PRIMER FOR MANAGEMENT pdf

1: www.enganchecubano.com - Configuration Management Primer for Project Managers

*Primer for Management 2ND EDITION on www.enganchecubano.com *FREE* shipping on qualifying offers. Primer for Management 2ND EDITION by Michael P. Dumler. South-Western Publishing Co.,*

Fewer variables and Continual Improvement The risk management process should be appropriately documented and verifiable. Procedures should include steps that have been designed to produce documentation that provides evidence of: The risks considered The roles of those assessing the risk factors The outcome of the assessment; made directly relevant to the risks considered and the mitigation steps taken An explanation of the decision made, including decisions that led to no action When Do We Manage Risk? Risk management programs and tools can be developed for each product or process and each decision type, in all phases of the product lifecycle, from development through change management. It can be usefully applied integrated with existing quality systems for facility systems management, materials management, production, laboratory controls, packaging and labeling as well as regulatory activities. An example of when integrating Risk Management tools into existing Quality Systems can be useful: How Do We Manage Risk? Identify the Risk Risk Analysis Managing risk begins with conducting risk analysis. Risk analysis is a systematic proactive identification of the specific sources of harm hazards and to estimate the risk, related to the situation at hand, with the ultimate objective of mitigating or eliminating the risk. The first step in the process is the analysis of potential risks: What can go wrong? What are the consequences if something does go wrong? This begins by proactively defining every way that the product or process could fail, and identifying the potential root causes of that potential failure mode and predicting the consequences impact with each potential failure mode. When the risk identification component of the program is being developed, the following should always be considered: How will failure mode information and potential risk be used by the decision makers? Who will the decision makers be, and what will the program need to provide them? How will risk management decisions impact future options for risk management? How do we ensure that the process repeats itself? How will identified risk be documented? What will the outcome of this step look like? The level of scientific knowledge of the processes involved in the product lifecycle that would be required to identify and assess and mitigate see steps 2 and 3 risk the level of scientific understanding of how manufacturing process factors affect product quality The sources of data within the company that could provide the necessary technical information e. Risk Assessment and Evaluation Once a list of identified risks has been completed, the program should require identification of team resources, providing a method of selecting team members with the appropriate expertise to fully execute the upcoming assessment. This step of the process should also require the clear identification of a team leader. Once a list of potential root causes of potential risks failure modes has been generated, and an appropriate team assembled, the next step is the assemblage of background information and data on the failure mode. This information should include: Conditions that would cause the failure and the likelihood of their occurrence probability Harm that would be caused by the failure mode impact to human health severity This step requires that the team assess and evaluate each identified risk of failure, in context with the impact statements. Risk evaluation compares the estimated risk against given risk criteria using a quantitative or qualitative scale to determine the significance of the risk. Once the significance is determined, risks can be prioritized in accordance with the qualitative scale. Once risks are prioritized, mitigation plans and deliverables can be developed with regard to priority; that is, risk factors, together with significance of impact, can be quantitatively prioritized so that the largest risk factors can be dealt with first. This entire process should be documented. The FMEA ,in simple terms, is a matrix document that by product or process, indexes all identified potential failure modes, supplemented with quantified or qualified impact statements. FMEAs should be formalized, reviewed, approved, and controlled. The FMEA should be considered and treated as a living document. Theoretically integrated with other quality systems all driving toward continual improvement, it should diminish in size as time moves forward. If used appropriately, it will continue to be revised after its initial production and then will be fed by all of the existing monitoring systems, including CAPAs, change control, complaints, product and manufacturing failures. Some examples of using the FMEA

in an integrated fashion moving toward continual improvement: Hopefully, as you begin to see how risk management integrates with other quality systems, it will make the value of the tool easier to see. It is critical to note, when developing any quality system, that each must produce output that is used as input to another system. Together, they should systematically pay information forward, funneling the knowledge routinely gained over time into each other allowing each system to achieve some measure of improvement, based on knowledge gained during execution of another system. Controlling and Mitigating Identified and Assessed Risk Once risks have been identified, assessed, prioritized and documented, it is time to develop action plans designed to reduce, mitigate or hopefully eliminate identified risks. Remember, this is why we began the process. Unless we develop meaningful action plans, and execute them, we wasted our time with steps 1 and 2. Each action taken has the same objectives: Reduce risk reduce the probability of occurrence Mitigate risk reduce the severity of harm ELIMINATE risk This step of the process should be executed by a well- qualified, cross- functional team, and together, with a deep knowledge of the technologies and products, they should ask themselves: What it would take to mitigate or reduce each of the identified risks failure modes? Are there options for mitigation and control? Will there be an impact on future options if we implement these options? Once this decision-making process is completed, formal plans should be developed to implement all mitigation, reduction or elimination plans. The most commonly overlooked element in this process is documentation justifying the actual decision-making progress. It is not enough to document the risk and decisions made; we have to produce documentation that explains how the decision was reached, who was involved and why they feel this is an appropriate path. This is especially critical when the decision is to accept risk. Communicating Risk Risk communication is the exchange or sharing of information about risk and risk management between the decision maker and other stakeholders. The information can relate to the existence, nature, form, probability, severity, acceptability, treatment, detectability or other aspects of risks to quality. The communication among stakeholders concerning identified risk, assessed risk and risk mitigation decisions can be achieved through existing channels, as long as it achieved. While for the purposes of this blog, we chose to represent these actions in a step-wise fashion, it is important to note that at times, it may make sense to execute steps three and four concurrently. That is, to communicate known risk as soon as possible, which is partially accomplished upon issuance of the initial FMEA. The most critical component of risk communication is the realization that everyone involved in the production, testing and distribution of the product must be made aware of all known risks. Monitoring Risk Like many of the components of quality systems, risk management processes are meant to be dynamic and iterative; they are not designed to be executed only once. Each quality system is meant to interact with every other, on a routine basis. They are meant to strengthen the original controls required by the cGMPs, by not only assuring control, but also by promoting improvement. Quality risk management processes, when integrated with other existing quality systems, should contribute to the overall knowledge base, providing the benefit knowledge to all other quality systems, including future risk management decision cycles. This integration of the risk management process with all other quality monitoring systems will enhance the overall knowledge base and promote continuous improvement. The Integrated Process The following illustration provides a view of the steps while allowing visualization of the living nature of the process. Summary Summarizing this topic is perhaps best done with a simple list of takeaways: Technical experts should manage and execute the risk management process. Risk management is a dynamic, iterative, interactive component of the quality systems. FMEAs are living documents; if they are part of a well-designed system, they will diminish in size overtime. The choice to accept risk is viable, if justifiable. Choosing to not communicate risk is choosing to not manage risk.

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2: Content Marketing and Management Primer for

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Presenting with a wide spectrum of multisystem involvement, medical management for some individuals is complex. This review of literature and expert opinion aims to provide medical guidelines for care of individuals with Loeysâ€”Dietz syndrome. Genet Med 16 8, â€” No specific clinical criteria exist, as the diagnosis is confirmed by a molecular test. This narrative review will describe the classification of LDS, genetic etiologies, cardinal clinical manifestations, and best-evidence management recommendations for the panoply of serious sequelae associated with this syndrome. Experts from the various fields who manage the various phenotypic manifestations of this syndrome were included in the literature review and description of best practices. This will alert clinicians caring for these patients to the need for specialized patient counseling and management and highlight the evidence-based expansion of the clinical spectrum of LDS to include patients with minimal or no dysmorphic features. Such reasoning and practices have proven productive in the diagnosis and care of patients with Marfan and vascular Ehlersâ€”Danlos syndromes. The size of the microdeletion may impact clinical presentation of these individuals, especially the presence of developmental delay. Mutations in all four of these genes have been associated with thoracic aortic aneurysm and dissection category of disease, though this probably represents the mildest end of the Loeysâ€”Dietz spectrum. These medical guidelines reflect the current literature and expert knowledge both generalized and specific to all four types of LDS, even though most of the literature so far has focused on LDS 1 and LDS 2. Clinical Manifestations and Management Recommendations, by Organ System Cardiovascular Rapidly progressive aortic aneurysmal disease is a distinct feature of LDS, requiring close monitoring. Several reports show successful vascular interventions with low rates of intraoperative mortality as compared with other connective tissue disorders with pronounced vascular friability. Minimally, this should occur yearly but may require more frequent imaging 13 Table 2. These cardiac features should be managed per typical protocols. Reported left ventricular hypertrophy was typically mild to moderate, mainly concentric, and occurred in the absence of aortic stenosis or hypertension. The decision to undergo aortic surgery is typically based on the absolute dimension of the aorta, rate of progression, valve function, severity of noncardiac features, family history, and information about genotype 1 , 13 Table 3. Unlike the increased risk of aortic dissection at or above the 5. For adults with LDS 1 or 2, this includes surgical repair of the aortic root once the maximal dimension of the aortic root reaches 4. Valve-sparing surgery is recommended to avoid the need for anticoagulation. For example, at Johns Hopkins, among patients who are on aggressive medical therapy, regardless of craniofacial severity, we are attempting to delay surgery until the aortic annulus grows to 2. In the absence of a rapidly growing aorta, allowing the aortic root dimension to approach the 4. Valve-sparing surgery may be contraindicated in the presence of leaflet fenestrations and asymmetry, acute aortic dissection in unstable patients, significantly enlarged root with leaflet irregularities, or bicuspid aortic valves with extensive calcification or dysfunction. Aneurysmal disease may present distally to the graft and in the aortic arch over time, and it is probably unrelated to the original procedure and due to underlying progression of LDS vascular disease. This raises the question of possible interventions including complete resection versus more conventional resection of the underneath side of the arch at the time of aortic root replacement. In children with severe disease who may have diminished ventricular function, this type of prolonged procedure should be avoided or considered with caution because of the requirement of prolonged cross-clamp time. Postoperative echocardiography at 3- to 6-month intervals is recommended for 1 year after surgery, and 6 months to 1 year thereafter. There has been one report of secondary surgery for revision of coronary buttons for aneurysmal dilation. Ultrahigh dosing of newer-generation angiotensin receptor blockers may be considered in patients with severely progressive vascular disease even on optimal losartan dosage H. Prophylactic medication use should be considered for individuals with LDS without aortic enlargement if they present with a family history

of LDS with aortic enlargement or if the same mutation has been previously seen with vascular disease. Exercise restrictions to reduce stress on the aortic and arterial tissue include avoidance of contact or competitive sports, isometric exercises sit-ups, push-ups, pull-ups, or weight lifting , and exercising to the point of exhaustion. Diagnostic or baseline vascular imaging through magnetic resonance angiography or computerized tomography angiography with three-dimensional reconstruction of the head, neck, chest, abdomen, and pelvis should be performed to assess for aneurysms throughout the aorta and arterial tree and arterial tortuosity Table 4. Aneurysmal disease including dissection is not limited to the aortic root and has been reported in all other portions of the aorta and arterial branches of the head, neck, and thoracic and abdominal aorta. Full vascular imaging should be performed on initial evaluation and at about a 2-year interval if there are no identified aneurysms or dissections H. Table 4 Open in a separate window Both magnetic resonance angiography and computerized tomography angiography technology are useful surveillance tools, but the trade-offs to consider include the risks of exposure to ionizing radiation, anesthesia, and different challenges to interpreting tortuous arteries or irregular anatomy versus aneurysm. Regardless of imaging technique utilized, the goal is obtaining serial measurements of all portions of the aorta and arteries. Arterial tortuosity can be generalized but is most typically observed in the neck vessels and has been reported in all types of LDS. The presence of tortuous arteries may complicate the interpretation of artery measurement. It has been reported that increased vertebral arterial tortuosity measured by magnetic resonance angiography is a marker of adverse aortic outcome. Additionally, pseudoaneurysms post surgery may be underappreciated in this patient population. This evidence suggests that individuals should be aggressively monitored postaortic dissection in the short days and long months and years term for progressive aneurysm growth within the dissection. Typical postdissection imaging should occur at 1, 3, 6, and 12 months and yearly thereafter. Concerns have been raised about using thoracic stent grafts in patients with genetic aortic aneurysm syndromes, including LDS. Open repair of descending and thoracoabdominal aneurysms is preferred because endovascular repair may result in late failure due to continued dilation of fixation zone or persistent perfusion of the false lumen. Stent-graft therapy may be justified in descending thoracic aortic rupture or to alleviate malperfusion syndromes such as recalcitrant hypertension after renal artery malperfusion secondary to acute dissection. With the likelihood of repeat surgeries, preference should be given to uncovered stents or bare metal stents because some stent types may cause complications in future surgeries, for example, deformation during cross-clamping. Retrograde dissection in patients with LDS has not yet been described in the literature. However, a study from China examining stent-graft repair of acute type B dissection demonstrated that retrograde dissection was the main complication of stent grafting in individuals with Marfan syndrome. Aneurysms in the abdomen and lower extremities have also been reported. Bilateral common iliac artery aneurysm repairs have been performed through both open and stent-graft repairs. Surgical intervention for visceral or iliac arteries should be pursued in rapidly expanding arteries or when arterial size exceeds two to three times the expected arterial diameter. Optimal neurovascular surgical strategies have not been developed. It is uncertain whether there needs to be a lower threshold for treating intracranial aneurysms in individuals with LDS as opposed to those in the general population. Endovascular strategies in this area have been successfully performed on saccular aneurysms. A clear understanding of the unique anatomy in individuals with LDS is crucial prior to surgical or endovascular intervention. Tortuosity of arteries and distal aneurysms, especially in access arteries, may impact surgery plan and choice of endovascular devices. Additionally, although the presence of dural ectasia does not contraindicate lumbar cerebrospinal fluid drainage for spinal cord protection during thoracoabdominal aortic aneurysm repair, a dural leak after drain removal may require epidural blood patching J. General strategies for vascular or endovascular surgery in LDS should include: Experienced anesthesia team with ultrasound-guided access for central lines given cervicovertebral arterial tortuosity. Strict hemodynamic control during surgical clamping or intra-arterial catheter manipulation to reduce iatrogenic dissection. Frequent postoperative monitoring in intensive care unit or intermediate care unit. Multiple surgical case reports suggest the complexity of aneurysmal disease in LDS and the need for personalized surgical strategies. Physicians should compare the benefits and limitations of open, endovascular, and hybrid repair, keeping in mind vascular tortuosity especially of the aortic arch and thoracoabdominal aorta

that may affect security of endovascular devices , past repairs, aberrant or multiple arteries e. Orthopedics Skeletal features in all types of LDS can show overlap with Marfan syndrome, including pectus deformity, scoliosis, and flat feet. Height and proportions are typically within the normal range, though evidence of skeletal overgrowth may be represented as arachnodactyly and pectus deformities. Extremity contractures in conjunction with joint hyperextension are unusual in the general population but common in LDS. Recommended management for orthopedics is summarized in Table 5. Table 5 Open in a separate window Many patients with talipes equinovarus respond well to stretching if the deformity is mild. Ponseti casting should be considered in moderate-to-severe cases P. Surgery is typically not recommended because it often results in overcorrection hindfoot valgus. Patients should be assessed for cervical spine abnormalities, subluxations, or instability, using flexionâ€"extension X-rays of the cervical spine. The frequency of repeat imaging has not been specifically identified for children. One recommendation is to perform imaging every 3â€"5 years during growth and after any surgery on the adjacent region of the spine P. Arthrodesis has been performed successfully for a variety of cervical spine malformations. Scoliotic and kyphotic curve patterns have been reported and should be treated per typical protocols. Spondylolisthesis may be more likely to progress in patients with LDS than in the general population and should be monitored at least once per year until skeletal maturity. Patients with LDS typically tolerate spinal surgeries, though delayed bone healing has been reported likely due to lack of fixation of pedicle screws. If concerns arise, Trendelenburg positioning should be used. Nutritional optimization should occur before any surgical intervention. All orthopedic concerns should be followed by an orthopedic surgeon and treated per typical protocols. Pes planus is typically associated with inward rotation of the ankles and can contribute to leg fatigue, muscle cramps, or difficulty with ambulation. Some individuals respond well to hard-soled inserts for support. Surgery is typically not indicated unless significant pain, calluses, or bunions are occurring. Orthotics may also be a consideration for these indications. Osteoarthritis is a significant feature in LDS 3, and first reports of individuals with SMAD3 gene mutations were described as aneurysms-osteoarthritis syndrome. Disk degeneration, meniscal lesions, and osteochondritis dissecans have been reported at early age of onset earliest age, 12 years. However, reports of LDS 4 have not described prominent degenerative joint disease. The skeletal phenotype related to low bone mineral density and skeletal fragility fractures in young individuals has been reported in patients with LDS 2. Patients with LDS have a higher incidence of fractures. Individuals should be counseled about low bone mineral density and higher risk of fractures. Dual-energy X-ray absorptiometry scans should be considered in the presence of fractures without significant trauma. However, dual-energy X-ray absorptiometry scans in children present a challenge because they are often difficult to interpret and may require serial imaging to track changes. Osteopenia or osteoporosis may become increasingly important in this aging population. Currently, the effectiveness and outcome of bisphosphonate therapy in this population is unknown. Allergy LDS has been associated with a high prevalence of immunologic features including asthma, food allergy, eczema, and allergic rhinitis. Symptoms range from acute, life-threatening reactions to more chronic gastrointestinal symptoms. Antihistamines should be used to treat cutaneous or milder reactions, and Epi-Pens should be retained only for life-threatening reactions because they rapidly constrict blood vessels and could be harmful for individuals with underlying vascular disease. An increased prevalence of asthma, allergic rhinitis, and eczema is also evident in LDS, consistent with an overall increased risk of allergic disease in this syndrome. Sinus disease and ear infections may indicate mucous buildup secondary to allergen exposure, as well as altered craniofacial anatomy.

3: Loeysâ€“Dietz syndrome: a primer for diagnosis and management

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5: Risk Management: A Primer for Lean Quality Assurance

Configuration management grew out of several industries, principally aerospace. They dealt with huge bill-of-materials hierarchies, including drawings of each part and assembly. That led to problems of how a revision to one part might necessitate a corresponding revision to another interlocking part.

6: Resources Â» www.enganchecubano.com

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development of a stand-alone primer that outlines a strategy for effective utility management. MAY JUNE Effective Utility Management: A Primer for Water and Wastewater Utilities is released.

9: Premier Community Management (AZ) - Home Page

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