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Medical Undertakings Should Be Quantified to Have A Potential to Be Improved

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The today's efforts of system engineers to assure adequate and reliable performance of electronic devices, including medical devices, use, as a rule, qualitative, rather than quantitative, considerations. This is even truer about the performance of the healthcare and medical personnel. In the best case, the available pertinent a-posteriori statistics is accumulated and taken into account. The author of this brief review developed, during his long professional lifetime, numerous predictive reliability models and accelerated test techniques in various areas of engineering and applied science and is convinced that the successful outcome of a medical mission or a more or less typical clinical situation cannot be expected, if it is not quantified. Every significant healthcare effort has to be quantified to be improved and because of the various inevitable intervening uncertainties, affecting its outcome, such a quantification should be done on the probabilistic basis.

Nothing and nobody is perfect. In effect, the difference between a highly reliable and insufficiently reliable medical instrumentation, or between the performance of a highly qualified medical doctor and the actions of a mediocre physician is "merely" the difference in the levels of their never-zero probability of failure. This probability could and should be assessed in advance and made adequate for the particular medical equipment, clinical tasks and even for general healthcare actions of importance. A good example is current vaccinations against COVID-19 virus. The agreed upon and, perhaps, when possible and appropriate, even specified, probability of failure of a medical device or an healthcare effort cannot be high, of course, but does not have to be lower than necessary either: when such a probability is assessed, it has to be made adequate for a particular device and/or an effort considering their specifics and consequences of failure. Devices that "never fail" are most likely "over-engineered", i.e., are more robust than they could and should be, and, because of that, could be much more costly than necessary.

In the recently published CRC book [1] it has been demonstrated, mostly in application to the aerospace domain, how methods and approaches of the applied probability (see, e.g., [2]) could be effectively employed in various human-in-the-loop (HITL) tasks and situations to quantify their outcome, with consideration of both the reliability of the electronic and/or photonic instrumentation and the role of the human factor (HF). The objective of the present review is to suggest that this effort is brought "down-to-earth" in application to reliability of medical electron devices and to performance of medical personnel, with an emphasis on the undertakings, when the reliability of medical instrumentation and the human factor contribute jointly to the outcome of a medical mission or an off-normal and often urgent situation. Accordingly, the following aspects of the attempt to quantify what is usually considered "unquantifiable" have been recently addressed and are briefly summarized in this communication.

Electron medical devices (MDs) that underwent more or less well established highly accelerated life testing (HALT) [3], passed the existing qualification tests (QT) [4] and survived burn-in testing (BIT) [5] often exhibit nonetheless premature field failures. It is concluded therefore that these efforts, the way they exist and applied today, are not always adequate and should be replaced [6, 7]. It is clear that there is a need to improve the existing practices to an extent that if an electronic MD passed the reliability tests, it will satisfactorily perform in the field, and that there is a way to assure its adequate performance [8]. The operational (field) reliability of electronic MDs is particularly critical [9, 10] and has to be predicted/quantified to be assured [11, 12], and if this effort is found to be necessary, could it be done on the deterministic basis, or a probabilistic approach should be applied [13]? Should manufacturers of MDs keep shooting for, perhaps, unachievable very long, such as, say, twenty years or so, lifetime of the device or, considering that every several years a new generation of MDs are developed and appear on the market and that a twenty years long time predictions are rather shaky, should the MD manufacturers settle for a shorter, but well substantiated, predictable, trustworthy, physically and economically feasible, and, to an extent possible, assured lifetime and, when a probabilistic approach is applied, a lifetime with an adequate anticipated probability of failure [14, 15]? It is clear that such a "useful lifetime" should be related to the acceptable (adequate and, if appropriate and doable, even specified) probability of failure for a particular product, depending on its use conditions and consequences of failure [16, 17]? Since understanding the reliability physics underlying the possible electronic materials and device failure is critical, and so is the accelerated testing in making a viable electron MD into a reliable product, is there an alternative to, or at least a suitable modification of, the currently widely used highly accelerated life testing (HALT)? HALT is a sort of a "black box" that supposedly improves reliability, but does not quantify it, even on a deterministic basis [18]. It has been suggested that a highly focused and a highly cost effective failure-oriented-accelerated test (FOAT) could be considered as the right accelerated life test [7, 18-20] for MDs. FOAT could be viewed as an extension and modification of HALT [21]. The kinetic constitutive Boltzmann-Arrhenius-Zhurkov (BAZ) equation [22] was recently suggested as a suitable analytical model that could be used to bridge the gap between what one obtains as the experimental FOAT data and what will most likely occur in actual operating conditions for the device of interest. It has been shown [23] that this equation can be obtained as a steady-state solution to the corresponding Fokker-Plank equation in the theory of Markovian processes (see, e.g. [2]), that this solution is conservative, i.e., results in higher stresses and strains than the transitional process and is advisable therefore for engineering applications. The BAZ equation was recently applied to a number of reliability problems in electronics engineering [24-29], including

MDs. Ability to quantify things is particularly important when it comes to optimization. The best engineering design is, as is known, the best compromise between the requirements for its reliability, cost effectiveness and time-to-market. Of course, cost effectiveness and time-to-market (to completion) are always "quantifiable". To make any optimization possible, reliability of such product should also be quantified. Using an elementary probabilistic model, it has been shown [30] that the minimum total cost of a product, considering its manufacturing cost and initial reliability vs. maintenance cost and operational reliability corresponds to the maximum availability of the product. Bathtub curve [31] is the experimental "reliability passport" of a mass-fabricated product. This curve reflects, as is known, the inputs of two critical and irreversible processes – the statistics-of-failure process and physics-of-failure process. The first one results in a reduced failure rate with time. This is particularly evident from the infant mortality portion of the curve. The second one is associated with aging and degradation of the material and results in an increased failure rate. This trend is explicitly exhibited by the wear out portion of the curve. There is not very much a designer could do about the statistics-of-failure process, but there is an obvious incentive to better understand the underlying physics of aging and degradation, i.e., to affect, to an extent possible, the second process. To do so, these two processes should be separated. Could this be done [32]? A related problem has to do with the fact that actual, operational, degradation is a very slow process. Could physically meaningful and cost-effective methodologies for measuring and predicting the degradation (aging) rates and consequences be developed, and, particularly, could physically meaningful and highly flexible BAZ model recently developed for aerospace metrology problems [33] be applied to provide the quantitative assessment of the MD degradation? It should be emphasized that all the results, conclusions and recommendation where obtained by the author using analytical ("mathematical") modeling [34]. It is suggested that such modeling is employed, in addition to computer simulations, in any major effort associated with the design for reliability of MDs. Computer simulations and analytical modeling techniques are based on different assumptions and use different calculation methods and techniques, and if the calculated data obtained using these techniques agree, then there is a good reason to believe that these data are sufficiently accurate and trustworthy [35]. Future work should address the extensions and modifications of the modeling techniques developed primarily for the aerospace devices and systems [36, 37] for MD development and use.

Human error (HE) (see, e.g., [38, 39]) affects, to a greater or lesser extent, all aspects of human activity, and the ability to understand the nature of various critical HEs and minimize the likelihood of their occurrence is therefore of paramount importance. While considerable improvements in various medical and public health related electron device technologies and human factor (HF) related missions and situations can be achieved through traditional and well established "unquantifiable" means that directly affect human behaviors and performances, there is also a significant opportunity (potential) for a further reduction in medical HF related casualties through better understanding the role that various uncertainties play in the planner and the performer worlds of work. By employing quantifiable and measurable ways to assess the role of these uncertainties and by treating human-in-the-loop (HITL) as a part, often the most critical part, of the complex man-instrumentation-equipment-environment-"object of control" (patient) system, one could improve dramatically human performance, and to predict, minimize and, when possible and appropriate, even specify the probability of the occurrence of a never-completely-avoidable mishap. As it is in the case of MDs, it is the author's belief that adequate human performance cannot be effectively assured, if it is not quantified and, since nobody is perfect, that such quantification should be done on the probabilistic basis. In effect, as has been indicated above in application to various instrumentations, both hard- and software, the "only difference" between what is perceived as a failure-free and an unsatisfactory human performance is, actually, the difference in the levels of his/hers never-zero probability of failure. Application of the quantitative predictive probability modeling (PPM) concept, which is analogous to the PDfR in medical instrumentation, should complement, in various HF related situations, whenever feasible and possible, the existing "unquantifiable" practices: qualitative a posteriori statistical assessments.

In the simplest way, this could be done by considering what is known as mental/cognitive workload (MWL) [40-50] (in a particular medical or healthcare mission and/or extraordinary situation) vs. the human capacity factor (HCF) [51-72], both long- and short-term. The long-term HCF should be considered vs. the elevated short-term MWL that the human has to cope with to successfully complete a critical task or withstand an off-normal (emergency) situation.

It is argued that both the traditional MWL and the recently suggested HCF should be considered, when quantifying the most likely outcome of a HITL related mission, medical or a healthcare related case, or an extraordinary situation. The famous 2009 US Airways "miracle-on-the-Hudson" successful ditching [73] and the infamous 1998 Swiss Air "UN-shuttle" disaster [73] are good illustration to this statement. The input data in the publication [73] are hypothetical, but realistic, and it is the approach, and not the numbers, that is, in the author's opinion, the major merit of this analysis that attracted quite a number of references in the ergonomics literature. As the great Gottfried Leibnitz put it, "there are things in this world, far more important than the most splendid discoveries—it is the methods by which they were made." It has been argued particularly that it was the exceptionally high HCF of the captain Sullenberger ("Sully") and his crew that made a reality what seemed to be, at the first glance, a "miracle". In addition to the application of the suggested new double-exponential-probability-distribution-function (DEPDF) based approach [62], it has been shown, using a well-known convolution approach in the applied probability [2], that the probability of safe landing/ditching can be evaluated by comparing the (random) operation time (that consists of the decision making time and the actual landing/ditching time) with the "available" anticipated, also random, of course, time needed for landing. A similar approach can be used, when evaluating, say, an outcome of a surgery, and effort is considered by the author at present as future work. The developed formalisms, after trustworthy input data are obtained (using, e.g., flight simulators [70] and/or by applying Delphi method (see, e.g., [2]) might be applicable even beyond the vehicular or medical domain and can be employed in various HITL situations, when a long term high HCF is imperative and the ability to quantify it in comparison with the short term anticipated MWL is desirable.

It has been suggested [51-72] that MWL vs. HCF is always considered as a suitable way to quantify human performance. In the simplest case such a failure should be attributed to an insufficient HCF, when a human has to cope with a relatively high MWL. Our MWL/HCF models and their possible modifications and generalizations can be helpful, after appropriate sensitivity factors are established and sensitivity analyses are carried out, in a number of critical cases, missions and situations: when developing guidelines for personnel selection and training; when choosing the appropriate simulation conditions (these, in the author opinion, should always be considered in any significant undertaking); and/or, in automated driving situations, when there is a need to decide, if the existing levels of automation and of the employed equipment (instrumentation) are adequate in off-normal, but not impossible, situations, and if not, whether additional and/or more advanced and, perhaps, more expensive equipment or instrumentation should be considered, developed, tested and installed, so that the requirements and constraints associated with a medical, vehicular, military, or other mission or a situation of importance that might be encountered, would be successfully coped with. Using an analogy from the reliability engineering field and particularly with the well known "stress-strength" interference model, the MWL could be viewed as a certain possible "demand" ("stress"), while the HCF - as an available or a required "capacity" ("strength").

The MWL level depends on the operational conditions and the complexity of the mission, i.e., has to do with the significance of the general task, while the HCF considers, but might not be limited to, the human's professional experience and qualifications, capabilities and skills; level and specifics of his/her training; performance sustainability; ability to concentrate; mature thinking; ability to operate effectively, in a "tireless" fashion, under pressure, and, if needed, for a long period of time (tolerance to stress); team-player attitude; swiftness in reaction, if necessary, etc., i.e., all the critical qualities that would enable him/her to cope with the high MWL. Note that adequate trust that is briefly addressed below is often also an important HCF.

It is noteworthy that the ability to evaluate the "absolute" level of the MWL, important as it might be for numerous existing non-comparative evaluations, is less critical in our MWL vs. HCF approach: it is the relative levels of the MWL and the HCF, and the comparative assessments and evaluations of their levels and likelihoods that are important. Note that testing on a flight simulator [67] and possible accelerated/preliminary testing in health care are analogous to the HALT and FOAT in electronics reliability engineering, including medical electronics. Our HCF vs. MWL approach considers elevated (off-normal) random relative HCF and MWL levels with respect to the ordinary (normal, pre-established) deterministic HCF and MWL values. These values could and should be established on the basis of the existing human psychology practices.

As has been indicated, adequate trust [73-76] is an important HCF constituent. It is shown particularly [76], using the DEPDF based approach, that the entropy of this distribution, when applied to the trustee (a human, a technology, a methodology or a concept), can be viewed as an appropriate quantitative characteristic of the propensity of a decision maker to an under-trust or an over-trust judgment and, as a consequence of that, to the likelihood of making a mistake or an erroneous decision. It was the 19th century South Dakota politician Frank Craine who seems to be the first who indicated the importance of an adequate trust in human relationships: "You may be deceived if you trust too much, but you will live in torment unless you trust enough". The analysis in [76] is, in a way, an extension and a generalization of the recent Kaindl and Svetinovic [75] publication, and addresses some important aspects of the HITL problem for safety-critical missions and extraordinary situations. It is argued that the role and significance of trust can and should be quantified when preparing such missions, including healthcare related (such as, e.g., surgical) missions. The author is convinced that otherwise the concept of an adequate trust simply cannot be effectively addressed and included into an engineering or a medical technology, design methodology or a human activity, when there is a need to assure a successful and safe outcome of a particular engineering or a medical effort or an aerospace or a military mission. It has been shown, particularly [76], that the calculated entropy of the DEPDF for the random HCF, when applied to the trustee, can be viewed as an appropriate quantitative characteristic of the propensity of a human to an undesirable under-trust or an over-trust. Captain Sullenberger, the above mentioned hero of the miracle-on-the-Hudson event did possess such a quality. He "avoided over-trust": 1) in the ability of the first officer, who ran the aircraft when it took off La Guardia airport, to successfully cope with the situation, when the aircraft struck a flock of Canada Geese and lost engine power, and took over the controls, while the first officer began going through the emergency procedures checklist in an attempt to find information on how to restart the engines; and 2) in the possibility, with the help of the air traffic controllers at LaGuardia and at Teterboro. He also "avoided under-trust"(as FDR has put it, "the only thing that we should fear, is fear itself"): 1) in his own skills, abilities and extensive experience that would enable him to successfully cope with the situation (57-year-old Capt. "Sully" was a former fighter pilot, a safety expert, an instructor and a glider pilot); that was the rare case when "team work" was not the right thing to pursue; 2) in the aircraft structure that would be able to successfully withstand the slam of the water during ditching and, in addition, would enable slow enough flooding after ditching (it turned out that the crew did not activate the "ditch switch" during the incident, but Capt. Sully later noted that it probably would not have been effective anyway, since the water impact tore holes in the plane's fuselage much larger than the openings sealed by the switch); 3) in the aircraft safety equipment that was carried in excess of that mandated for the flight; 4) in the outstanding cooperation and excellent cockpit resource management among the flight crew who trusted their captain and exhibited outstanding team work (that is where such work was needed and was useful) during landing and the rescue operation; 5) in the fast response from and effective help of the various ferry operators located near the USS Intrepid museum and the ability of the rescue team to provide timely and effective help; and 6) in the good visibility as an important contributing factor to the success of his effort. As is known, the crew was later awarded the Master's Medal of the Guild of Air Pilots and Air Navigators for successful "emergency ditching and evacuation, with the loss of no lives…a heroic and unique aviation achievement…the most successful ditching in aviation history."

We would like to suggest several possible next steps (future work) that could be conducted using, when necessary, simulators to correlate the accepted DEPDF with the existing practice and to make this distribution applicable for the evaluation of the roles of the MWL and HCF not only to the general field of ergonomics science [77], in various HITL related navigation situations, including avionic [78], automotive driving [79, 80], railway obstruction [81], and even outer space related missions [82-85], but to various medical electronic devices and critical healthcare tasks, missions and problems as well. These areas have a lot in common, as well as, of course, numerous differences and quite a few critical specifics.

Acronyms

BAZ=Boltzmann-Arrhenius-Zhurkov (equation)
BIT=Burn-in testing
DEPDF=Double-Exponential-Probability Distribution Function
FOAT=Failure Oriented Accelerated Testing
HALT=Highly Accelerated Life Testing
HCF=Human Capacity Factor
HE=Human Error
HITL=Human-in-the-Loop
MD=Medical Device
MWL=Mental Workload
PDfR=Probabilistic Design for Reliability
PPM=Probabilistic Predictive Modeling
QT=Qualification Testing
SoH=State of Health

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