

A learning health system for a clinical problem- Lay Summary

Arunima Ghosh¹, Maria Aslam²

¹Graduate School for Interdisciplinary Studies, University of St Andrews, Scotland, UK

²Department of Zoology, University of Punjab, Lahore, Pakistan

Abstract

The future of healthcare depends on integrating the past research results in healthcare with the researchers, clinicians, and informaticians' innovative ideas to form a platform where continuous learning can occur. The concept of continuous learning and the best use of the knowledge and technologies develop a Learning Health System. The Learning Health System is used to address clinical issues and make healthcare a better version. In this study, we searched on the Learning Health System(LHS) concepts, LHS features, advantages, and challenges from Google Scholar, PubMed, and the University of St Andrews' learning guidelines. We also focused on how opioid overdose is increasing at an alarming rate in the United States of America. This rise in opioid use in patients suffering from chronic pain is a clinical issue and causes more extended hospital stay due to opioid treatment. Based on the previous study and research carried out in the United States of America, we proposed a model. The proposed model's design is based on the concept of a continuous Learning Health System that can be used to address chronic pain, which is a clinical issue in patients who are on long-term opioid use.

Keywords: Learning Health System, Opioid, chronic pain, clinical problem

Introduction

Due to the increase in the number of diseases and health data availability, it is challenging for the researchers and physicians to handle this information manually. Peter Sondergaard, former Senior Vice President for Gartner Research company, mentioned in one of his speeches - "Information is the oil of the 21st century, and analytics is the combustion engine" [1]. New emerging technologies have shown their importance in every sector, including healthcare. By utilizing the knowledge of innovative technologies, the healthcare system is stepping towards the digitization process. There is a rising demand for "A Learning Health System (LHS)" to make the healthcare system cost-effective and care driven. This learning should be a continuous process and could be achieved by utilizing Computer Science, Information Technology, Biomedical Research, and Health Research.

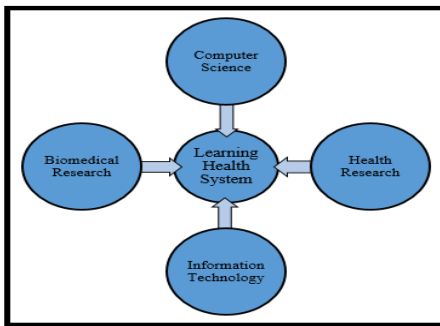


Figure 1: Integration of knowledge to build a LHS

Literature Review

In the early ninety's the term Evidence-Based Medicine (EBM) significantly impacted medical practice [2]. EBM is the integration of existing clinical expertise with the external clinical evidence that is available through systemic research to provide a valuable clinical decision towards individual patients [3]. Also, healthcare data and patient information are increasing every minute at a rapid rate. It has been a continuous challenge to share data across healthcare settings as it deals with personal health information (PHI). To get access to the healthcare data, we need to follow specific protocols and policies set by different regulatory bodies like Healthcare Insurance Portability and Accountability Act (HIPAA). It is essential to enable the decision-makers like researchers, clinicians to access the healthcare data, analyze them, and share their views and reports of analysis with their colleagues. This will enable them to work hand in hand and share the comments and reactions about their works. All these processes will enhance further exploration and discovery to make healthcare a better version.

Therefore, to improve EBM and develop innovative ideas to make health practice more efficient and cost-effective, in 2006, the Institute of Medicine (IOM) in the USA focused on the term Learning Health System [4]. The LHS is defined as- "*science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral byproduct of the delivery experience*"¹

Characteristics of the Learning Health System

The LHS is an approach towards improving care quality by making it cost-effective [5]. This can be done by setting up a well-organized healthcare setup by developing a system to integrate care delivery experiences, analyze the information available from healthcare data, and use advanced technology, leadership, and management skills. LHS is the scientific movement from data to knowledge and knowledge to practice [6]. The participants of the LHS can be Patients, Family, Caregivers, Physicians, Providers, Researchers, Policy Makers, and Community.

¹ https://www.ncbi.nlm.nih.gov/books/NBK207218/#ref_000432

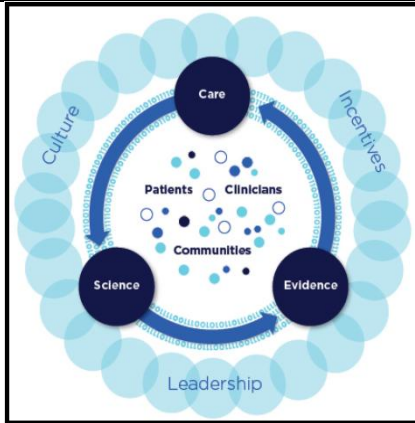


Figure 2: LHS Schematic presentation
Source: (Smith M, et al. 2013)

According to McGinnis, J.M. et al., there are several characteristics of a LHS [7]. Table 1 summarizes the LHS's characteristics as described by McGinnis, J.M. et al.

Table 1: Source: (McGinnis, J.M. et al. 2011)

Learning Health System Characteristics	
Culture	participatory, team-based, transparent, improving
Design and processes	patient-anchored and tested
Patients and public	fully and actively engaged
Decisions	informed, facilitated, shared, and coordinated
Care	starting with the best practice, every time
Outcomes and costs	transparent and constantly assessed
Knowledge	ongoing, seamless product of services and research
Digital Technology	the engine for continuous improvement
Health Information	a reliable, secure and reusable resource
The data utility	data stewarded and used for the common good
Trust fabric	strong, protected, and actively nurtured
Leadership	multi-focal, networked, and dynamic

Therefore the key characteristics of the LHS can be summarized as follows:

Science and Informatics- Using the digital platform to capture and manage the real-time healthcare data and integrate it with the available evidence to make a better clinical decision.

Patient-Clinical Partnership- LHS is based on a patient's need. Therefore, patients, families, caregivers, and healthcare professionals should collaborate and influence each other while making healthcare decisions.

Incentives and Transparency- Recognition and awards should be given to the healthcare organizations that are successful in rendering quality care at a reduced cost to the patients. There should be a systematic tracking of the evidence aligned towards continuous improvement.

Continuous Learning Culture- Finally, we can build an ideal healthcare system with the urge to learn and improve from evidence, research, and practices. This can be achieved with strong leadership, teamwork, training, and the entire system's management.

Enablers to Learning Health System

Electronic Health Records and EBM can be the enablers for the LHS. The concept of Electronic Health Records came into practice from the American Health System [8]. With the exponential increase in healthcare data, there is an increase in clinical trials' complexity [9]. Electronic Health Records (EHR) are used to collect data. EHR comprises information about Hospitals, Electronic Medical Records (Physicians and Clinicians dealing with patient's record), Vitals of Patients, laboratory Data, Radiology Reports, and Insurers. It can also be used in addressing clinical-based research questions. So EHR is the enabler for the LHS, but it is not sufficient when the data's scalability comes into question. The clinicians use Evidence-Based Medicinal practice to render treatment to the patients based on the previous information available. The LHS can be used to make Evidence-Based Medicine a better version [4].

Key Elements of Learning Health System

Professor Charles P. Friedman, in the year 2014, proposed the cyclic feature of the LHS. According to him, the LHS should be a closed-loop to ensure continuous transparency at every step of development aligned to health, wellness, and care delivery for every individual. To give the LHS a better concept and make it more effective, efficient, and sustainable, Professor Charles P. Friedman mentioned that there should be a platform within which the developmental loop should run continuously [10]. Continuous iteration of the loop within the infrastructure will ensure that all the stakeholders are benefitted from the shared platform.

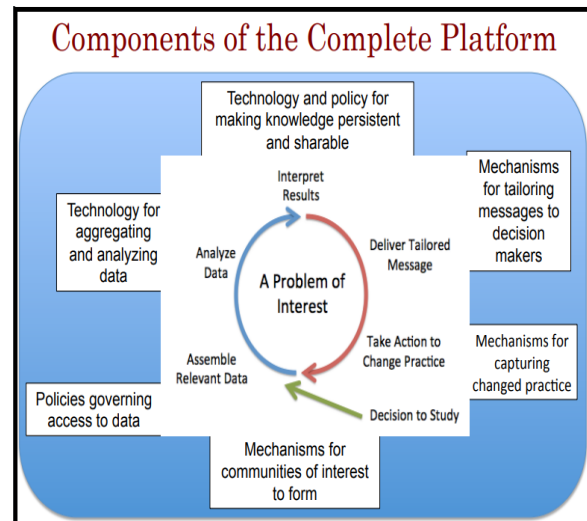


Figure 3: Components of the LHS inside a complete platform.
Source: (Friedman, C. P. et al. 2014)

The components of the complete platform in the LHS could be-

- **Policies governing access to data-** Ensure access to the data by following the right guidelines and protocols.
- **Technology for aggregating and analyzing data-** New emerging technologies ensure analyzing the accessed data.
- **Technology and policy for making knowledge persistent and shareable** – Integrating policy and technology to continue knowledge flow and sharing.

- **Mechanisms for tailoring messages to decision-makers** – The system for endearing feedback to the decision-makers should be developed.
- **Mechanisms for capturing changed practice**- A strategy to maintain and track the changes introduced towards implementing the LHS should be developed.

Based on figure 3, Professor Charles P. Friedman mentioned there are three key elements of any LHS-

- ✚ **Blue side:** The functioning of the steps represented with the blue arrow of aLHS loop is carried out by using the ideas of new technologies. The actions associated with the afferent blue side are as follows-
 - Assembling of data from different sources like patient records, radiological images, genomic sequences, etc.
 - Analyzing the information gathered from various sources.
 - Interpretation of the analyzed data.
- ✚ **Red side:** The steps associated with the LHS's red arrow are aligned towards the behavioral change due to implementing new ideas. The key areas of the red side are as follows-
 - Delivery Tailored Message, which means the feedback given towards the changed system. This feedback can be in several formats.
 - Take Action to Change Practice means implementing the changes in the healthcare settings that have been learned from the entire process.

- ✚ **Scale:** The changes achieved till now can be from a smaller group to a larger group. i.e., the difference can be at institutional, national, or international levels. Figure 4 represents the LHS cycle with its three key components reproduced from "Toward complete & sustainable learning systems" by Professor Friedman, C. P. in 2014.

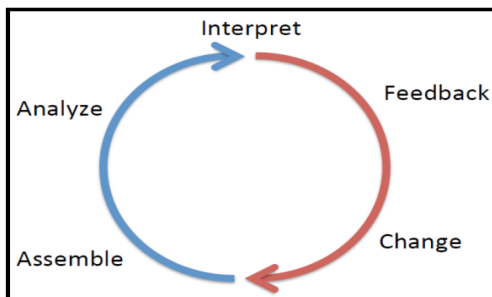


Figure 4: Key Components of the Learning Health Cycle. Source: (Friedman, C. P. et al. 2015)

Thus, we can understand from the above figures that the LHS is implementing advanced technologies in the healthcare system for the betterment of society. Dr. Paul Wallace stated in one of his interviews in 2015 that the LHS bears socio technical features.

Advantages of Learning Health System

The Healthcare system can be embraced happily by every individual if we can get the best care at a lower cost. To achieve this success, we need to promote learning at every healthcare system stage in a systemic way. This can render the best care at a lower cost and ensure lower mortality rates [11]. The increase in healthcare complexity in several areas, such as increased diagnosis, availability of treatment options, increased clinical evidence, etc., has put the healthcare system into a challenging platform. These challenges are not limited to one specific area; instead, it includes science and technology, evidence-based care rendered by clinicians, patient's feedback from the treatments, impact of changes on the community and society. Figure 5 represents the challenging areas of a healthcare system that needs to be addressed. Addressing these challenges are out of the scope of human to handle the issues manually.

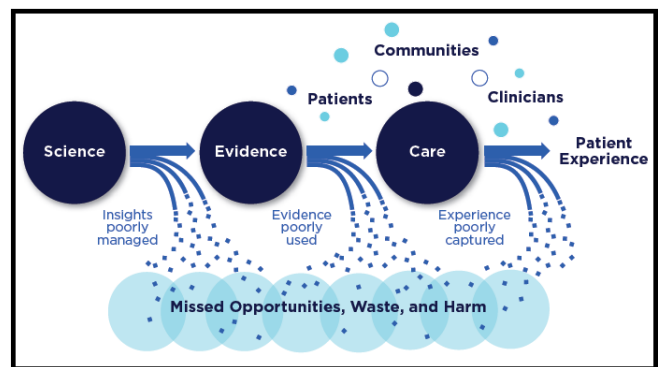


Figure 5: Challenging of the healthcare system.

The number of research papers published since the year 2007 to 2017 has increased in number. All these publications are aligned to the topic of LHS. Figure 6 and 7 represents the increasing trend by frequency and category, respectively.

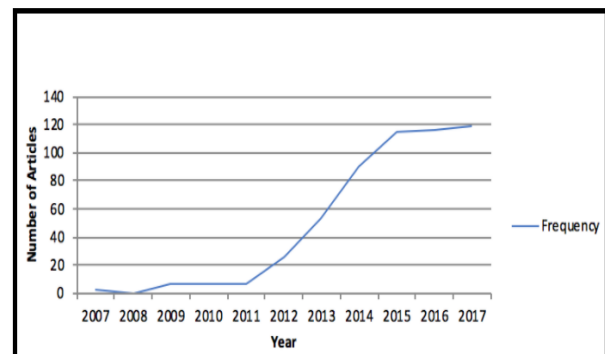


Figure 6: Frequency of articles published by year. Source: (Platt, J. E. et al. 2020)

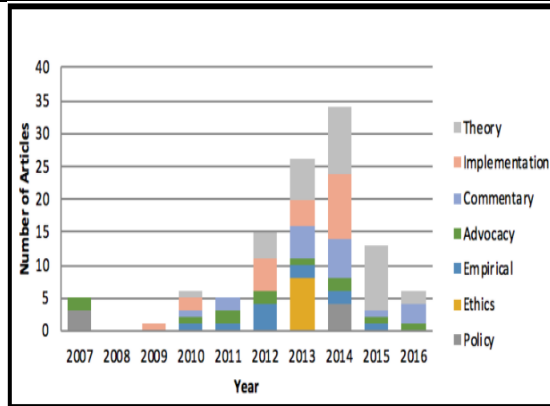


Figure 7: Trends in article categories among frequently cited articles based on the review of frequently cited articles.

Source: (Platt, J. E. et al. 2020)

The issues encountered in different areas of the healthcare system can be addressed with the emerging technologies to get a fruitful result. Some of these advantages are-

Automatic Summarisation of the clinical notes – The Automated Summarisation method reduces the data and represents the most relevant information out of the whole context. HER contain information about patient care. This information is enormous in number. Going through all the details in the EHR at the time of treating a patient is tedious and time consuming for the clinicians. The Automatic Summarisation technique ensures the delivery of summarized information about the patient's past medical history to the clinicians [12]. Figure 8 illustrates the Automatic Summarization of Electronic Health Records.

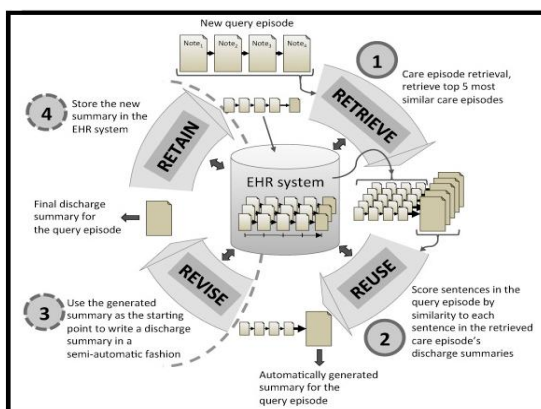


Figure 8: Automatic Summarisation of Electronic Health Records. Source: (Moen, H. et al. 2016)

❖ **Make data collection easy** – Clinical research forms the base for EBM. The randomized clinical trials (RCTs) determine a treatment's efficacy and safety before it is practiced in a patient. Based on the RCTs, the regulatory authorities control the launching of a new drug in the market [13]. Despite being a standard method in determining the level of efficiency of a

patient's treatment, RCTs have limitations in determining whether a specific treatment will be efficient for a particular patient in a specific setting or not [14]. This gives rise to a scarcity of information available to the clinicians, thereby building a gap in the EBM. Not only this, but also, the clinical trials are costly and time-consuming. To get access to all the clinical information, some healthcare leaders are interested in using EHR to ensure access to data within less time and at a low cost. The information stored in EHR can be used further for evidence-based treatment. In the year 2014, Christopher A. Longhurst et al. Suggested a model called "green button" [15] that functions within the electronic health record and helps in decision making at the time of treatment.

A LHS needs to access and analyze the data at the population level to manage population health. Later in the year 2020, the SMART/HL FHIR Bulk Data Access API [16] system was designed. This system can access patient data across a patient population.

❖ **Clinical Decision Support System** – Clinical Decision Support Systems (CDSSs) are the software that helps the clinicians in clinical decision making while rendering treatment to patients. CDSSs can make clinical decisions by advising on specific treatments based on the patient's characteristics. The clinicians then use the decision made by CDSSs to make final clinical decisions. CDSSs are not the clinicians' replacement; instead, it is an integration of the information's and suggestions generated by the systems with the clinicians' knowledge. CDSSs are usually classified into knowledge-based and non-knowledge-based. The knowledge-based CDSSs are program-based, where this system runs on the logic of *if-then* statements. The non-knowledge based CDSSs, are designed based on the concept of Artificial Intelligence, Machine Learning, and Statistical Pattern Recognition. There are several real-time applications of CDSSs, out of which one is the AI-Pathway Companion product designed by **Siemens Healthiness**. The **AI-Pathway Companion product** is an intelligence-based support system that enables clinicians to make diagnostic and therapeutic decisions. Apart from this, there are several other advantages of CDSSs like – Clinical Management, Cost Management, Patient Support Decision Making, etc [17].

Challenges of Learning Health System

Apart from having several advantages and real-time applications, there are certain barriers to successfully implementing and accepting a LHS. EHRs and the LHSs share some common barriers among them [18]. Some of these barriers are-

❖ **The high cost of implementation** – Designing and developing a concrete infrastructure with the idea and concept of Learning Health System requires hefty funds. Therefore, the small group of industries cannot adopt these ideas despite the urge to implement them.

❖ **Regulatory barriers** – Access to patient data needs to cross specific regulatory barriers like getting approval

from the governing bodies. This is a time taking process due to the data privacy and security act.

- ❖ **Interoperability** – Accurate interoperability among all the LHS participants is challenging, as the clinical guidelines put restrictions on sharing information.
- ❖ **Slow adoption** – It is challenging to convince the senior doctors due to their overbearing sentiments to use the latest technologies. From the patient's perspective, it is hard to collect feedback from the elderly patient about benefiting from the latest technology and changed treatment process.

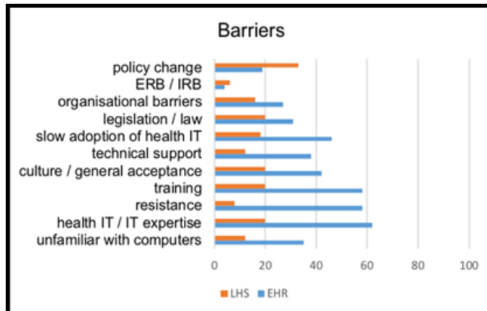


Figure 9: Barriers to LHS and Electronic Health Records. Source: (McLachlan, S. et al. 2019)

Learning Health System in addressing a Clinical problem

To improve patients' health, accurate diagnosis, specific treatment plan at the correct time, continuous monitoring of health, future care, and preventive measures are essential. So, a systemic process needs to be followed to address any clinical issue. Addressing a clinical problem is not the clinician's sole responsibility. Patient engagement and knowledge of the researchers to make the best use of emerging technologies are also equally important.

As per the **Centers for Disease Control and Prevention (CDC)**, the dispensing rate of Opioid medication prescriptions increased drastically in the United States of America between 2006 and 2014. Even though the CDC statistics show a fall in number from 2014 to 2019, it is still alarming to the nation.

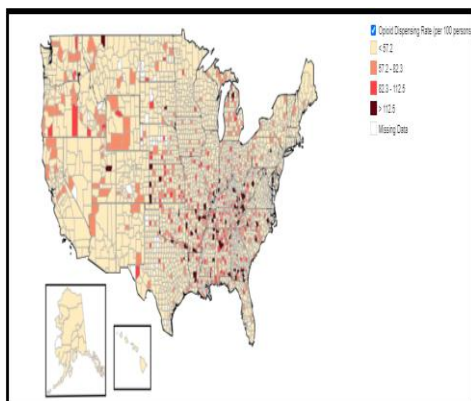


Figure 10: U.S. Country Opioid Dispensing Rates, 2019

An opioid is an analgesic [19] drug (methadone, fentanyl, morphine), which is widely used in the treatment of pain like-cancer pain, acute pain, and chronic non-cancer pain. According to the Institute of Medicine report, one in every three adults in America suffers from **chronic pain**. The use of opioids in treating pain has shown several side effects like- nausea, drowsiness, constipation, etc [20], which results in a longer hospital stay. As per the Neurobiological and Psychological research, pain can bring change in our emotional behavior. An unfavorable change in emotional behavior can affect our social life as well [21]. This gives rise to a clinical issue and a threat to healthcare professionals, researchers, and patients.

A recent study conducted on Opioid Use Disorder (OUD) showed that patients under prolonged treatment of intravenous antibiotics due to infectious pain resulted in longer hospital stay [22]. This study was carried out based on the patients' discharge records admitted to acute care hospitals in the USA. The inpatient information list was collected from the **National Inpatient Sample Database** for the year 2016. This study showed the adverse effect of opioid treatment on patients and the longer hospital stay cost.

The concept of the LHS features and the pain management guidelines can reduce opioid overdose in case of chronic pains, which will also reduce the length of hospital stay.

The steps that need to be followed to achieve the goal of continuous LHS are:

1. Building a database center to collect relevant information about the patients of a particular region.
2. Make an inpatient list of patients of that specific region.
3. Filter the list to get the information about the patients with opioid overdose due to chronic pain from the Electronic Health Records. A threshold value for opioid dose/day for a patient must be set as per the **Center of Diseases Control**.
4. Based on step 3, make the list of patients under opioid treatment due to chronic pain for more than five days admitted in the hospital. Segregate the list based on the patient's age.
5. Physicians with the patient's consent should plan the treatment based on the principles of the Biopsychosocial model [23]. The treatment method should address the patient's - physical and biological factors, psychological behavior, thoughts, beliefs, family, social life, and work balance. The first aim of this treatment method is to achieve a fitness goal in a patient. It is good to select the patients between the age group of 16 – 18 years in the first round.
6. Carry out continuous professional education for all health professionals.
7. Conduct regular feedback sessions from the physicians and the patients involved in step 5.
8. If a positive response is obtained from the patients and the physicians, keep the record in the database as evidence of support for future use.
9. If not successful with steps 5, 6, and 7, then carry future research and survey.

Figure 11 represents a proposed model of the LHS to treat patients on opioid overdose due to chronic pain. The model is proposed based on the nine steps explained above.

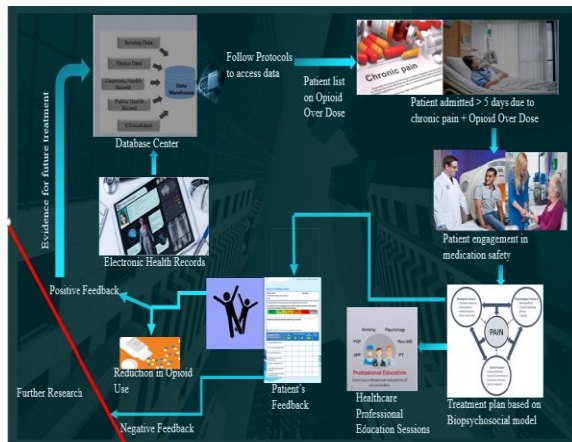


Figure 11: Proposed model on the LHS to address opioid overdose due to chronic pain

This is a loop-based model where the data extracted from the data center is used to collect information. Finally, the positive feedback is stored back in the data center. This evidence of feedback can be used as a support system in clinical decision making by the physicians to treat patients with similar conditions. This model's steps can be iterated by carrying out the trial in different age groups of patients.

A similar study on prescribing trends of Opioid drugs in treating non-cancer pains was also carried out at the primary care centers in some parts of the U.K. The study concluded that patients in the South West regions of England, Yorkshire, and the Humber were at an alarming rate of long-term opioid use [24].

Conclusion

The Healthcare industry is one of the fastest-growing sectors in the world today. Leaps in digital technology have shown the potential and benefits of a well-managed healthcare system in many parts of the world. However, the quality of care cannot be managed single-handedly by clinicians or informaticians alone. To render better care at a lower cost to the patients, the researchers, informaticians, and clinicians should work as a team. There should be a platform where the team members can share their feedback on work. To achieve this goal, IOM focused on the concept of the LHS. This learning is a continuous process. The LHS is a loop with three key elements. Using the LHS concept, healthcare has been re-designed in several areas like collecting the information and using this information in the future to treat similar illnesses further. Using some of the LHS features, it was possible in the USA to control the overdose of Opioid medicine. Based on the LHS idea and using the Pain Management guidelines, I proposed a model under Figure 11 to reduce opioid dependency in patients with chronic pain. Research on opioid dependence in patients suffering from non-cancer pain has been carried out in some U.K. regions. Future research in other parts of the U.K. should also be carried, and the information should be kept as a record for further treatment in the National Health Service (NHS).

References

1. Leitner, L. *New Degree Program Proposal Master of Science in Data Science and Strategic Analytics (This new program will replace the current Master of Science in Computational Science)* (Doctoral dissertation, Federal Aviation Administration)
2. Kamath, S., & Guyatt, G. (2016). Importance of evidence-based medicine on research and practice. *Indian journal of anesthesia*, 60(9), 622.
3. Sackett, D. L. (1997, February). Evidence-based medicine. In *Seminars in perinatology* (Vol. 21, No. 1, pp. 3-5). WB Saunders.
4. Institute of, M. *The Learning Health System Series*. 2015 [cited 2015 4 June]; Available from: <http://www.nap.edu/catalog/13301/the-learning-health-system-series>.
5. McGinnis, J. M., Stuckhardt, L., Saunders, R., & Smith, M. (Eds.). (2013). *Best care at lower cost: the path to continuously learning health care in America*. National Academies Press.
6. Hultman, G. M., Rajamani, S., Wilcox, A., & Melton, G. B. (2020). Expert Perspectives on Definitions, Drivers and Informatics Contributions to Learning Health Systems. *AMIA Summits on Translational Science Proceedings, 2020*, 251.
7. McGinnis, J. M., Powers, B., & Grossmann, C. (Eds.). (2011). *Digital infrastructure for the learning health system: the foundation for continuous improvement in health and health care: workshop series summary*. National Academies Press.
8. Evans, R. S. (2016). Electronic health records: then, now, and in the future. *Yearbook of medical informatics*, (Suppl 1), S48.
9. Bertagnolli, M. M., Anderson, B., Quina, A., & Piantadosi, S. (2020). The electronic health record as a clinical trials tool: Opportunities and challenges. *Clinical Trials*, 1740774520913819.
10. Friedman, C. P., & Macy Jr, J. (2014). Toward complete & sustainable learning systems. *University of Michigan*.
11. Committee on the Learning Health Care System in America; Institute of Medicine. *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*. Smith M, Saunders R, Stuckhardt L, McGinnis JM, editors. Washington (DC): National Academies Press (US); 2013 May 10. PMID: 24901184.
12. Moen, H., Peltonen, L. M., Heimonen, J., Airola, A., Pahikkala, T., Salakoski, T., & Salanterä, S. (2016). Comparison of automatic summarisation methods for clinical free text notes. *Artificial intelligence in medicine*, 67, 25-37.
13. Kabisch, M., Ruckes, C., Seibert-Grafe, M., & Blettner, M. (2011). Randomized controlled trials: part 17 of a series on evaluation of scientific publications. *Deutsches Ärzteblatt International*, 108(39), 663.

14. Mulder, R., Singh, A. B., Hamilton, A., Das, P., Outhred, T., Morris, G., ... & Lyndon, B. (2018). The limitations of using randomised controlled trials as a basis for developing treatment guidelines. *Evidence-based mental health, 21*(1), 4-6.
15. Longhurst, C. A., Harrington, R. A., & Shah, N. H. (2014). A 'green button' for using aggregate patient data at the point of care. *Health affairs, 33*(7), 1229-1235.
16. Mandl, K. D., Gottlieb, D., Mandel, J. C., Ignatov, V., Sayeed, R., Grieve, G., ... & Culbertson, A. (2020). Push Button Population Health: The SMART/HL7 FHIR Bulk Data Access Application Programming Interface. *npj Digital Medicine, 3*(1), 1-9.
17. Sutton, R. T., Pincock, D., Baumgart, D. C., Sadowski, D. C., Fedorak, R. N., & Kroeker, K. I. (2020). An overview of clinical decision support systems: benefits, risks, and strategies for success. *NPJ Digital Medicine, 3*(1), 1-10.
18. McLachlan, S., Dube, K., Johnson, O., Buchanan, D., Potts, H. W., Gallagher, T., & Fenton, N. (2019). A framework for analysing learning health systems: Are we removing the most impactful barriers?. *Learning health systems, 3*(4), e10189.
19. Majumdar, S., Grinnell, S., Le Rouzic, V., Burgman, M., Polikar, L., Ansonoff, M., ... & Pasternak, G. W. (2011). Truncated G protein-coupled mu opioid receptor MOR-1 splice variants are targets for highly potent opioid analgesics lacking side effects. *Proceedings of the National Academy of Sciences, 108*(49), 19778-19783.
20. Baldini, A., Von Korff, M., & Lin, E. H. (2012). A review of potential adverse effects of long-term opioid therapy: a practitioner's guide. *The primary care companion to CNS disorders, 14*(3).
21. Lumley, M. A., Cohen, J. L., Borszcz, G. S., Cano, A., Radcliffe, A. M., Porter, L. S., ... & Keefe, F. J. (2011). Pain and emotion: a biopsychosocial review of recent research. *Journal of clinical psychology, 67*(9), 942-968.
22. Kim, J. H., Fine, D. R., Li, L., Kimmel, S. D., Ngo, L. H., Suzuki, J., ... & Herzig, S. J. (2020). Disparities in United States hospitalizations for serious infections in patients with and without opioid use disorder: A nationwide observational study. *PLoS medicine, 17*(8), e1003247.
23. Steglitz, J., Buscemi, J., & Ferguson, M. J. (2012). The future of pain research, education, and treatment: a summary of the IOM report "Relieving pain in America: a blueprint for transforming prevention, care, education, and research". *Translational behavioral medicine, 2*(1), 6-8.
24. Jani, M., Birlie-Yimmer, B., Sheppard, T., Lunt, M., & Dixon, W. G. (2020). Time trends and prescribing patterns of opioid drugs in UK primary care patients with non-cancer pain: a retrospective cohort study. *medRxiv*.
25. Platt, J. E., Raj, M., & Wienroth, M. (2020). An Analysis of the Learning Health System in Its First Decade in Practice: Scoping Review. *Journal of Medical Internet Research, 22*(3), e17026.)
26. Moen, H., Peltonen, L. M., Heimonen, J., Airola, A., Pahikkala, T., Salakoski, T., & Salanterä, S. (2016). Comparison of automatic summarisation methods for clinical free text notes. *Artificial intelligence in medicine, 67*, 25-37.