



LNP 78

Lean Six Sigma: Is There Hope for Improving Health Care?

Ian Laurence (Larry) Cohen MD

Pat: This is Pat Iyer with Legal Nurse Podcasts. This is a program that's designed to help legal nurse consultants improve their skills, increase their knowledge and expand their businesses.

I have with me Dr. Larry Cohen who is an individual that I've known for several years. He's done some expert witness work for me in the past and screened some medical malpractice cases. He draws on his experience as an intensivist working in a comprehensive cancer center in Buffalo, NY. Larry is also a tenured associate professor at the Jacob School of Medical & Biomedical Science.

When I met Larry he was involved with a partner in running an ICU and then stepped up into a leadership position and became the chief of critical care of a unit that now has 27 beds. Just recently he's been able to reduce his clinical practice to part-time after practicing for 40 years as a physician. Larry's also got a deep involvement in process improvement and became a certified Lean Six Sigma Black Belt. He's also been involved in and published in both medical science and management science.

One of the things that Larry has focused on with his team has been to develop a robust database that has become an essential component of their quality initiatives. He says it allows them to achieve rapid improvements in their operations that have had a very positive impact on their outcomes, including reduction of mortality, length of stay and costs. Those are all important metrics in the healthcare system. At the same time his organization has been able to deploy their own innovative approaches. This recently netted them a National Society Award for Safety and Quality.

Larry, I'm so pleased that we have an opportunity to talk today.

Larry: Why, thank you Pat and it's a pleasure to be invited.

Pat: I know in your bio I talked a little bit about Six Sigma and Lean Six Sigma. Let's start first of all with the definition of Six Sigma.

Larry: If one thinks about the bell curve and standard deviations the bell curve can be very wide and the standard deviations can be wide. Six Sigma implies that we count an error at a certain point and you're allowed to have six standard deviations on either side.

In a Lean Six Sigma you're allowed 3.4 errors in a million, so if you're producing a product there's no such thing as an absolute single standard. Every product has a little bit of variability, everything that comes off a production line. What you're looking at is the tolerance is 3.4 errors in one million. If you think about medicine and the perfect drug delivery, we measure something like medication error and we're probably up around 5% or 10% or 50,000 out of a million or 100,000. Far off from the 3.4 tolerances that you will see in electronics in most very sophisticated industries.

The best example of quality of process improvement in Sigma is actually 7 and 8 Sigma levels that get up extremely high. In the airline industry it's up around 7 Sigma, which is like 1 out of 10 million, one or two errors in 10 million.

Pat: That certainly has impact for us in terms of what we do as legal nurse consultants because just anecdotally as well as looking at studies we know that healthcare is not rocking along with 3.4 errors in a million patient encounters. It sounds like this is a perfect system to look at in terms of reducing medical error. Is that correct?

Larry: Yes absolutely and if I can comment on the Lean part of this because Lean Six Sigma is actually that Lean is getting rid of waste. It's well recognized that waste and error are very strongly connected. If you're wasting time, there's more opportunity for error. That doesn't mean you just rush through things, but if you build your systems and processes well you can eliminate so much waste. Eliminating waste will improve your error rates and vice versa. The whole idea here is if you do things well you will also reduce costs and improve outcomes.

Pat: It sounds to me like the concept of waste encompasses more than medical supplies, which is what immediately comes to my mind

-thinking about sterile trays that are opened and then discarded because there's something that's missing or there's a change in the plan. I think you're talking about waste in a broader sense than that. Is that right?

Larry: Yes.

Pat: That encompasses the use of people's time. Can you give us an example of what that would mean or what that would look like?

Larry: In Lean Six Sigma there are eight wastes. I won't go through every single waste, but its things like transportation, overproduction, poor designs and errors in using resources. There's a bunch of wastes and along with that there's a whole idea of how you build your process. Is each step of the process value added or non-value added?

A lot of the things we do are non-value added - all the policies that are still in effect. We have 10 Steps instead of 4 Steps, so anytime you can simplify and anytime you can eliminate. . . Things that have been done in industry are actually to synchronize even how people work together.

On a production line people are working closer together than in a big huge plant. In medicine we have tremendous areas of waste, even in designs in hospitals. Some hospitals are extremely poorly designed and other hospitals are well designed where transportation from one area to another is very quick. You're in radiology from an ER or OR right around the corner or right next door as opposed to two floors up.

Pat: I can think of multiple examples of working in hospitals where things were spread out and it seemed like a good portion of a nurse's time was spent pushing stretchers from one area of a hospital to another.

Larry: Absolutely, so everything that we do and every process that we look there's no perfect process, but you will find areas that you can improve. I'll give you just a quick list:

- Transportation
- Inventory

- Motion
- Waiting
- Overproduction

All these things that we do. As you look at processes looking for ways to improve, any way you look and see that why are we doing this, why can't we simplify and we don't need to use this product. I can give examples as we go along of little things, but little things ultimately end up being big things. Once you start doing these little things, it's easy and people get a little more bold and brave. We end up doing bigger and bigger things with just as much ease.

Pat: I can see how this would apply in particular to critical care. If you have somebody who's clinically unstable and then end up wasting time waiting for somebody to be available to do that emergency MRI or to take the patient to the OR or to insert a pacemaker at the bedside, all of those seconds and minutes can add up and make a difference.

Larry: Exactly and you have to look at if you're waiting to do something then something else is going to get missed if there's a hold up just like in a traffic jam. You're going to be late. Some people are not going to be able to get to work in time. There's a downstream affect of inefficiency. In a system where you want everything synchronized extremely well from the minute somebody walks into a clinic. You get in on time, or you do you have to wait two hours? It's dysfunctional and then you wait, go for an x-ray and wait another two hours. Everything downstream and upstream gets affected.

Pat: I know in your bio that I shared with the listeners that we talked about the fact that you're a Certified Lean Six Sigma Black Belt. What does that mean?

Larry: It doesn't mean that I could take on Bruce Lee if he was still alive. There are different levels of black belt. There are different levels of belts in Lean Six Sigma. There are many systems very similar to it which do the same things. Most people in well run organizations don't even realize they are involved in quality management improvement tactics.

There are a lot of ways of doing this, but if you do Lean Six Sigma it starts off with a white belt, which is just a few hours of time to get a sense of what goes on. There's a yellow belt, green belt and black belt. I'm a black belt, but the top level is a red belt and those are people who train others. A Lean Six Sigma Black Belt typically takes about a year to get certified where a green belt is about six months.

Pat: I can see how having that additional training and certification would help you in terms of being able to be in a leadership position, take the data and look at what changes need to be made. It all flows together if you've got a healthy database and then you can make decisions based on what has been proven to be effective.

Larry: We have in our group three other black belts who have been trained. One person actually does nursing data management. We have another who's an ICU nurse. We have another person who's our database manager and myself, so we have four people plus we've trained a lot of people with yellow belts.

Pat: I know that you've spent a lot of years in critical care. There's a lot at stake in that setting. Can you give us a sense of what changes you and your team have been able to make as a result of being involved in Lean Six Sigma?

Larry: I go back over 20 years and initially when I was getting involved everything was kind of project oriented. You find the problem and come up with a plan. It could be very complicated and doing a project can be extremely difficult, especially if you don't have good data and readily available data.

I've been doing this for many years and I've had a number of good things go on over those years. But in the past four or five years we've managed to put together a great database. We don't collect data. We gather data from other systems, from finance and from the EMR. We gather data and we integrate it the way we want to see it.

I would like the whole idea of a dashboard. If you were driving a car and you didn't have your gas gauge and your speed gauge, you would have no idea how much gas you had now and how fast you were going. We operate now with a great database. We track things every

month. We update it. We look for trends and people come up with ideas. We just ask people, “Do you have an idea?”

Just for an example people have come up with all kinds of very simple things. We got rid of buretrols in our critical care environment. The nurses were asking why were we using buretrols and they ended up saving about \$90,000 a year. We're doing all kinds of things. We tell people that if you have an idea just do it. We have the data tracking. We can track every drug, every lab and everything that goes on, particularly resource utilization and outcomes for patients. We have good tracking systems, so if you want to do something you do it. We'll monitor and see what comes of it.

We've had some real good ones recently. We've reduced lab use. We've shortened the length of stay of surgical patients in critical care by two days and cut \$5,000 per case of critical care costs for surgical patients coming through our units. That's been a big impact because the payers, as you know, are looking for improvements in cost and reductions in cost. At the same time, we've had a significant reduction in mortality from 3% to 1%.

Pat: That's a huge difference, particularly for the family of the parent who's able to pull through a really critical period of life. The human costs are phenomenal.

Larry: What we've done with the surgical teams is we've actually created a more intermediate environment for them and their critical care so that we can focus more on earlier interventions in the medicine patients. There was always a battle for beds. We now have very good outcomes, much better outcomes for the medicine patients because we focused on getting them earlier and earlier. All that has to do with the data we've analyzed. We can tell where the patient came from, how many days they were in the hospital and did we get them directly.

In the past few years I think we've convinced people to call us early. That's the whole thing in critical care and that's early detection and early prevention would be ideal.

Pat: I'm assuming that you have an active rapid response team that is funneling patients to you as quickly as they can when it's warranted?

Larry: Yes and in fact 80% of our emergency cases come to us without a rapid response because people just call us. We do have rapid responses, of course, and we have a team that goes, but a lot of our cases are emergencies. People just call and say, "Can you take a look at Mrs. Jones" and then we send somebody. We're quick to take them up. Probably most of the people we get called to look at we'll take to the ICU. Often they are just there for a day or two with a little bit of fine tuning.

Pat: I've never thought of ICU care as fine tuning, but that's an apt description.

Larry: It's probably not the best use of words, but that's early intervention because we have the technologies, the nursing and the skills that we can really turn things around very quickly. If we intervene early the outcomes are much better.

Pat: I can see that. I know that you are familiar with what legal nurse consultants do in terms of looking at medical records for people who come into the healthcare system for a whole variety of reasons whether that be as a result of trauma, personal injury or a workers comp catastrophe that ends up with some serious injuries. I know that you live a lot of the time in this world of an unexpected admission to ICU, the unplanned admission whether that's from the recovery room or from a medical surgical unit.

Some of those could be due to medical error. Some of them are simply unstable people who need your more direct involvement. What have you seen over the years in terms of the most common clinical scenarios that result in that unexpected ICU admission?

Larry: I would say that most of the cases that we get are not clear errors, an error that's occurred. I look at errors very differently nowadays, so any time we see somebody that comes to ICU and they're very unstable I look at it and say, "Okay there ought to be a way that we could have detected this earlier even if it occurred on the outside before the patient came in." If we're looking at systems and we're looking at errors, it depends how you want to define errors. I think quick and early intervention will lead to better outcomes, but what about

prevention?

Just when you look at analyzing an airplane crash that's great and if you can prevent the airplane crash, then you've got something going. I think that's part of what we need to do nowadays and that's how I look at it. Blanket errors and obvious errors are not common for us to see, but we often see opportunities where if we could have gone earlier. . . That's why when people call us and we encourage it, we will go and evaluate the person. Are they sick enough to come?

Absolutely, we will bring them up there and in six or eight hours the person is looking okay then won't need to stay in the ICU anymore. I think this is how you approach this because in a lot of places they just wait until somebody gets sick enough and crosses a threshold. I think part of this is changing your perception of where that threshold should be.

Pat: I think that is something that infused the medical world when rapid response teams were first identified as being needed was don't wait until the person is all the way down in the trough. Catch them on their way down so that they won't hit bottom and have a code in a medical surgical unit for example and then you're working against so many factors to bring them back.

Larry: Yes the earlier the better for sure.

Pat: In another part of my life I've been doing some moderation of podcasts dealing with the subject of opioid overdoses and respiratory depression related to having too much opioids in the system. (See <http://PPAHS.org>.) That is something I have seen that is one of the common factors that can result in an unexpected ICU admission.

Do you see that within the intensive care world in your setting or are you aware of those types of clinical situations elsewhere?

Larry: For sure it's a big problem. In our environment it's very different. We're a cancer center and the places that have ERs this is an epidemic with narcotic overdoses. In our environment it's the medical use of these agents are very common because patients have a lot of pain, so we do see issues.

On the other hand one of the big issues we also see now is polypharmacy use. I think is just a general problem that a lot of people are on a lot of different medications. They are on narcotics. They are on anti-psychotics. They are on anti-depressants. They are on benzodiazepines.

You get somebody in the hospital and it can be very difficult after surgery if they start to have withdrawal from these agents to really control it. That's where we also see a lot of over-sedation. It's very difficult to control the agitation. It's a real alteration in brain chemistry that these patients go through. That's one of our biggest problems, people who are on polypharmacy and you're stopping the drugs or trying to rebalance people who are doing their own self-medication at home.

Pat: Absolutely, so you can have the person who is opioid naïve and the person who is opioid experienced. There's probably a much better clinical term than that, but that's what comes to my mind at the moment.

Larry: We're cutting down in our elective surgery. The big trend now is ERAS or Early Recovery After Surgery. The use of narcotics is dramatically dropped in those cases. People are even fed on the day of surgery, tubes are out and people are up walking. That's been coming for a long time, but now it's become even a whole new level of aggression in getting people up and mobilized, and to reduce all these drugs.

Pat: I know that nurses will be able to appreciate that because we see the complications that are associated with prolonged bed rest or the problems associated or the risks with nasogastric tubes in particular or pulmonary emboli from DVTs from being in bed. It will resonate with our audience that getting people out of bed faster will reduce the risk of complications that can occur from being in bed.

Larry: Yes. We're walking people around the unit while they are still on a ventilator. These are things that are not so easy to do, but excuse the expression "Bag and Drag". This is what they used to do 30 years ago. They would bag patients while they were up and getting mobilized and that kind of fell by the wayside, but it's resurfaced. Mobilizing

people also helps their mental status.

Pat: Now you've given me a whole different picture of somebody holding onto the patient and the other person wheeling the ventilator. That's something that I have never imagined. Thank you for that, Larry.

Larry: I guess there is a better term than "Bag and Drag".

Pat: I wanted to ask you one last question before we wrap this up, which is that a lot of legal nurse consultants see the negative end of the healthcare system in the fact that we don't see the people who get better, go home and have no lingering problems because they are typically not in the legal system. They don't have damages that are worth filing a lawsuit about.

We also don't see what happens when people have an incident in a healthcare system. There is a suit that's filed and then the risk managers look at what happened, what led up to that, what do they need to change in the system so that type of situation will not recur.

Could you give us some insights about improvements that you've seen in the healthcare system that have taken place as a result of incidents or medical errors?

Larry: A lot of government agencies and a lot of nongovernment agencies have really focused on improving health care. Health care as an industry is nowhere near industries such as the airline industry and electronics. If you had an iPhone that had the same level of problems that we have in health care, you wouldn't even use that product again. Samsung is probably a good example right now when you have these things exploding.

In health care I think people are starting to recognize what I said before in that we have to change the threshold and the expectations. 3.4 million is a Lean Six Sigma. I think, rather you know, Lean Six Sigma or not it's that tolerance that you're only allowed 3.4 medication errors in a million and how do you get to that level.

Right now I think the whole idea of benchmarking is out there in a big way and so people are looking at your data. We have to report a lot of things as most people do to the federal databases. There are excellent

databases out there like NSQIP (National Surgical Quality Improvement Program) and that's one of the best programs there is. The database is excellent and we are involved in that one. That's not a government agency, but these things are all surfacing. I think we're all being kept a little more honest because of that and that's great.

The thing that really is going to I think drive all of this is the cost of health care. Those that cannot provide high quality care at a very reasonable price are not going to stay in business. The only way that they can do that is by being efficient and the only way they can do that is by minimizing problems. If they're not preventing problems, patients are going to stay in much longer. They are going to be much sicker and much costlier. The systems are going to be forced to really improve (just like other industries) their quality in getting rid of error and getting rid of waste.

Pat: I think you're pointing to something that has really ramped up in recent years, which is the governmental oversight of some of the markers of inadequate care and the changes in reimbursement that have resulted from increased government attention to those areas. The dollars have a huge impact on how people can behave within a healthcare system.

None of us as legal nurse consultants or medical malpractice attorneys wish that there were more errors. We see the cost associated with that and we always are rooting for ways that can improve the outcomes in healthcare.

Larry: People don't like to call health care a business, but I think it's the very thing we should be calling it and running it like a good business, and running it like a good industry.

Pat: Yes, it's such a complex system and it sounds to me as if Lean Six Sigma has made some inroads into helping take that information from outcomes and turning it into more positive outcomes for the people in your institution.

Larry: I think there are many institutions that are really leading the way in this. There are some great systems out there, healthcare systems that are making big strides.

Pat: Well thank you so much for sharing your perspective and your experiences in a critical care unit and how the data has driven the changes that have occurred within your facility. I appreciate the time that you have spent with us today Larry.

Larry: Thank you Pat, it's been an honor.

Pat: This is Pat Iyer with Legal Nurse Podcasts talking with Dr. Larry Cohen about outcomes, Lean Six Sigma, the improvements that can be made by using data in empowering the staff to make changes and continually focusing on what's going to be best for the patient.

Thanks everybody for listening and joining us in this show today. You may connect with Larry Cohen through email at Larry.Cohen@Roswellpark.org or call 716-866-8685.

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LNP 79

Infection Control as a Measure of Quality of Health Care

In our previous legal nurse podcast, (which is LNP 78), Dr. Larry Cohen spoke about the quality of health care. As an intensivist, Dr. Cohen has developed expertise about measuring quality indicators and making adjustments in care in response to trends the data revealed.

Hospital or healthcare acquired infections are one of the indicators of quality of care. Legal nurse consultants who work on medical malpractice cases may be asked by attorneys to offer opinions on whether an infection was preventable or properly treated.

In this edition of *Iyer's Insights*, I focus on infections.

Healthcare providers used to freely prescribe Vancomycin to treat infections. This intravenously administered drug is powerful, but stimulated a generation of bacteria that is resistant to its use. Vancomycin is often used to treat organisms that are resistant to other antibiotics. The available treatment options are reduced if resistance develops.

Vancomycin-resistant enterococcus or VRE was first detected in 1986. This organism is now prevalent in most hospitals in the United States, where the vancomycin-resistant gene can be transferred to other microorganisms. This can result in spread to many patients.

VRE causes infections in multiple body sites including the bloodstream, wounds, and urinary tract. Enterococci are normal body flora found in the gastrointestinal tract and are naturally resistant to many antibiotics other than vancomycin. Colonization with VRE, once established, may be indefinite, leaving the colonized patient and others at risk of possible infection.

Healthcare providers must control the spread of VRE to minimize risk. There are four areas of control, which are the standards of care in treating these high-risk patients:

*** Prudent and appropriate use of vancomycin** (i.e., limit the use of this antibiotic to those circumstances known to be effective).

* **Educational programs for staff.** These need to be tailored to the specific audience for which intended. For example, physicians need a greater appreciation of the ultimate outcomes of inappropriate prescriptions and use of vancomycin, and to recognize the need to not use this drug in cases of colonization but to “save” it for treatment interventions

* **Infection control measures should be implemented.** These include appropriate use of isolation for colonized or infected patients, proper hand decontamination before and after touching patients and contaminated surfaces.

* **Detection and reporting of the occurrence of VRE are essential to identify and control the spread.** Recognition of the occurrence of VRE allows for proper implementation of control measures including epidemiologic studies to determine those at greatest risk, and measures most effective in minimizing the occurrence of these infections. These may include prompt notification of staff caring for VRE patients.

Let’s look at another aspect of infection control: urinary tract infections.

We used to think it was inevitable that patients got urinary tract infections from Foley catheters. We used to keep catheters in any incontinent patient and for days or weeks longer than necessary. Now hospital acquired urinary tract infections are never events. Centers for Medicare and Medicaid Services will not pay for care associated with these infections after they develop in a hospitalized patient. The lack of reimbursement for health care creates a powerful incentive to prevent these infections.

The Centers for Disease Control and Prevention published guidelines for the prevention of catheter-associated infections. Here is one of their key concepts: avoid using a catheter if at all possible. If catheters must be used, remove them as soon as these devices are no longer necessary. The CDC defines when catheters are and are not necessary.

Lengthy use of indwelling catheters increases the likelihood of infections with over 20 percent of catheterized patients acquiring a catheter-associated infection. One hundred percent of patients will get a UTI if a catheter is left in place for a month. The recommended prevention methods require healthcare providers to:

- use sterile aseptic technique during catheter insertion;
- maintain a closed sterile drainage system;
- avoid routine catheter irrigation as this requires opening the system which leads to likely microbial contamination and the possibility that the irrigant solution may be contaminated;
- maintain unobstructed urinary flow;
- keep the catheter drainage system lower than the level of the patient's bladder to prevent backflow of urine from the drainage bag;
- collect specimen through needle aspiration to avoid opening the catheter-tubing juncture; and
- change the catheter only as indicated and not on a routine arbitrary schedule.

Healthcare providers are responsible for the care of patients with catheters and need to follow the above recommended methods. Nurses and physicians have to be aware of overall patient conditions, as this affects the likelihood that patients may get a UTI. Proper fluid intake is important for cellular metabolism and maintenance of urine flow through the bladder.

However, staff are to be mindful of conditions in which fluid intake needs to be restricted, avoiding procedures that have been shown to be ineffective in preventing UTI. These include treating bacteria collecting at the opening of the urethra or using antibiotics for patients who do not have symptoms from the bacteria in their urine.

In determining possible negligence, the attorney or legal nurse consultant should review the documentation include changes in urine color, odor, etc. Did the facility follow their own policy and procedure for catheterization and care? for Legal Nurse Consultants

Infections in Hospitals – Barriers to Prevention

These are 8 reasons why it is difficult to control hospital infections. Part of your role as an LNC is understanding these reasons and educating your attorney clients.

1. **All medical staff do not wash their hands when they should.** The single most important and effective means for preventing infections is proper hand hygiene. Unfortunately this is a challenge for healthcare staff because of the demands of constant patient care. The advent and scientifically proven value of waterless alcohol-based hand gels, foams, and liquids has added a powerful weapon to the arsenal of effective hand hygiene products.
2. **There could be a delay in diagnosing the infection.** Many hospitals may not analyze their own laboratory tests and thus the facility may “outsource” these services by sending the specimen to the laboratory. There can be a delay in obtaining the laboratory results when outsourcing specimens. “Stat” laboratory results may not be obtainable.

While bacterial culture results are usually available within about forty-eight hours, gram stains can be done and read in a matter of minutes. This provides acute care infection control efforts with more rapid results. Gram staining, however, does not provide definitive results. The final culture needs to be reviewed, and if necessary a change in treatment may be initiated.

3. **There could be a delay in starting the right antibiotic.** Often treatment is initiated based on the usual causal organisms. Once these culture results are available and reviewed by the physician, a treatment plan will be reevaluated. Some organisms are resistant to certain antibiotics. If organisms are resistant to the antibiotic used as treatment, a change in antibiotic is indicated. Some providers do not order the correct antibiotic or the correct dose because of lack of knowledge or not checking the culture and sensitivity report when it is available.

4. **There are strains of bacteria and viruses that are not killed by antibiotics.** The “super bugs” may invade a patient’s body and cause death. Antibiotics are lifesaving and at the same time lead to the development of microbial resistance to these drugs.

5. **There are multiple opportunities for staff (or the patient) to transmit the organism from the patient to someone else.** Accommodations can be made for those patients who require isolation in the hospital setting. A hospital stay is temporary, which makes it possible to confine patients to their rooms when controlling communicable diseases. However, hospitals

have to face the necessity of the infected patient leaving the room for therapy, diagnostic tests, and surgery. In some instances patients may leave to visit other patients, go to the lounge, or even the cafeteria. Thus, patient transport to other locations complicates the ability to control infections.

6. Treatment of infections is expensive. Another barrier includes the costs of medical care, which have risen at the same time payments for care provided have declined. Coincidentally, patients in hospitals today tend to be much sicker; and people living longer increases the incidence of chronic diseases, often requiring more sophisticated and costly care. This conundrum demands greater resource availability, yet less is available.

7. Staffing for most infection control departments is limited and can be another major barrier to fighting infections. For years the infection control community has unsuccessfully attempted to identify the proper infection control specialists and epidemiologist-to-patient ratio, as health care is in constant flux. Many smaller facilities lack an infection control department.

8. The art and science of acute care infection control is far more complex now. Hospitals now have numerous intensive care units filled with critically ill susceptible patients. Patients are living longer and acquiring diseases or treatments that diminish the effectiveness of the immune system. Sophisticated medical diagnostic techniques and interventions are double edged as they may save and prolong life but not without risk of adverse consequences such as infections.

As an LNC, you have a role in reviewing cases involving infections. This may include looking at the timing and appropriateness of antibiotics, the detection of signs of infections, and other aspects of infection control.

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