the newsletter of
RELIABILITY, MAINTAINABILITY, & SUPPORTABILITY

September 2016 • Volume 20 • Issue 3

THIS EDITION

Published Quarterly

Jun Hyong Kim, Ph.D. & Philip Heifetz, MBA

Reliability Management in Precision Medicine

Cara Greene was a toddler when she developed inexplicable coordination problems and muscle weakness. Eventually she stopped walking. None of the doctors she saw had any definitive answers, offering possible causes ranging from neuro-muscular degeneration to auto-immune disease. At the same time, extraordinary advances in genome technology had just started to make it economically feasible to sequence (read) individual genomes. So with all conventional diagnostic paths exhausted, her parents turned to Dr. David Goldstein at the Institute for Genomic Medicine at Columbia with the remote hope that genomics might offer clues as to what was behind Cara's disease. Dr. Goldstein sequenced Cara's genome, along with her parents' genomes, so that he could explore whether inheritance of a specific genetic mutation was somehow linked to Cara's condition. Comparison of the three genomes indeed led to the discovery of a mutation in the vitamin B12 pathway. The Greene's were extremely lucky: a new genomics-based diagnosis suggested a simple therapeutic approach. After a high-dose oral supplement of B12 Cara's condition immediately improved and she was essentially "cured".[1]

This remarkable case is just one example of how Precision Medicine (PM; also sometimes called personalized medicine) is forever changing the way we approach treatment of disease. Many of the most important human diseases result from a combination of genetically determined individual risk factors and environmental influences. Genetic changes can be inherited or accumulated over a lifetime, and interact with environmental factors to produce organismal dysfunction. The promise of PM is that through an understanding of a patient's unique genetic composition and physiological characteristics, clinicians can predict disease risk, diagnose cryptic symptoms, and help select therapeutic strategies tailored to that patient. The most dramatic example of this approach is cancer immune-therapy where a patient's own immune system is manipulated to target cancer cells that are specific to the patient. Recently, clinical trials have demonstrated complete remission in several patients who had failed virtually every other known treatment for their cancer. The revolutionary promise of PM led to President Obama's announcement of the Precision Medicine Initiative (PMI) launch with $215 million in the 2016 budget.[2]

Much of PM is driven by the truly astonishing advances in genome technologies. When the Human Genome Project (HGP) was launched in 1990, the newly developed automated sequencing machines were able to read approximately 600 letters per machine per day. It was a truly ambitious undertaking trying to read 3 billion letters with such technologies. The HGP was completed in 2004 (ahead of projections) with approximately 99% of the genome sequenced at a cost of ~$3 billion. Like the Apollo program,

1 http://newsroom.cumc.columbia.edu/blog/2016/08/09/37011/

2 https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative

Russell A. Vacante, Ph.D.

Different Systems, Common Theme

The two articles published in this issue of the RMS Partnership newsletter are indicative of the topical inquiries I have been receiving increasingly from the national and international RMS community. There seems to be a burst of interest in improving system reliability and safety in disciplines such as medicine, environmental, and transportation, just to mention a few. While much, but not all, of the RMS Partnerships training, consulting and contracting efforts have been focused on defense industry related matters, it has long been recognized by many RMS professionals that reliability concepts and analysis have interdisciplinary applications, irrespective of the overarching industry. That is, the fundamentals of reliability concepts, and other related -ilities such as logistics and sustainability, consist of standard design practices and life cycle principles,

continued on page 10

the HGP spurred on uncountable numbers of other advances, both in engineering and biomedical sciences. The greatest advances came in the sequencing machines themselves. The original automated sequencing machines started out with chemical reactions and detections carried out in vessels at the centimeter scale (10^{-2} m). Repeated advances in miniaturization, integrating technologies from the semi-conductor industry, led to today's Next Generation Sequencing (NGS) machines that carryout chemical reactions and detection at the sub-micrometer scale (10^{-7}m). The San Diego company Illumina (www.illumina.com) dominates 75% of the DNA sequencing market and their latest machines can sequence 400 billion letters per day. This almost billion-fold increase in efficiency over a mere 25 years is unprecedented in human technology. An individual's entire genome can now be sequenced for under $1,000, a 3-million-fold decrease in cost from the HGP, making the core idea of Precision Medicine economically feasible.

While PM holds unbelievable promise for a new age of disease treatment, there remain many challenges ranging from basic sciences, to engineering, to physician training.[3] The basic sciences problem is that we have only begun to scratch the surface of these cryptic relationships between individual's genomes, environments, and diseases. Continued research, especially recruiting very large cases (e.g., the Million Veterans Project[4]), is expected to help make great strides in understanding complex genomic disease risk factors. A separate problem is finding the appropriate treatment regime when precision medicine reveals a possible problem. For example, in cancer, genome sequencing matches uncovered mutations with available drugs (so-called "actionable" mutations) only 25% of the time. The miraculous example noted at the beginning of this article is still frustratingly rare.

Other problems related to process engineering, regulatory frameworks, and physician training all involve a common underlying cause: PM technologies are incredibly complex and constantly evolving. Unlike an out-of-box MRI machine, PM involves a web of many moving parts, from the specialized sample collection process, to complex measurement machines, to high-performance computers and sophisticated data analytics. At the system engineering level, it is an incredible challenge to implement safe, robust, and efficient processes to give doctors information within an actionable window of time. Cancer is one of the areas where PM practice is best developed with several commercial companies already delivering genomic diagnostic products. Yet, it is common to see more than four weeks pass from patient biopsy to results in the hands of the doctor. To quote an anonymous, practicing oncologist: "this genome thing isn't working."

Even when all processes are efficiently executed the results are often a cornucopia of complex information. For example, sequencing a patient's cancer sample typically reveals thousands of mutations. If we are lucky, some of these match known actionable cases. If we are not lucky, we have to narrow the thousands to a few that might be key to treatment and expand the set of possible therapeutics. Additional technologies can be applied, but this requires optimal decision-making for the appropriate next step. Considering all possible actions requires a team of highly trained experts, many of them engineers or information scientists, making on-the-fly decisions. Only a handful of medical facilities in the world have capacities and procedures in place for such team-based approach to PM. What is clearly needed is systems engineering support that helps modularize the complex processes and provides integrated knowledge systems that will scale personalized and precise medicine to everybody.

The complex and dynamic nature of true PM also makes it extremely difficult to regulate. FDA regulations are designed under a model of a static disease-drug relationship. For PM, everything is dynamic. As a small example, when a patient's genome is sequenced, it must be matched against a reference standard through a computational process called "genome alignment." But, the reference standard is regularly updated. Currently, FDA and similar regulatory agencies around the world are struggling with the regulatory framework for PM.[5] Medical Devices model provides rigorous metrics and GMP (Good Manufacturing Practice) but the need to control, document, and validate every process is a huge barrier in a field where the "best practice" may change every few months. Governance under Laboratory Developed Test (LDT) framework provides more flexibility. But, the framework was originally developed for simple laboratory tests and how it should be applied to complex processes like PM is unclear. In some countries a hybrid model is being considered where drug, medical device, and LDT model are applied to different components of PM (e.g., Japan). The problem of regulatory governance of PM is still a work in progress but it is clear that as the use of PM widens new regulatory regimes will be established.

The amount of data generated by genomic sequencing and other measurement technologies is almost incomprehensible—comprising terabytes or more of data per individual patient. Yet for it to be clinically useful, we need to translate this data into simple outputs that drive decision-making. This data translation is handled by sophisticated computer programs using large clusters of high-performance computers. We call these activities

3 http://www.newyorker.com/tech/elements/problem-precision-medicine

4 http://www.research.va.gov/mvp/

5 http://www.fda.gov/ScienceResearch/SpecialTopics/PrecisionMedicine/ucm510027.htm

Precision Medicine Information Systems (PMIS). PMIS involves multiple complicated steps using various (often open-source) programs (see Figure 1), and this is even before application of any sophisticated analytics. The size of the data is so vast that optimal processing on a single machine is simply impossible. Instead, a web of local and internet-based programs is invoked to return specific complex analyses, and the results of these are later recombined to provide a full picture of the situation. Furthermore, virtually all of these programs use other evolving external information sources (e.g., reference genomes). This inter-reliance provides a most daunting challenge when it comes to the task of keeping track of what data underlies any individual result—otherwise known as "data provenance."

How to ensure reliable process practice for PMIS computation and keep track of data provenance is a critical problem. As an example, we analyzed one of the most popular tools called STAR alignment program (doi:10.1093/bioinformatics/bts635). This program, like all programs, has undergone a series of bug fixes and feature updates. When we applied the version 2.3.0 and 2.3.1 to the same dataset we found 42% of the 572 annotated cancer genes with differing results. The clinical impact of such difference is impossible to know a priori: it may lead to misdiagnosis, better diagnosis, or no impact on decisions. STAR is far from alone in this kind of problem. Both commercial and public computational tools have complicated interactions and undocumented impact on diagnostic results. The key is that much of these vagaries are not due to sloppy practices but due to the computational complexity of the problems and the developers' best effort to improve sensitivity and precision. This produces an untenable conundrum: software by its nature must be constantly updated to provide the best practice, yet any change can lead to unanticipated impact on critical clinical decisions. From a regulation point of view, we simply cannot apply something like a GMP framework to constantly evolving technologies.

We propose that the solution to computational problems in PM is to establish a "best practice" standard by which PMIS pipelines' operations are continuously documented at execution. For every PM result, comprehensive provenance should be always available such that anybody can point to a data item and ask "how was this (number) obtained"? Such provenance capture could be used to continuously test or improve a system by associating any results with known processing parameters. When particularly good or bad diagnostic results are found, a physician could immediately retrieve all patients processed with

the same informatics pipeline. Genome Appliances LLC is a pioneer in the field of PMIS reliability, and we have developed a prototype of the first-ever system specifically designed to track data provenance in PM. The PREcision MEdicine Information System Analytics (PREMISA) is an integrated system for insuring reliability of the data underlying PM-based clinical decisions. PREMISA provides 1) diagnostics for PM computational outputs; 2) automatic procedural compliance checks; 3) processing audits; and 4) automated reporting and alerts. The core part of the PREMISA architecture and user interface is shown in Figure 2. PREMISA continually monitors each software component of a client's informatics 'pipeline', such that all run-time provenance is automatically captured and sent to a cloud-based backend database. Customized data models enable users to carry out structured queries. For example, if the clinician discovers a diagnostic problem with a particular version of a pipeline or component therein, PREMISA can immediately provide a list of all affected samples or outputs. And a real-time dashboard continually reports back on all informatics processes being carried out as part of a particular analysis. The result of this is that genomic analyses can be completed faster and more efficiently, with much higher reliability than has previously been possible.

Computation is the backbone of precision medicine. Hundreds of researchers are developing novel analytic tools that helps uncover complicated relationships between personal genetic and physiological information, disease symptoms, and therapeutic targets. However, just as important are the development of systems that help manage this complex information and reliability problems in face of dynamically evolving tools and information sources.

Figure Legends

See figures on following page.

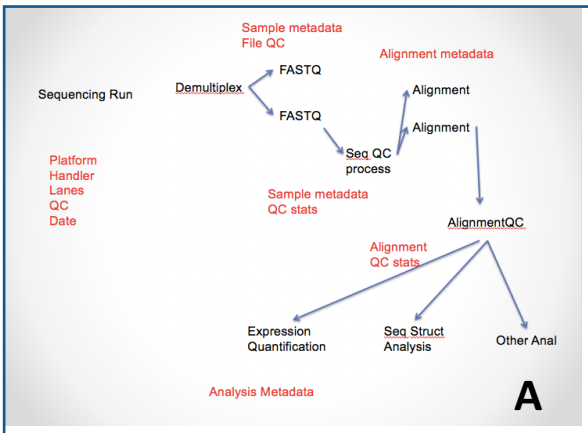
Figure 1: Precision Medicine Information Systems (PMIS) involves an array of programs and a high-performance computing cluster that processes complex genome-scale data. A) Multiple data objects and processing steps are required for deriving human-readable data from a patient. B) Typical PMIS involves multiple computational "pipelines." Example pipeline for quantifying gene expression data from sequencing is shown. C) Complex meta data associated with just one program in a PMIS pipeline.

Figure 2: Overview of PREMISA (Genome Appliance, LLC) system for automatically capturing the computational provenance of Precision Medicine Information Systems (PMIS). A) Architecture diagram. Each program in the client's pipeline is wrapped with an executable that provides identical functionality but reports real-time processing information to local data-logger. The data logger collects all provenance information from every component of the PMIS and sends it to a cloud-based backend that stores the information in a data schema. B) Example browser-based user interface showing run-time information dashboard. C) Example reports and analytics generated by PREMISA. ●

About the Authors

Jun Hyong Kim, Ph.D. *is a Computational Biologist, Bioinformatician, and Genomicist. He has worked at the interface of computing and biomedical sciences for 30 years developing many algorithms and analysis methods. He is also one of the pioneers of single cell biology, measuring genomic information at the level of individual cells. He is currently the Patricia M. Williams Professor of Biology, Adjunct Professor of Computer and Information Science, and Co-Director of Penn Program in Single Cell Biology at the University of Pennsylvania. Dr. Kim received his Ph.D. from SUNY Stony Brook in Theoretical Biology and completed a Postdoctoral Training with Margaret Kidwell at University of Arizona in Genetics. He previously held positions of Assistant and Associate Professor of Biology at Yale University and he was the Founding Director of Ph.D. Track in Computational Biology and Bioinformatics. His honors include, Visiting Fellow at Churchill College and Newton Institute, Cambridge University, UK, Visiting Fellow at the Institut des Hautes Etudes Scientifique, and at the CoMPLEX Institute at University College London. He received the Sloan Foundation Young Investigator Award, Yale Seessel Anonymous Award, and Ellison Medical Foundation Senior Scholar Award. In 2010 he became a J. S. Guggenheim Fellow.*

Philip Heifetz, MBA *is a digital health and life sciences entrepreneur in the Philadelphia region. He has held C-level positions in four different companies where he successfully led operations, deal-making and fund-raising activities. In addition, he is the co-Founder and co-Head of the Philadelphia Health IT Circle, a 700+ member grass roots organization dedicated to growing and nurturing health care innovation in the region. He is also serves on the Innovation Committee at the national level with HIMSS, and he previously served on the WHCMAA board.*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Alignment
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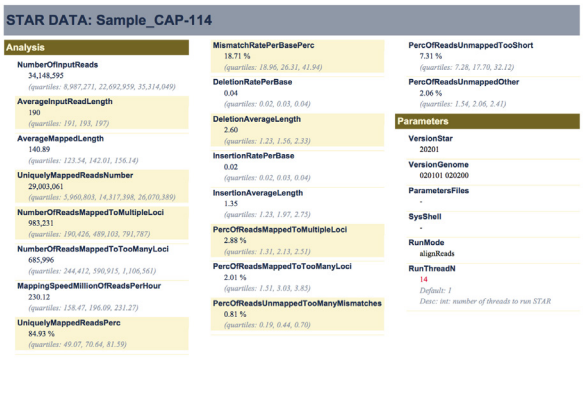
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Analysis
NumberOfInputReads
34,148,595
AverageInputReadLength
190
AverageMappedLength
140.89
UniquelyMappedReadsNumber
29,003,061
NumberOfReadsMappedToMultipleLoci
983,231
NumberOfReadsMappedToTooManyLoci
685,996
MappingSpeedMillionOfReadsPerHour
230.12
UniquelyMappedReadsPerc
84.93 %
MismatchRatePerBasePerc
18.71 %
DeletionRatePerBase
0.04
DeletionAverageLength
2.60
InsertionRatePerBase
0.02
InsertionAverageLength
1.35
PercOfReadsMappedToMultipleLoci
2.88 %
PercOfReadsMappedToTooManyLoci
2.01 %
PercOfReadsUnmappedTooManyMismatches
0.81 %
PercOfReadsUnmappedTooShort
7.31 %
PercOfReadsUnmappedOther
2.06 %
Parameters
VersionStar
20201
VersionGenome
020101 020200
ParametersFiles
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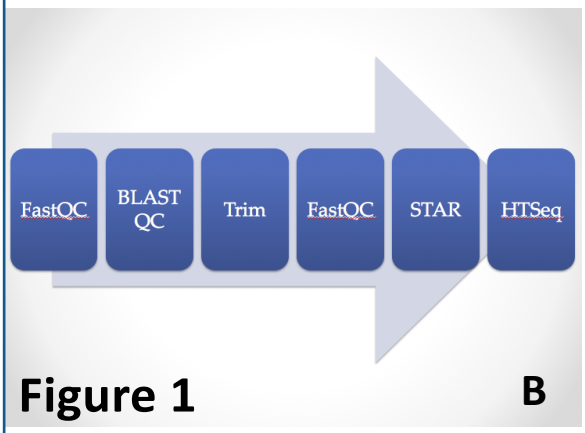
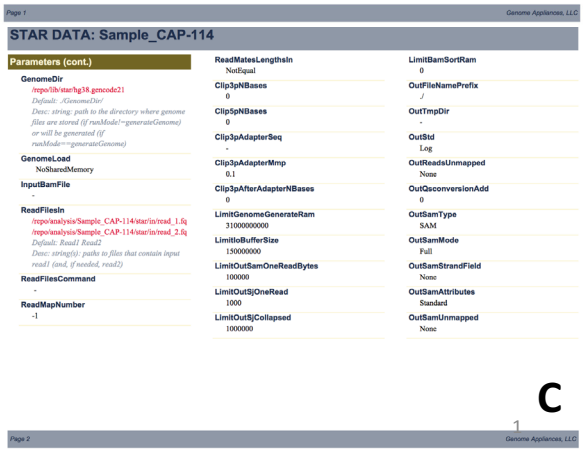
SysShell
-
RunMode
alignReads
RunThreadN
14


FastQC
BLAST QC
Trim
FastQC
STAR
HTSeq
Figure 1
B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Parameters (cont.)
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GenomeLoad
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InputBamFile
ReadFilesIn
ReadFilesCommand
ReadMapNumber
ReadMatesLengthsIn
NotEqual
Clip3pNBases
Clip5pNBases
Clip3pAdapterSeq
Clip3pAdapterMmp
Clip3pAfterAdapterNBases
LimitGenomeGenerateRam
LimitIoBufferSize
LimitOutSamOneReadBytes
LimitOutSjOneRead
LimitOutSjCollapsed
LimitBamSortRam
OutFileNamePrefix
OutTmpDir
OutStd
Log
OutReadsUnmapped
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SAM
OutSamMode
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None
OutSamAttributes
Standard
OutSamUnmapped
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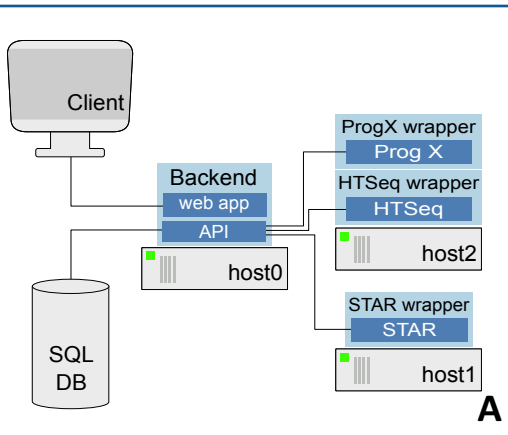
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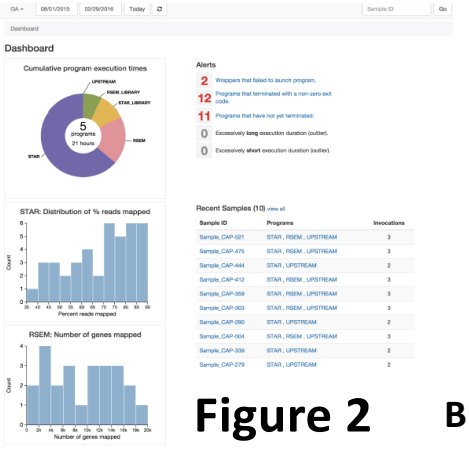
ProgX wrapper
Prog X
Backend
web app
API
HTSeq wrapper
HTSeq
host0
host2
SQL
DB
STAR wrapper
STAR
host1
A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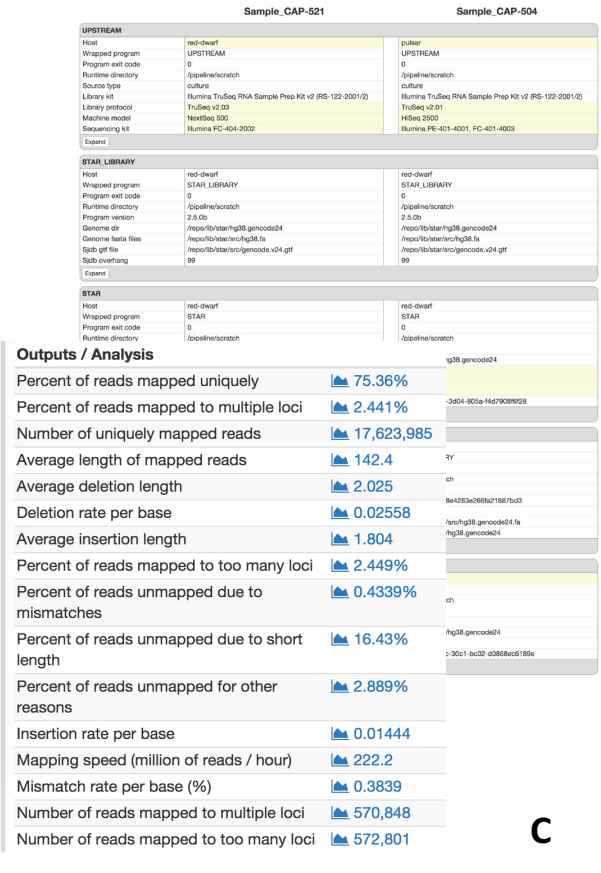
Cumulative program execution times
Alerts
STAR: Distribution of % reads mapped
RSEM: Number of genes mapped
Recent Samples (10)
Figure 2
B


Sample_CAP-521
Sample_CAP-504
UPSTREAM
STAR_LIBRARY
STAR
Outputs / Analysis
Percent of reads mapped uniquely 75.36%
Percent of reads mapped to multiple loci 2.441%
Number of uniquely mapped reads 17,623,985
Average length of mapped reads 142.4
Average deletion length 2.025
Deletion rate per base 0.02558
Average insertion length 1.804
Percent of reads mapped to too many loci 2.449%
Percent of reads unmapped due to mismatches 0.4339%
Percent of reads unmapped due to short length 16.43%
Percent of reads unmapped for other reasons 2.889%
Insertion rate per base 0.01444
Mapping speed (million of reads / hour) 222.2
Mismatch rate per base (%) 0.3839
Number of reads mapped to multiple loci 570,848
Number of reads mapped to too many loci 572,801
C

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Dev Raheja & Maria C. Escano, MD

Using System Engineering Principles to Decrease Preventable Deaths

This article was originally published in the Journal of System Safety, September 2016 issue. Reprinted with permission.

The popular theory that human error, such as making the wrong diagnosis, marking the wrong body part for surgery, or prescribing the wrong medication, causes harm to patients may not always be completely true. According to the system safety theory[1] and the Swiss Cheese theory for healthcare[2] at least two things have to go wrong for harm to occur. The primary cause usually is a poorly designed care system that allows human errors to happen. Each weakness in the system is called a "hazard." The human error is a trigger event, which finally results in the harm. Therefore, human error can be a symptom of a poorly designed system, not always necessarily the primary cause for harm. Taking the analogy of a gun, the loaded gun is a hazard, pulling the trigger can result in harm. If the gun is not loaded, the trigger (human error) is not an issue. In the examples above, an initial error in diagnosis can be corrected with diagnostic tests and laboratory findings, marking the wrong body part for surgery can be corrected with patient and staff verification and time-outs and even if the wrong medication was prescribed, this error can be caught with pharmacy and nursing cross-checks.

Current Practices in the Development of Robust Systems

Problem solving starts with a series of questions. The answers lead to hypotheses testing. We call it the scientific method or evidence based practice. But this practice is sometimes time consuming and does not always address all the causes of system failures. The health care system involves the integration of interactions among clinical care staff, processes, detailed procedures, electronic medical records, patient participation, facility design, environment and anything else that can influence the safety and reliability of care.

The system requirements can be flawed. They sometimes fail to identify the key components, including what the system "shall not do." For example: In a California hospital, a radiology technician was delivering a high dose of radiation to a patient as part of a therapeutic regimen. He did not set the level of radiation correctly after the regimen. For six months, most of the patients were harmed from high radiation. The system requirement was obviously flawed. It depended on the skill and attention of the technician to select the right levels instead of automatic reset to a safe radiation level after each use. The system did not specify that "patients shall not get the wrong level of radiation under any circumstance."[3] One can say that hospitals are not doing enough to prevent harm to patients because of lack of systems-based thinking.

Another problem is called the "Groupthink." During the process of breaking down the process into meaningful questions, the team members often tend to agree with each other in the interest of time and cohesiveness. They may fail to challenge the assumptions and soundness of the improvements.

Are We Creating Effective Systems to Prevent Errors?

In an article by the British Medical Journal, more than 250,000 deaths due to medical error occur in the United States alone. This article noted that what's more alarming than the news is that a profession dedicated to making us better is doing the exact opposite (albeit by accident), resulting in patient deaths."[4] In the article, it recognizes that hospitals are still far from being highly reliable. Medical education usually does not cover the theory of reliability. The Institute of Healthcare Improvement (IHI) has taken the initiative to apply industry methods of system reliability to healthcare systems. It defines reliability as "failure-free performance over time." This concept is simple and aims to have no failures over an extended time period in spite of variability in the patient environment.

What Can Be Done to Revolutionize the Change?

Several suggestions have been published. Some hospitals and healthcare leaders currently experience serious safety failures as routine and inevitable parts of daily work. To prevent the harm that results from these failures, which affects millions of Americans each year, major changes involving leadership, safety culture, and robust process improvement are necessary. This framework is designed to help hospitals make progress toward high reliability. The achievement of extremely high levels of safety need to be maintained over long periods of time and comparable or higher to that demonstrated by the commercial air travel, nuclear power, and amusement park industries. Understanding these challenges involve the realization that human error is inevitable. Although we cannot eliminate human error, part of the solution is to design

1 Raheja, D., and Allocco, M., *Assurance Technologies Principles and Practices*, Wiley 2006

2 Department of Community and Family Medicine website, *Anatomy of an Error*, Patient Safety-Quality Improvement, Duke University School of Medicine, no date given, downloaded on July 1, 2016 from http://patientsafetyed.duhs.duke.edu/module_e/swiss_cheese.html

3 Zarembo, Alan, *Cedars-Sinai radiation overdoses went unseen at several points*, Los Angeles Times, October 14, 2009, http://articles.latimes.com/2009/oct/14/local/me-cedars-sinai14

4 Wong, Michael, *What Can Be Done about Medical Errors?*, TheDoctorWeighsIn.com, June 21, 2016, downloaded on July 1, 2016 from https://thedoctorweighsin.com/what-can-be-done-about-medical-errors/

safer systems mitigating its frequency, visibility, and consequences. Another article recommends strategies to reduce death from medical care which includes three steps: 1) making errors more visible when they occur so their effects can be intercepted; 2) having remedies at hand to rescue patients; and 3) making errors less frequent by following principles that take human limitations into account.[5] There are many ways to improve patient safety such as the development of a process improvement program that incorporates a system to capture and track the data associated with medical errors, which will, in turn, drive the creation of better practices to improve patient safety. Sadly, there is less room for innovation in the business of health. The high litigation environment sometimes discourages openness in order to welcome errors as opportunities for growth.

System Engineering: The Most Effective Tool

We need to use systems engineering approaches from high performance industries in healthcare if we want to make dynamic improvements. In 2005, the National Academy of Engineering (NAE) and the Institute of Medicine (IOM) highlighted the need for a systems approach to the health care system and the application of systems engineering tools to improve health care.[6]

Systems engineering uses a variety of methods to model, analyze, predict, improve, and optimize the performance of complex systems, sometimes supported by informatics to harness information in new and innovative ways. Each IOM dimension of the care system—efficiency, effectiveness, safety, access, equity, and patient-centeredness, can be improved by systems engineering. Despite the NAE/IOM's recommendations, only narrowly focused efforts to implement these recommendations have occurred, and no substantive systems approach has gained traction or success.[5] The authors of this reference written in 2013 add that as a result, we contend that the health care system has not been adequately addressed from a systems perspective at all.

Later in 2014, the President's Council of Advisors on Science and Technology (PCAST) in May 2014 wrote a report[7] that systems engineering, widely used in manufacturing and aviation, is an interdisciplinary approach to analyze, design, manage, and measure a complex system, but in spite of excellent examples, systems methods and tools are not yet used on a widespread basis in U.S. health care.

Here's the bottom line. Healthcare delivery is so far behind and will take years to improve its systems to prevent human errors resulting in patient harm. According to the famous world quality guru Dr. Edward Deming, 85% of the responsibility for good systems belongs to senior management, not the doctors and nurses! But we believe that the responsibility belongs to all of us. We all play a role and should make every effort to contribute to make our healthcare system better. ●

About the Authors

Dev Raheja, *MS, CSP, risk management consultant and author of the books Assurance Technologies Principles & Practices, and Design for Reliability, is a world leader in system reliability engineering, quality management, and system safety engineering. He has conducted training in several countries and at several universities: (George Washington University, University of Alabama, University of Maryland, and UCLA). He served as Associate Professor at University of Maryland for its PhD degree program in Reliability Engineering.*

Dr. Maria C. Escano *completed her medical degree at University of Miami School of Medicine. She received her post-graduate training at Columbia University/New York Presbyterian Hospital in New York City and St. Agnes Hospital in Baltimore, Maryland. She completed her advanced trauma surgery fellowship at R. Adams Cowley Shock Trauma Center at the University of Maryland. She has been a regular contributor to the Journal of Patient Safety for many years and has presented across the country on various topics advocating systems and patient safety initiatives. Dr. Escano is also an extensive traveler, having forged friendships across six continents.*

INTERESTED IN CONTRIBUTING?

If you are interested in sharing your knowledge in future editions, please contact Russ Vacante at:

president@rmspartnership.org

Articles can range from one page to five pages and should be of general interest to our members.

5 Wong, Michael, *What Can Be Done about Medical Errors?*, TheDoctorWeighsIn.com, June 21, 2016, downloaded on July 1, 2016 from https://thedoctorweighsin.com/what-can-be-done-about-medical-errors/

6 Ravitz, Alan,D., et al, *Systems Approach and Systems Engineering Applied to Health Care: Improving Patient Safety and Health Care Delivery*, Johns Hopkins APL Technical Digest, Volume 31, Number 4, 2013, http://www.jhuapl.edu/techdigest/TD/td3104/31_04-Ravitz.pdf

7 The President's Council of Advisors on Science and Technology, Report To The President, Better Health Care And Lower Costs: Accelerating Improvement Through Systems Engineering, May 2014 https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_systems_engineering_in_healthcare_-_may_2014.pdf

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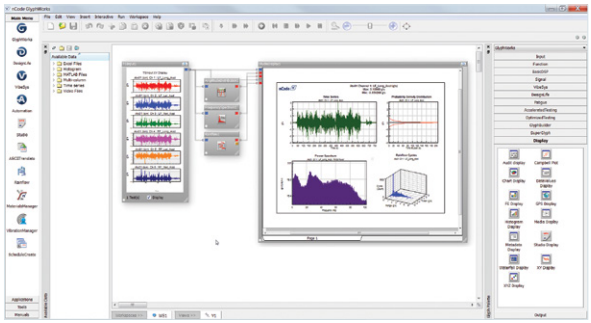

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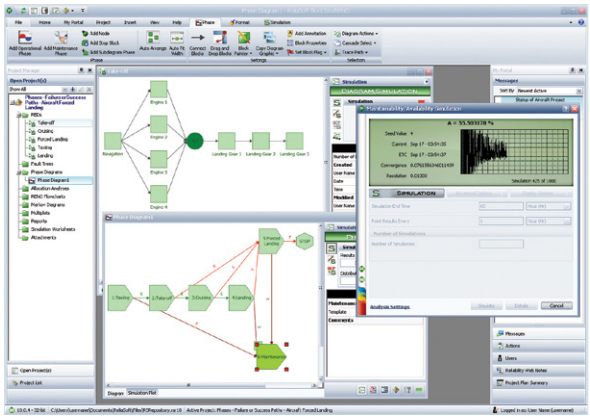

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Editorial, from page 1

requiring a common, overarching technical and managerial training.

Medicine is a complex professional field that, increasingly, can use core reliability training. This field, with its increased use of technical devises to save or prolong people(s) lives and minimized patient risks, evokes a full understanding of the reliability of such devises and their various applications together with their long-term integration consequences. For instance, the reliability of implanted heart, limb, hearing and eye transplant devices should be fully understood with respect to life cycle reliability (how long the device will last), its failure mechanisms, maintenance and support requirements and its impact on a patient's longevity. There reportedly are millions of technical devices inserted into human bodies that the manufactures and doctors have little or no idea of if and when they will require replacement, the impact that such devices have on a person's overall functional health nor the health consequences and risk associated with replacement surgery.

There are, however, professional reliability tests and protocols that can be employed to help minimize the risk related to technical implant devices. There are design parameters, test methods and procedures that are available that could improve the effectiveness of such devices that can, for instance, identify failure modes and frequency. Life cycle testing and analysis of transplant and related mechanical devices would be done in a laboratory as opposed to being conducted within patients. The implementation of reliability methods and procedures can be very useful in understanding the durability of mechanical medical devices beyond the five-year longitudinal studies conducted after they are inserted into patients. At the end of it all, once a device is inserted in to a patient the need for any corrective action should be remote.

With respect to environmental reliability issues the foremost and often newsworthy subject is the assurance of safe and plentiful drinking water. We want to greatly reduce the risk of contamination and increase/stabilize its availability for human consumption. This requirement is becoming significantly more important for our world in which the population is rapidly increasing and the desire and availability for clean air and water has the chance of becoming a menacing future global challenge.

Many in the scientific community see a shift from major wars over oil to worldwide struggles for/over clean air and water. Reliability concepts, tools and technologies can be utilized to address such challenges while helping to ensure that present and future generations have clean air to breath and clean, safe water to drink. Among them are standardized reliable measurement tools that can be increasingly used to monitor and measure air and water quality. There are technical and organizational changes that can be implemented to reduce the streams of pollutants into our air and water, as well as, reliability models that can effectively contribute towards the management of land resources and farming methods that can reduce the amount of waste products and chemical release into our streams, rivers and air. Reliability professionals can readily, with the use of advanced technologies, increase the availability of portable water in arid regions and to revitalize once fresh, now polluted water and air resources.

The design of safer and more efficient transportation systems—self-driving passenger vehicles—using state-of-the-art technology recently has been in the news recently. For this self-driving technology to properly work and gain wide public acceptance it has to function as well as, or better than humans behind the steering wheel. A fundamental question that requires a very precise and timely answer is while traveling down a road at 60 mph with your family in a vehicle what is the acceptable level of self-driving devices reliability. Is it 80%? 90%? 99%? This is both a cultural and a technical issue. Culturally, because it will be the public's level of comfort that will determine the acceptability of such technology. On the other hand, it is the reliability professional that has the knowledge and capability of meeting the design expectations and requirements regardless of the reliability metrics found to be publicly acceptable.

By adopting a systems engineering approach, with high emphasis on total life cycle reliability design, the accident risk to passengers in self-driving vehicles can be predictably reduced. Reliability professionals are keenly aware that manufactured products often reflect trade-off reliability requirements in favor of cost savings. In the case of self-driving vehicles inappropriate trade-offs between reliability and company profits certainly will contribute to the viability of this technology. It is the reliability engineer's tasks/burden to be part of the design total life cycle team. They have the knowledge and tools to advance state-of-the-art, self-driving technology. The motto "pay now or pay more later" is very applicable with respect to the successful implementation of self-driving vehicles. The reliability profession is in the proverbial "driver(s) seat" with respect to creating highly reliable self-driver vehicle technology and informing the market place when manufacturers willingly sacrifice reliability requirements in favor of larger profits.

Technological advances hold great promise towards improving our quality of life in an increasing number of disciplines. However, there needs to be an accommodating insatiable interest among professionals and the general public to understand the long-term impact of such technology. Thankfully, such inquiries are related to reliability issues, some of which were discussed above. The best source for providing answers to such questions is the reliability professionals. The proper and continuous training of these individuals on an annual basis is critical given the rapid turnaround and introduction to/of new technologies! ●

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