Virtual Reality & the Opioid Crisis

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By

Vy Lan Tran

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Approved by Prof. Kent Wayland, Department of Engineering & Society

Introduction

In recent decades, opioids have been historically relied on for pain management. However, opioids, once thought to be a "one size fits all" solution, have now received global attention as opioid-related deaths continue to increase. According to the Centers for Disease Control and Prevention, (CDC), opioid-related deaths have increased by nearly six times as much since 1999 (Holly Hedegaard, Miniño, & Warner, 2019). In 2017 alone, about 68% of the more than 70,000 drug overdose deaths in the United States involved the use of an opioid. Such a statistic is extremely alarming in that it even supersedes the amount of U.S. deaths lost to war efforts post 9/11 by six times (Felter, 2019). Despite this, however, the U.S. currently consumes over 80% of the world's opioids (Bajpai, 2020). One major issue prolonging the opioid epidemic and its increasing mortality rates is the continuous reliance on alternative sources of opioids, with each new opioid alarmingly much stronger than the one before. Rather than turn to alternative sources of opioids, we should combat the crisis by exploring alternative sources of pain management.

While virtual reality (VR) technology is commonly known for its presence in the gaming world, it has recently been recognized as a potential viable alternative for pain therapy with its drug-free nature, wide-spread availability, and ability to distract during painful procedures. The technology has seen several remarkable successes in areas such as chemotherapy and physical therapy. However, in order to seriously consider the implementation of virtual reality as a clinical tool, one must understand how the opioid epidemic started in the first place. By understanding how the problem first developed, one can then identify major factors to consider that would shape the development of a potential solution such as VR pain therapy. Such background will ultimately lead this paper to explore three major areas: past pain therapy studies

utilizing virtual reality, healthcare industry influencers, and regulation on the opioid crisis. Overall, by exploring alternatives to opioids such as virtual reality, we can take a step towards decreasing reliance on opioids and thus mitigate the crisis to save more lives.

The Origins of the Opioid Crisis

Opioids, derived from the opium poppy plant, are known as a class of drugs that are commonly utilized to treat pain. While some opioids can be manufactured legally, others can be obtained illicitly. The CDC describes the evolution of the opioid epidemic in three waves: prescription opioids, heroin, and synthetic opioids. When healthcare professionals started over-prescribing pain killers, patients became addicted and later turned to the illicit use of heroin. According to the National Academies of Sciences (NAS), a major contributing factor to the opioid crisis concern is the rise in the availability and accessibility of heroin, which is cheaper than prescription opioids (National Academies of Sciences, 2017). This sheds light upon the idea that though the impact of the opioid crisis is felt across nearly all sociodemographic groups, it may be affecting those more economically disadvantaged more heavily. However, the most recent cause for concern lies with the "third wave," or synthetic opioids. From just 2016-2017, the age-adjusted rate of drug overdose deaths involving synthetic opioids such as fentanyl increased by 45% (Holly Hedegaard, Miniño, & Warner, 2019). Overall, this three-wave development of the opioid epidemic reveals a pattern that is undeniable: once a new opioid is introduced, patients become addicted, deaths increase rapidly, and users yet again turn to alternative sources of opioids.

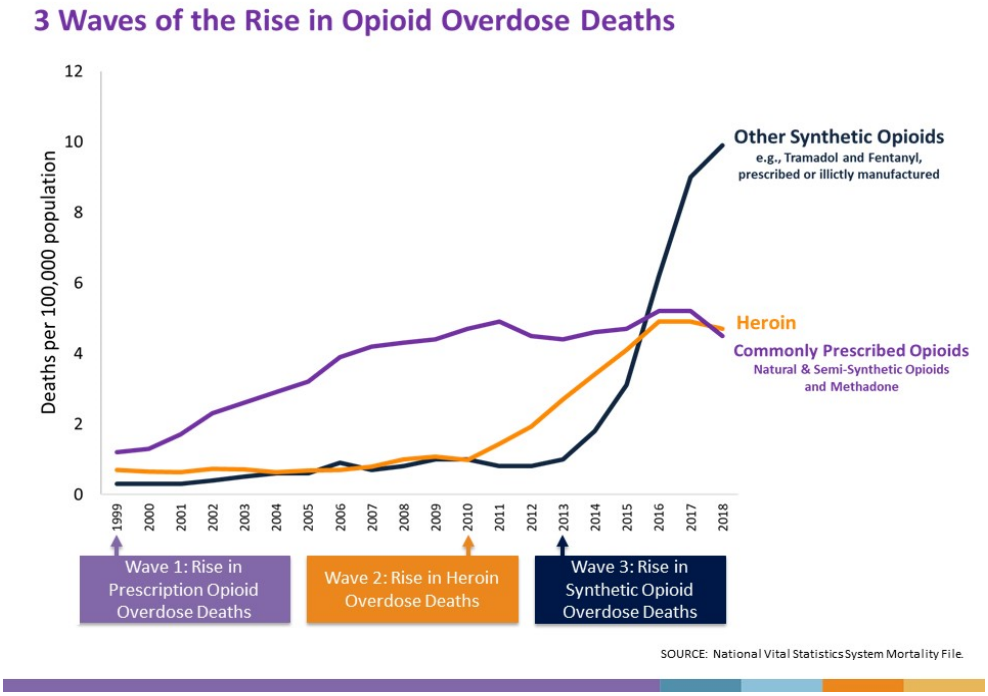

Figure 1*:* A graph depicting the 3 wave pattern of opioid overdose deaths over time. Reprinted from the *CDC*, by the National Vital Statistics System Mortality File, 2019, Retrieved from https://www.cdc.gov/drugoverdose/images/epidemic/2018-3-Wave-Lines-Mortality.png.

The groundwork for the first wave of the opioid crisis, prescription opioids, can be traced back to the misrepresentation of one specific study. In 1980, the *New England Journal of Medicine* (NEJM) published a letter in its "Letter to the Editor" section from Dr. Hershel Jick of the Boston University Medical Center. Dr. Jick claimed that, out of the 11,882 patients he studied receiving opioids, only 4 patients (<1%) became addicted (Jick, 1980). The letter concluded that, "...despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction." Despite the one paragraph letter providing no specific evidence to back its claim, it became popularly cited over 600 times from 1980 to 2017, with 70% of the citations using the letter as evidence for claiming that opioids are not addictive (Jones et al., 2018). Furthermore, over 80% of those cited who cited the article failed to mention that the patients who were studied were all hospitalized patients that

were constantly monitored. The widespread misconceptions about this study therefore played a major part in the increase in the prescription of opioids.

It was this very misrepresentation of Dr. Jick's study that influenced the false marketing campaigns of opioids by big pharma companies in the mid-1990s and early 2000s. At the heart of the true takeoff of the first wave of the crisis lies Purdue Pharma, the producer of the opioid OxyContin. Purdue Pharma and other big pharma companies marketed their products heavily, and, to Dr. Jick's horror, used his <1% addiction to opioids statistic as a blanket statement for their own products. Despite knowing that the opioid was addictive, Purdue Pharma even went so far as to market OxyContin as "the less addictive opioid" with the FDA's approval (deShazo et al., 2018). It was after such false marketing campaigns that opioid prescriptions surged. In just 5 years, Purdue's aggressive promotion of OxyContin played a major role in causing OxyContin prescriptions for non-cancer-related pain to increase from about 670,000 in 1997 to 6.2 million in 2002, nearly 10 times as much (Van Zee, 2009). Purdue Pharma would later admit to such false marketing in a 2007 settlement with the FDA for $635 million dollars. However, the damage had already been done. By 2004, OxyContin had already become the leading drug of abuse (Jones et al., 2018).

In addition to false marketing, big pharma companies also possessed major influence through advocacy groups for opioid treatment of pain. Such advocacy groups would continue spreading the idea that opioids were not addictive. This eventually led to influencing powerful legislation and changes in pain treatment. For example, Purdue Pharma provided most of the financial support for advocacy groups such as the American Pain Society, or APS. The APS referred to pain as the "5th Vital Sign" in its campaigns, arguing that pain was being undertreated and proposing that the measurement of pain become a norm in clinical settings in

addition to existing standard measurements like heart rate and blood pressure (deShazo et al., 2018). The APS was later supported by other influential groups on this matter, such as the American Medical Association and the American Academy of Family Physicians. It is through such advocacy groups and big pharma companies that a pain treatment advocacy movement ensued, convincing Congress to initiate "A Decade of Pain Control and Research" in 2000. It is therefore important to realize that big pharma companies' influence is much more far-reaching in the healthcare system than one would initially think.

Such influence from the pain movement contributed to the growing over-prescription of opioids in that it also influenced regulatory bodies such as the FDA. In the 1990s, the FDA implemented a protocol known as the "Enriched Enrollment Protocol," which sped up the process for the approval of new pain medication (deShazo et al., 2018). Interestingly, this protocol was developed by a group also funded by the pharmaceutical industry. When the FDA was reviewing the approval of OxyContin, it missed the original label's claim that addiction to the product was "very rare." While OxyContin is designed to release the narcotic oxycodone over a controlled twelve-hour period, crushing the tablets immediately releases 68% of the oxycodone (Van Zee, 2009). The FDA overlooked the implications of the inclusion of this disclosure, and thus the drug became popularly abused. Even when OxyContin was relabeled to caution users not to chew or bite the tablet, this only further gave drug abusers the idea to crush the drug. Unfortunately, even when OxyContin was modified to become harder to abuse, drug addicts simply turned to heroin— and thus the second wave of the epidemic was born.

Overall, such background on the roots of the opioid epidemic identifies major sources of influence to consider when tackling this problem. By understanding how the problem developed in the first place, one can now understand major factors that would shape the development of a

potential solution. If an alternative treatment for pain such as VR therapy were to be adopted, its development would surely be shaped by not only medical providers and patients, but also by the same sources of influence witnessed above: past pain treatment studies, the big players of the healthcare industry, and government regulation. The NEJM "Letter to the Editor" case reflected that the success (or interpretation of success) of past studies can have a significant effect on public opinion and future research. Purdue Pharma's strong influence with aggressive marketing and advocacy groups reveals that many of the decisions within the healthcare space are controlled by big pharma companies with substantial funding. If VR therapy were to become widely adopted, large healthcare industries such as the pharmaceutical and insurance industries are sure to play a key role as major roadblocks to overcome. Lastly, regulation can be impactful in setting the tone and demand for future research in alternatives for pain management. It is for these reasons that there will be three sections of analysis: past clinical studies utilizing VR for pain management, healthcare industry influencers, and finally another section on government regulation of the opioid crisis.

By dividing the paper into such sections, the paper explores the roles and interactions of various actors affecting the development of this novel therapy. Specifically, the past studies section will collect evidence from secondary sources on where VR has been utilized in pain management in order to understand the technology's evolution among different user groups and how such studies are impacting future research. This information will be sought from recent articles from established journals, such as in the *Public Library of Science* or the *Annals of Behavioral Medicine*. These previous cases may also suggest whether VR therapy could be used in replacement of opioids, together with opioids, or not at all. The healthcare industry section will explore how medical professionals, "big pharma" companies, and insurance companies as a

whole could impact the development of this technology. Finally, the regulation section will detail the influence of governing bodies from reliable sources such as the CDC, the FDA, or the White House.

Past VR Pain Therapy Studies

SnowWorld is known as the first immersive VR pain therapy experience ever developed. Originally designed by Hunter Hoffman for severe acute burn pain patients who undergo excruciatingly painful procedures, *SnowWorld* remains one of the most well-known examples of clinical virtual environments today. In cases where burn wound patients are not resting, such as during staple removal, wound cleaning, and bandage changes, standard opioids are nowhere near sufficient enough to manage patients' unimaginable pain (Hoffman et al., 2011). In *SnowWorld*, patients are immersed in a sharply contrasting environment with characters such as snowmen, penguins, flying fish, and wooly mammoths. While undergoing a painful procedure, the burn patient is distracted by the VR magic of flying through an icy world and the launching of snowballs at the animated characters (Fig. 1). As a result, patients reported feeling a striking 35-50% reduction in pain by using VR combined with standard medications in comparison to solely using medication (Hoffman et al., 2011).

The success of this first VR therapy experience sparked a new era of pain therapy as more and more people began to explore the benefits of virtual reality. *SnowWorld* established the value seen in VR therapy, which can be explained by our limited capacity for attention. Because patients in VR therapy are occupied by distracting, captivating stimuli, less attention is allowed to be diverted to processing neural signals from pain receptors. Though *SnowWorld* has seen much success and set the ground running for VR pain therapy by encouraging many other studies, more studies must be completed to analyze the effectiveness of VR in replacement of

opioids or perhaps the effect of VR therapy intervening early before opioid use.

Figure 2*:* On the left, a burn wound patient undergoes wound debridement while viewing the immersive virtual reality environment, *SnowWorld*, on the right. Reprinted from "Virtual Reality as an Adjunctive Non-pharmacologic Analgesic for Acute Burn Pain During Medical Procedures," by Hoffman et. al, 2011, *Annals of Behavioral Medicine*, 41(2), 183–191. Retrieved from https://doi.org/10.1007/s12160-010-9248-7.

While there is growing research supporting VR's effectiveness for treating acute pain such as with burn wound patients, few studies exist about the use of VR for chronic pain. However, progress in the field of chronic pain was made when Howard Rose, a researcher from the same exact lab that developed *SnowWorld*, and his colleague left academia to come up with commercial VR products under their own company, Firsthand Technology. In one study that investigates the impact of VR for chronic pain, 30 patients with varying types of chronic pain were immersed in a 5 minute VR session with Firsthand Technology's application, *Cool!* (Jones et al., 2016). For example, patients had severe spine pain, hip pain, shoulder pain, or other types of chronic pain for an average of 16 years. Rose describes *Cool!* as "a sort of next generation of what we learned in *SnowWorld*," explaining that it provides more environments and interactivity (Marchant, 2017). During this experience, users travel in a fantasy world with otters, trees, hills, caves, snowy environments, and fire flames (Fig. 2). The user can cast fish and orbs at either the

otters or the flames. However, there is no violence involved in that when the otters or flames are hit, they merely change colors, move around, or make sounds in a playful way. Throughout the study, patients were asked to rate their pain on a scale of 0-10 pre-session, during the session, and immediately after the session. On average, patients reported a 60% reduction in pain from before the experience to during the experience, and a 33% reduction in pain from pre- to post-experience (Jones et al., 2016). By comparison, morphine is thought to reduce pain by about 30% (Furlan et al., 2006). Therefore, patients in this study experienced a similar reduction in pain to morphine from pre- to post-session, and about double the reduction in pain from pre-session to during the experience.

If VR therapy is indeed just as effective as morphine for chronic pain, this supports the idea that VR pain therapy should be further explored as an alternative to opioid use. In this way, we could either limit the length or dosage of the initial prescription or avoid opioids altogether for chronic pain patients. Furthermore, while there may be some reservations about VR therapy's impact catering toward younger, more technologically savvy populations, the median age for the *Cool!* study was 50 years (Jones et al., 2016). Such adults ranged from age 35 to 79 years, and the older adults experienced little to no complications with the technology. Therefore, the *Cool!* study supports the idea that VR pain therapy serves to be helpful for users across not only a diverse age group, but also for both acute and chronic pain patients. While this study shows great potential, more studies must be conducted to further investigate the promise of VR therapy for chronic pain patients.

Figure 3*:* Scenes from *Cool!* are shown, with the scene on the *left* displaying a snowy scene with otters and the scene on the *right* displaying caves and flames. Reprinted from "The Impact of Virtual Reality on Chronic Pain," by Jones et. al, 2016, *PLOS ONE*, 11(12), e0167523. Retrieved from https://doi.org/10/1371/journal.pone.0167523.

Healthcare Industry Influencers

However, extensive research alone cannot suffice for the wide-spread adoption of VR as a pain therapy. Ted Jones, a clinician who contacted Firsthand Technology and personally funded the first clinical trials of *Cool!,* stresses the existence of two major obstacles to developing VR into a routine treatment: reluctance to unfamiliar technology and inadequate funding (Marchant, 2017). Jones explains that he is still met with reluctance from healthcare centers to adopt a therapy technology as new as VR. Despite Jones raising $15,00 for a children's hospital and explaining the benefits of the VR technology with strong research evidence, the hospital still declined to use the new technology. Interestingly, Jones actually now discourages his fellow physicians from referring their patients for VR— not because he does not believe in the therapy, but because he can no longer afford it. Jones further explains that VR pain therapy needs a "champion" to fund clinical trials and convince insurance companies to take the novel therapy seriously (Marchant, 2017). Overall, Jones's experiences reveal that his exploration of VR pain treatment happened because of his own personal efforts and interests as a physician, not because of support from hospitals or insurance industries. Therefore, in order for a

new pain therapy such as VR to successfully develop, several sectors of the healthcare industry must come together.

Insurance companies prove to be a major roadblock for alternative forms of pain therapy. Interestingly, it was found in a study by *Pro Publica* and the *New York Times* that insurance companies often provide far more favorable coverage for addictive opioids than for less-addictive or non-opioid alternatives (Thomas & Ornstein, 2017). This is because opioid treatments are usually much cheaper than safer alternatives. For example, UnitedHealthcare, the leading health insurer in the U.S., places morphine on its lowest-cost drug coverage tier ($29 a month) with no prior authorization requirement. This means that a physician does not have to obtain approval from the health insurer to prescribe morphine. In contrast, UnitedHealthcare excludes Butrans ($342 a month), a painkilling skin patch that contains a less-risky opioid, buprenorphine, from most of its plans. It is also interesting to note that non-addictive treatments such as lidocaine patches, which cost much more, require prior authorization by every plan included in the study that covers them. By requiring a lengthy process such as prior authorization, health insurers are delaying access to safer treatment for the patients who are willing and ready to receive it. This raises significant concerns because it allows for a period of waiting time in which many patients will find their pain unbearable, and thus it forces patients to resort to the more addictive treatments that are readily accessible. Furthermore, many health insurers implement a fail-first policy as a means to cut costs, meaning that a patient must fail with a less-expensive treatment option before coverage can be given for the more expensive treatment option (Blake, 2019). By placing less addictive or non-opioid pain therapy alternatives on higher-cost tiers, requiring prior authorization for such prescriptions, and implementing fail-

first policies, insurance companies are making it much more difficult to access safer alternatives for pain therapy and seemingly further fueling the opioid crisis.

While one could argue that insurance companies have a right to enforce cost-control measures, this issue poses a major ethical concern in that such measures conflict with the ability to provide for patients' well-being and needs. Realistically, in order for a shift to occur with insurance companies' policies, the shift would somehow need to be largely motivated by profit. Therefore, in order for non-opioid therapies such as VR pain therapy to progress, such alternatives would need to somehow demonstrate that while safer alternatives might be costlier upfront to insurers, they could decrease insurer's long-term costs through reduced hospitalizations or curving medical costs associated with potential opioid addiction. Because VR technology has become much more affordable in recent years and exhibits potential to treat pain outside of the hospital with its portability, VR pain therapy serves as a promising viable alternative that could potentially grow support from the insurance industry. However, this does not mean that friction will not be met with the big-pharma companies (who also reserve a right to pursue profit) that are ensured to continue to heavily market their newer, even stronger opioid products. It is therefore important to stress that shifts to safer, alternative therapies will require a multi-industry approach.

Regulation

While such shifts in policies always take time, the federal government has the overall power to enforce impactful regulation and set forth initiatives that trickle down into several parts of the healthcare system. In March 2016, the CDC responded to the opioid crisis by publishing a voluntary guideline to physicians for prescribing opioids (Dowell et al., 2016). The guideline encourages the use of non-opioid therapies and, should opioids be used, to combine them with

non-pharmacologic and non-opioid therapies. The CDC also encourages prescribing the lowest effective dosage at the start of opioid therapy for no more than 3 days and very rarely beyond 7 days. This is because the likelihood of long-term opioid use is heavily correlated with the length of the initial prescription. According to the National Conference of State Legislatures (NCSL), several states reacted to the CDC guideline by enforcing laws to limit opioid prescriptions (*Prescribing Policies: States Confront Opioid Overdose Epidemic*, 2019). As of October 2018, thirty-three states have enacted legislation that limits initial opioid prescription duration or dosage. Such legal action therefore creates the demand necessary for the development of non-opioid pain therapies. If we can limit the number of patients' utilizing opioids in the first place, the amount of dosage prescribed, or the length of the prescription in general with non-opioid therapies such as virtual reality, we can therefore limit opioid misuse and addiction.

In the time that has passed since the publication of the CDC guideline, significant progress has been made throughout government regulation. In October 2017, the opioid epidemic was declared a national public health emergency (Gross & Gordon, 2019). Since then, the national emergency has spurred several actions aimed at tackling the ongoing opioid epidemic. In 2018, the President issued an Initiative to Stop Opioid Abuse. According to a briefing from the White House, the initiative consists of three parts: educating the public about opioid misuse and reducing opioid over-prescription, cutting down the supply of illicit drugs, and helping those with addiction (*President Donald J. Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand,* 2018). A goal was even implemented to decrease opioid prescriptions by one third within 3 years. In a one-year update on the President's Commission on Combating Drug Abuse and the Opioid Crisis, it was highlighted that the Administration invested $500 million dollars in the National Institutes of Health's (NIH) "HEAL" Initiative, or Helping to End

Addiction Long-term (Executive Office of the President, 2019). Through HEAL, the NIH funds research to support new alternatives for pain management, such as through clinical trials for new pain therapies. Just as Congress was influential when it initiated "A Decade of Pain Control and Research" during the pain movement that encouraged opioids in 2000, pressure from the Initiative to Stop Opioid Abuse has necessitated progress tackling the opioid epidemic today among federal, state, and local governments.

Moving forward, just as the FDA had to grant approval for OxyContin, approval will also need to be granted for new virtual reality clinical therapies. This may pose a challenge as it was seen how big pharma companies held significant influence over the FDA in the case of OxyContin. However, the federal initiative may encourage the FDA to approve more alternative pain therapies. This was therefore a major step needed for the progress of virtual reality pain treatment in that official government action and funding encourages the research, support, and approval of alternative methods of pain treatment. Overall, whether it is favored or not— and whether the outcomes are good or bad— the federal government possesses the power to enact major change and unite several industries in times of crisis.

Conclusion

When analyzing the development of the opioid epidemic, it was found that several lessons can be learned from history to be applied to analyzing the development of a potential solution. A closer look at the background of the beginnings of the opioid crisis revealed that past research studies, big healthcare industry players, and government regulation are sure to be power houses of influence in the development of VR pain therapy as a potential part of the solution. Past VR pain therapy studies such as *SnowWorld* and *Cool* have been extremely impactful in establishing the groundwork for future studies to come. Because *SnowWorld* was the first VR

pain therapy experience ever developed, it opened doors for and inspired countless studies for the new technology. While *SnowWorld* has been a major influencer as a research tool in that it has helped provide ample literature about VR pain therapy for acute pain, *Cool!* serves as a significant example in that not many studies exist about VR pain therapy for chronic pain. While research has come a long way, there is still much work to be done to further solidify VR pain therapy's potential in that more research must be conducted not only in the field of chronic pain, but also for analyzing the effectiveness of VR in replacement of opioids or intervening early before opioid use. Furthermore, the case of physician Ted Jones's support for *Cool* reflected that even if one truly believes in the success of the new therapy, research can only come so far without funding or support from others in the healthcare industry. Therefore, just as research alone could only come so far, a physician's personal efforts and interests alone can only push the technology so far. While enterprising physicians like Ted Jones are actively exploring pain therapy alternatives on their own accord, big industry players such as big pharma and insurance companies serve as barriers to the wide-spread adoption of the technology. Though profit is rightful to pursue for such industries, a proper balance must be achieved so that patients can receive the safe treatment that they need and also reserve a right to. In times of crisis, however, the government has the overall power to push otherwise reluctant industries of the nation together. Regulation can push initiatives for alternative therapies and provide necessary funding for clinical trials, so that physicians like Ted Jones no longer have to struggle to support research by themselves. Therefore, a multi-industry approach is necessary for the development of alternative means of pain therapy such as VR.

Overall, it is the combined effort of researchers, medical physicians, pharmaceutical and insurance industries, and government regulation that will shape the development of VR as a pain

therapy approach. While much work remains to be done, a multi-industry approach is favorable to any one industry working alone. As the recent COVID-19 pandemic proves, there is strength in unity. On that note, in a time where everything is going virtual in the midst of a pandemic, the thought of virtual reality pain therapy as a solution for the opioid epidemic doesn't seem too far off.

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