

Clinical Measure of Cervical Movement Sense Changed

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Description

Root Cause Analysis (RCA) is a method of problem solving in science and engineering that is used to identify the root causes of faults or problems. It is used in industrial process control, IT operations, manufacturing, telecommunications, accident analysis (e.g., in aviation, rail transport, or nuclear plants), medicine (for medical diagnosis), the healthcare industry (e.g., for epidemiology) and other fields. Because it requires an understanding of the underlying causal mechanisms of the potential root causes and the issue, root cause analysis is a type of deductive inference. In most cases, RCA is used as input into a remediation process in which corrective measures are taken to stop the problem from happening again. This process has a variety of names depending on the application domain.

Imagine an investigation into a machine that stopped because it was overloaded and the fuse blew. The investigation reveals that the bearing in the machine was not sufficiently lubricated, so the machine was overloaded. The investigation continues and it turns out that the automatic lubrication mechanism had a pump that was not pumping enough to provide adequate lubrication. The pump's shaft appears to be worn after investigation. When the reason for the worn shaft was looked into, it turned out that there wasn't enough of a mechanism to keep metal scraps from getting into the pump. Scrap was able to enter the pump as a result of this.

Root Cause Analysis

Therefore, the potential for metal scrap to contaminate the lubrication system appears to be the problem's underlying cause. If this issue is fixed, the entire sequence of events won't happen again. If there is no filter to stop the metal scrap from entering the system, the real problem may be a design flaw. Or, if it has a filter that was blocked because it wasn't checked on a regular basis, the real problem is a problem with maintenance. These contrasts with an investigation that fails to identify the underlying cause: The machine will probably be able to resume operation for some time after the fuse, bearing, or lubrication pump are replaced. However, there is a possibility that the issue will simply reappear until the underlying cause is addressed.

Cost-benefit analysis is not included in the preceding: Does the expense of downtime until the fuse is replaced outweigh the expense of replacing one or more machines with filters? As an

unrelated illustration of the conclusions that can be drawn in the absence of the cost/benefit analysis, think about the trade-off between some claimed benefits of population decline: There will be fewer short-term contributors to pension and retirement systems; whereas stopping the population will necessitate raising taxes to pay for the construction of additional schools. The issue of the cure being worse than the disease may be better explained by this.

Electronic Data Capture

Information technology has become increasingly used in the planning and execution of clinical trials over the past ten years. Research sponsors or contract research organizations frequently make use of clinical trial management systems to aid in the planning and management of the operational aspects of a clinical trial, particularly with regard to investigational sites. Web-based Electronic Data Capture (EDC) and clinical data management systems are utilized in the majority of clinical trials to collect case report data from sites, manage its quality and prepare it for analysis. Advanced analytics use public and private information about on-going research to identify researchers and research sites with expertise in a particular area. Sites use interactive voice response systems to enrol patients over the phone and assign them to a particular treatment arm (although web-based tools that are sometimes part of the EDC system are increasingly replacing phones). Measurements are increasingly being collected using web portals or handheld ePRO (or eDiary) devices, sometimes wirelessly. Statistical software is used to analyse the collected data and prepare them for regulatory submission. In the past, patient-reported outcome were frequently based on paper. Web-based clinical trial portals increasingly aggregate access to many of these applications. A Phase I trial that used telemonitoring, also known as remote patient monitoring, to electronically transmit biometric data from patients' homes to the trial database was approved by the FDA in 2011. Patients save time and money by not having to make as many trips to trial sites with this technology, which also provides significantly more data points.

Pharmaceutical researchers not directly employed by pharmaceutical companies frequently seek grants from manufacturers and manufacturers frequently look to academic researchers to conduct studies within networks of universities and their hospitals, such as for translational cancer research. In response to specific instances in which unfavourable data from

pharmaceutical company-sponsored research were not published, the Pharmaceutical Research and Manufacturers of America published new guidelines urging companies to report all findings and limiting researchers' financial involvement in drug companies. According to one study, approximately 75% of articles to combat the effect, they tightened editorial restrictions. According to the editorial, by the year 2000, contract research organizations had received 60% of US pharmaceutical company grants. Tohen warned in 2013 of the persistence of a gap in the credibility of conclusions arising from industry-funded clinical trials and called for ensuring strict adherence to ethical standards in industrial collaborations with academia, in order to avoid further erosion of the public's trust. Issues referred for attention in this regard include potential observation bias, duration of the observation time for

maintenance studies, the selection of the patient populations, factors that affect placebo response and funding sources.

During the development of a drug, it is crucial to collect safety data from multiple clinical trials because trials typically aim to determine how well the drug works. The sponsor, investigators and regulatory agencies are able to monitor the overall safety profile of experimental medicines as they are developed by aggregating the safety data from multiple trials. The following are the benefits of evaluating all safety data: a) During the medicine's development, decisions based on the overall safety assessment can be made; b) It prepares the sponsor and regulators well for assessing the medicine's safety after it is approved.