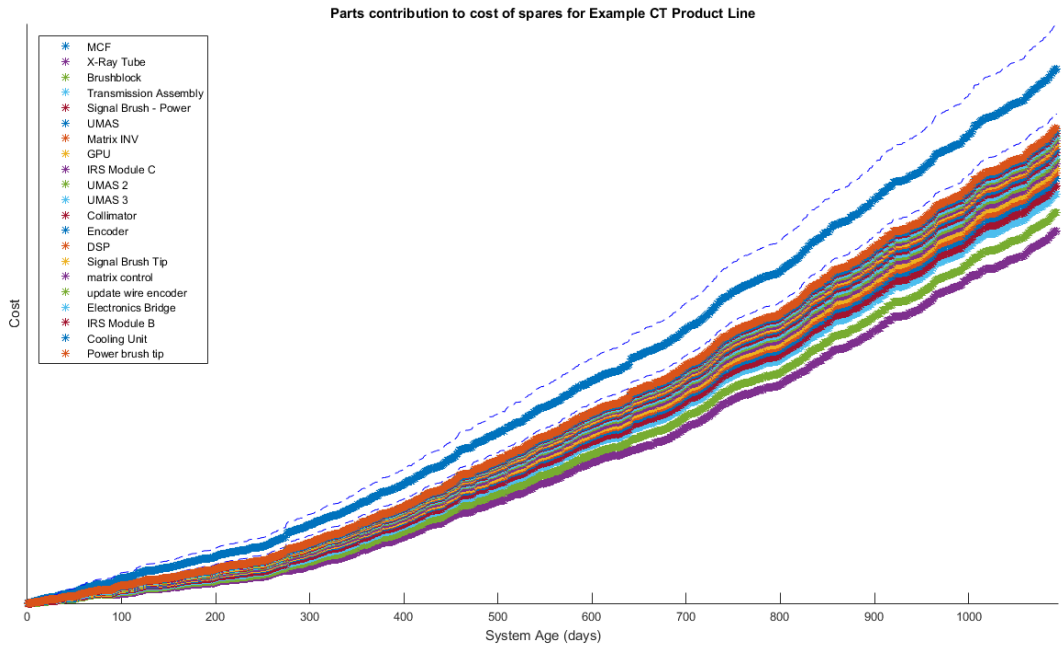

Figure 4: X-Ray Computed Tomography repair cost MCF estimate, showing top twenty contributing parts on relative cost scale

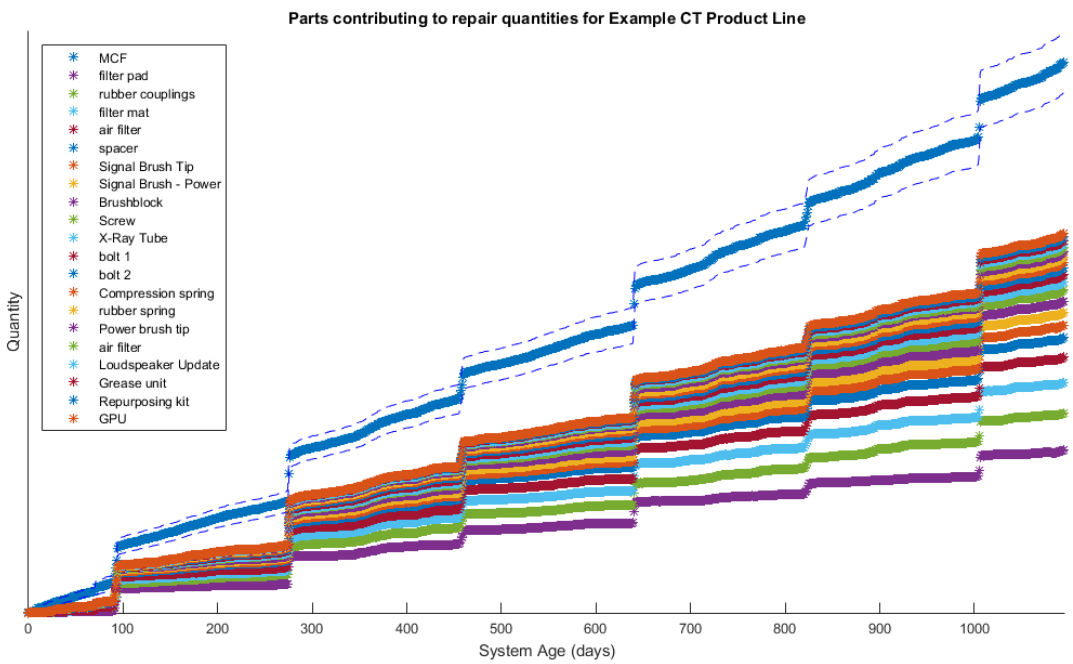

Figure 5: Accumulated repair quantities in example CT product line. Highest contributing items tend to be low-value maintenance consumable, however items such as the X-Ray tube warrant particular attention

In fact, as seen in Figure 4, twenty parts in these product line (out of ~1100 unique observed part types) contribute to more than 80% of the expected cost incurred by the third year of a CT system. These results can guide subsequent efforts, from a business, design, or modeling perspective. The empirically determined rankings indicate where subsequent resources may be best allocated.

It is worth noting that this estimate already provides actionable information. Abstractly, given a newly observed system, problematic system histories can be indicated based on their relation to the MCF for that product line. For instance, for some point κ, this estimate has been used to indicate systems with unusually high cumulative repair costs or quantities compared to the MCF estimate $M^*[\kappa]$. Alternatively, for an organization tasked with maintaining a fleet of systems from a given product line, the costs incurred during a period $\tau = [\kappa_1, \kappa_2]$ can be estimated as Equation (5)

$$cost(\tau) = \sum_{\forall i} (M^*[a_i + \kappa_2] - M^*[a_i + \kappa_1]) \quad (5)$$

where a_i is the age of system i, assuming that the MCF is defined for $\max(a_i + \kappa_2)$. In cases where the product line MCF is linear, such as Figure 3, this estimate is trivial to compute.

Finally, the ranking procedure may illuminate unexpected maintenance problems. In Figure 5, maintenance personnel experienced with the product line were immediately able to identify the excessive replacement of filter pads, which can be cleaned on site rather than replaced as indicated in records. Across a large enough product line, the repair quantities indicated here amount to a sizable financial burden.

We present here a diagrammatic flow of a program for automating maintainability analysis over an entire product line, aimed at data sets too large for direct operation. The program produced here was then demonstrated on extensive records for medical imaging products in active use in the United States, representative of two major imaging modalities. Finally, we present a discrete formulation of a familiar estimate, the mean cumulative function, as well as a novel approach to ranking contributions based on MCF. All results are implemented with automation in mind, and findings indicate where future modeling may be targeted.

ACKNOWLEDGEMENTS

This material is based upon work supported by the National Science Foundation Graduate Research Fellowship Program under Grant No. DGF 1106401 J. This research was conducted during the primary author's paid internship with Siemens Healthineers, a division of Siemens AG.

REFERENCES

1. J. W. Senders, "On the complexity of medical devices and systems," *Qual Saf Health Care,* vol. 15 Suppl 1, pp. i41-3, Dec 2006.
2. H. Ascher and H. Feingold, *Repairable systems reliability : modeling, inference, misconceptions and their causes*. New York: M. Dekker, 1984.
3. J. F. Lawless, *Statistical models and methods for lifetime data*. New York: Wiley, 1982.
4. S. E. Rigdon and A. P. Basu, *Statistical methods for the reliability of repairable systems*. New York: Wiley, 2000.
5. W. Nelson, *Recurrent events data analysis for product repairs, disease recurrences, and other applications*. Philadelphia: Society for Industrial and Applied Mathematics, 2003.
6. R. A. Ion, P. J. M. Sonnemans, and T. Wensing, "Reliability prediction for complex medical systems," in *Reliability and Maintainability Symposium, 2006. RAMS '06. Annual*, 2006, pp. 368-373.
7. S. Taghipour, D. Banjevic, and A. K. S. Jardine, "Reliability analysis of maintenance data for complex medical devices," *Quality and Reliability Engineering International,* vol. 27, pp. 71-84, 2011.
8. S. Taghipour, "Reliability and maintenance of medical devices," Thesis (Ph D), University of Toronto, 2011., 2011.
9. A. Rushton, P. Croucher, P. Baker, ebrary Inc., and Ford Library E-Book Collection. (2010). *The handbook of logistics & distribution management (4th ed.)*. Available: http://proxy.lib.duke.edu/login?url=http://site.ebrary.com/lib/dukelibraries/Top?id=10404161

BIOGRAPHIES

Rafael B. Fricks
Department of Biomedical Engineering
Duke University, Box 90291
Durham, NC, 27708-0291, USA

e-mail: rafael.fricks@duke.edu

Rafael Fricks is a Duke University Dean's Graduate Fellow, and NSF graduate research fellow under Professor Trivedi. In 2013, he received his Bachelor's degree in Biomedical Engineering from the University of Texas in Austin.

Kishor S. Trivedi
Department of Electrical and Computer Engineering
Duke University, Box 90291
Durham, NC, 27708-0291, USA

e-mail: ktrivedi@duke.edu

Kishor Trivedi is Hudson Chair Professor at Duke University. He heads the Duke High Availability Assurance Laboratory and for over 40 years has authored numerous texts and publications on modeling performance and dependability.