

Example of the Design and Operation of an ICU using Reliability Principles

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Introduction

This short analysis illustrates how statistics may help in the Logistics (design and operation) of ICUs and other health facilities that support the struggle against the Covid-19. There is no long-term health care activity if it is not supported by an efficient and effective Logistics operation (e.g. ensuring that all its equipment and the PPEs for the healthcare workers are available and suitable for safe use).

We will first illustrate two very useful reliability techniques to support the design and operation of ICUs: *Failure Modes and Effects Analysis (FMEAs)* and *Fault Tree Analysis (FTAs)*. Then, we provide an example of the use of *reliability data analysis* to establish management and operation of key ICU equipment.

Facilities Design using FMEA and FTA techniques

A Summary of FMEA/FTA is in: <https://web.cortland.edu/matresearch/FMEA&FTASummaryS2017.pdf>

Example: Assume that the ICU is a System composed of the following *five subsystems*: Doctors; Nurses; Support Staff; Ventilators; Additional equipment. In addition, assume that the ICU requires a Reliability¹ of 95%. We will apportion reliability of 99% to each of its five integrating subsystems:

$$R(\text{ICU}) = R(D) * R(N) * R(SS) * R(V) * R(AE) = 0.99^5 = 0.95099 \text{ (Total System Reliability)}$$

Assume we cannot rely on each of the above five subsystems to work failure-free for an entire Mission Time. Then, to achieve said 95% reliability for the entire system we have to either: (1) compensate by increasing some other subsystem reliabilities, so that the product still yields 0.95. Alternatively, we can (2) build some redundancy² in the faulty subsystems, to achieve the same goal.

Example of Failures Mode & Effects Analysis/FMEA: the Doctor *subsystem's critical elements* are (1) PPEs; (2) readiness (e.g. start shift rested and free of virus); (3) medical equipment; etc. Consider, for each component, possible failure, cause, type, frequency, occurrence probability, seriousness, effect, corrective action and failure alternatives.

¹ Probability that an ICU works successfully during its Mission Time (e.g. a shift, a day, a week, etc.)

² Redundancy is the inclusion of parallel similar functions. For example, having enough extra PPEs available, so that at the time of failure of any PPE, we can immediately replace it by a similarly capable PPE.

Example of Use of Fault Tree Analysis/FTA to assess key problems occurring in the ICU that invalidates it. Assume we want to study the impact of a Ventilator Failure on a patient. We need to start by analyzing all possible causes and impacts of such failures. The starting point is the (Top) Failure Event. It can be caused, say by (1) electrical, (2) mechanical, or (3) human problems. This is the first level of the Tree. We then build a second level by analyzing the possible respective causes of each of the above three events. For example, an electrical failure can occur, say by an (4) internal electrical failure, (5) by a faulty wiring connection, or by a (6) power outage. And we continue in this manner until all possibilities are analyzed.

Examples of Covid-10 Use of FTAs are in: <https://web.cortland.edu/matresearch/Covid-19FTAGrp5.pdf>

Reliability data analysis to establish the Maintenance Proceedings

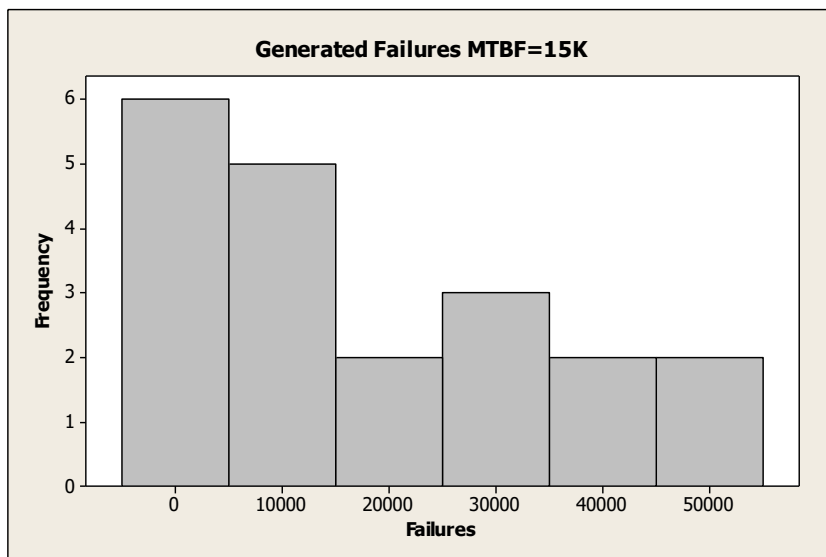
We should implement them for all key health care equipment: PPEs, Ventilators, medical equipment etc.

Example of Operation: receiving and assessing a lot of $n = 20$ ventilators.

Implement a Life Test (put a random sample of $n = 20$ ventilators to work, until they reach their time to failure). Assume Ventilators have an Exponential Life, with Mean Time Between Failures (MTBF) of 15K minutes (equivalent to 250 hrs or 10.5 days). Assume the Life Test yields the following failure times:

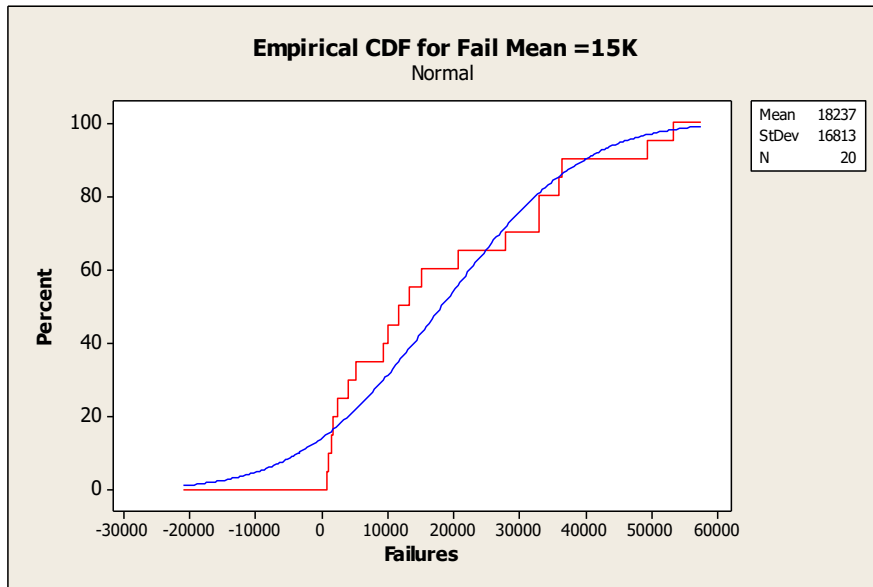
1003.4	9242.1	20624.1	4140.9	11713.1	32888.5	35971.6
5111.9	36306.6	27796.1	49362.8	13232.0	2309.5	753.3
32904.8	1764.3	53233.0	15027.1	1404.6	9944.1	

Describe these 20 times to failure: $T = Total\ Time\ on\ Test\ (sum) = 364734$



The above histogram supports the assumption of an Exponential, with mean μ and rate $\lambda=1/\mu$. See two Tutorials from Reliability Analysis Center (RAC): [Statistical Assumptions of the Exponential Distribution](https://web.cortland.edu/matresearch/ExpAssumSTART.pdf) [and Reliability Estimations for Exponential:](https://web.cortland.edu/matresearch/RExpLifeSTART.pdf) both authored by this analyst.

We then build an empirical Probability Plot for the Life of this device, based on such sample of $n=20$. For example, device failure Probability, at 30K hours, is about 60%. A larger sample will yield better results.



We need Confidence Intervals for the MTBF of the device. We obtain them from the distribution of $2T/\mu$ (T is Total Time on Test) which is distributed as Chi Square (χ^2) with $2n = 2*20 = 40$ Deg. Freedom (γ).

Such $1 - \alpha = 95\%$ Confidence Interval (CI) for the Mean is obtained by using the formula:

$$[2T / \chi^2(\alpha, \gamma), 2T / \chi^2(1-\alpha, \gamma)] = [2*364734/59.3417 ; 2*364734/24.4330] \text{ (Note: } 2T=729467)$$

$$\text{Where: } \chi^2(\alpha, \gamma) = 24.4330; \chi^2(1-\alpha, \gamma) = 59.3417 \text{ (Chi Square table values)}$$

Then, we obtain the following results for both, Mean Time Between Failures and the Failure Rate:

$$\begin{aligned} &95\% \text{ CI for Ventilator Mean Time Between Failures is (12.3K, 29.9K)} \\ &95\% \text{ CI for Ventilator Failure Rate is (1/29.9K, 12.3K) = (3.3 E-05; 8.1 E-05)} \end{aligned}$$

Assume now we need to *define a Ventilator non-stop work time as 5000 minutes (= 83.3 hrs = 3.5 days):*

95% CI for *Reliability on this Mission Time* (working without stopping for schedule maintenance, or fail):

$$[\text{Exp}(-5K/12.2K) ; \text{Exp}(-5K/29,9K)] = [0.66 ; 0.84]$$

Such low Reliability (Max 84%) is not acceptable: 1/6 of such Ventilators would fail in less than 83.3 hrs!

We now decrease the Mission Time to 720 min = 12 hours:

$$[\text{Exp}(-720/12.2K) ; \text{Exp}(-720/29.9K)] = [0.943 ; 0.976]$$

Now, Ventilator Reliability (Min 94%) is acceptable (only 1/20 will fail). Therefore, based upon this experimentation we will schedule preventive maintenance for ICU Ventilators every 12 hours.

Assume we do not have the testing time nor the resources to wait for the Complete sample of all $n = 20$ ventilators to fail. We stop (Censor) our test at the First Failure X_k : $k = 1$ (assume occurred at time=753.3)

$$T = X_1 + (n-k) * X_1 = 753.3 + 19 * 753.3 = 15066 \Rightarrow 2 * T = 30132 \text{ minutes}$$

$$\text{Now DF } \gamma = 2 * k \text{ instead of } 2 * n: \chi^2(\alpha, \gamma) = 0.05063 ; \chi^2(1-\alpha, \gamma) = 7.37776$$

$$[2T / \chi^2(\alpha, \gamma), 2T / \chi^2(1-\alpha, \gamma)] = [2 * 15066 / 7.37776; 2 * 15066 / 0.05063] \text{ (Note: } 2T=30132)$$

The new 95% CI obtained for the MTBF is: [4084.17, 595141]

We have reduced testing time from 53233 to 753 min, but paid a price of a much larger CI.

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About the Author:

Jorge Luis Romeu was, for sixteen years, a Research Professor at Syracuse University. He is currently an Adjunct Professor of Statistics. Romeu retired Emeritus from the State University of New York. Romeu worked for many years as a Senior Research Engineer with IIT Research Institute, which operated the Reliability Analysis Center/RAC, an Air Force Information and Analysis Center, and later for RACs other operating organizations. Romeu holds a doctorate in Statistics/O.R., is a C. Stat Fellow of the Royal Statistical Society (RSS), a Member of the American Statistical Society (ASA), the American Society for Quality (ASQ), Past ASQ Regional Director, and holds Reliability and Quality ASQ Certifications. Romeu created and directs the *Juarez Lincoln Marti Int'l. Ed. Project* (<https://web.cortland.edu/matresearch/>) dedicated to support higher education in Ibero-America. Its QR&CII (Quality, Reliability and Continuous Improvement Institute: <https://web.cortland.edu/matresearch/QR&CIInstPg.htm>) includes all our work on the Covid-19 Pandemic.