



SYSTEMATIC REVIEW

Human factors in ECLS – A keystone for safety and quality – A narrative review for ECLS providers

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Abstract

Introduction: Although the technology used for extracorporeal life support (ECLS) has improved greatly in recent years, the application of these devices to the patient is quite complex and requires extensive training of team members both individually and together. Human factors is an area that addresses the activities, contexts, environments, and tools which interact with human behavior in determining overall system performance.

Hypothesis: Analyses of the cognitive behavior of ECLS teams and individual members of these teams with respect to the occurrence of human errors may identify additional opportunities to enhance safety in delivery of ECLS.

Results: The aim of this article is to support health-care practitioners who perform ECLS, or who are starting an ECLS program, by establishing standards for the safe and efficient use of ECLS with a focus on human factor issues. Other key concepts include the importance of ECLS team leadership and management, as well as controlling the environment and the system to optimize patient care.

Conclusion: Expertise from other industries is extrapolated to improve patient safety through the application of simulation training to reduce error propagation and improve outcomes.

KEYWORDS

behavioral skills, ECLS, ECMO, extracorporeal life support, extracorporeal membrane oxygenation, human factors, simulation, training

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1 | INTRODUCTION

The use of extracorporeal life support (ECLS), while dependent on high-performing technology, remains heavily reliant on human factors, requiring extensive training of individual team members as well as the whole team. In the literature, definitions of the requirements for organizing and coordinating ECLS procedures are summarized, as well as the general structures of a team and descriptions of the cannulation procedure, indications, contraindications, and device requirements have been published.^{1–6} However, successful resolution of a medical emergency and procedure troubleshooting also depends on the individual and team behavioral skills, leadership, communication and teamwork of key participants on the ECLS team.⁷ Human factors science was established to understand how people perform under different circumstances focusing on improving efficiency while minimizing errors as well as of appropriately reacting in the presence of complications.⁸ With the significant increase in ECLS utilization and mounting understanding of the challenges for centers, teams, and individual providers, we argue that patient care is a team effort that is dynamic, subject to review, and effectively trained, commonly via simulation.^{7,9,10} The need for effectively functioning ECLS teams has been affirmed by the recent COVID 19 outbreaks.^{11–14}

The objective of this manuscript is to support physicians, perfusionists, nurses, respiratory therapists and other specialists who perform ECLS or who are starting an ECLS program by establishing standards for safe and efficient ECLS procedures through elevating human factor capabilities. We reviewed the literature concerning leadership, guidance, and mentorship in situations where ECLS is used and initiated. Recommendations with respect to behavior and illustrate the ideal setting in which a ECLS program could be run are provided. We developed an idea of managing yourself, the ECLS team, the environment, and the system to optimize patient care guidance and characteristics of a leader of ECLS, including their organizational talents, skills in communication and initiating medical decisions (Figure 1).

2 | METHODS

An advanced search of MEDLINE through the PubMed database using the following Medical Subject Headings (MeSH) terms: “Extracorporeal Membrane Oxygenation” OR “ECLS” OR “ECMO” AND “High Fidelity Simulation Training” OR “Computer Simulation” OR “Patient Simulation” OR “Simulation Training” OR “Simulator”, assessed on February 20th, 2020, identified 47 records.

From those, 25 publications indicated that the authors addressed human behaviors, communication and leadership skills, situational awareness and teamwork related to ECLS education and simulation training.^{7,15–38} Although much literature has emerged on identifying and optimizing human factors in high-stress situations, little has been published on the specific ECLS-related challenges. Guidance on the human factors influencing approach of creating ECLS teams, and managing these patients is lacking and mostly relies on individual institutional practice. While literature explicit to human factors in ECLS is still scant, provider and teams that are involved in ECLS have recognized the human challenges and non-specific literature could be applied well to this subspecialty.

Meanwhile, Free Open Access Medical Education (FOAM) on social media represents an important building block in the acquisition of information in the context of further medical training.^{8,39–41} Finally, the EmCrit blog and podcast, summaries of REANIMATE conferences organized by the ED ECMO team, including ED ECMO website and podcast, which provide dedicated contributions to understanding of multidisciplinary teamwork and human factors, were reviewed.^{40,42} The EmCrit and ED ECMO Projects are the work of three resuscitators to bring extracorporeal life support to Emergency Departments and Intensive Care Units around the world, being the ultimate resource for the background, logistics, and evidence for resuscitative ECMO.^{8,40}

3 | ECLS AS A TEAM APPROACH

Guidelines on ECLS, such as provided by Extracorporeal Life Support Organization (ELSO)^{9,43} and other recommendations primarily focus on drugs and procedures,^{1,3,5,6} with little focus on the influence of team performance and human behaviors. Human factors contributing to decision-making during resuscitation have been identified and may be mitigated by tailored stress training and cognitive aids.⁴⁴ Understanding these factors may have implications for clinician education and the development of decision-support tools.⁷ However, ECLS performance is also affected by how individuals and teams perform.⁴⁵ Released critical incident reviews provide proof that, when teams work well, it is not by chance alone; rather, members think, behave, and interact to the benefit of others while maintaining individual responsibility for patient safety. Regarding ECLS performance and quality, team training seems to be well received by staff, facilitates clinical learning, and positively alters staff behaviors. However the duration of the behavioral changes is unclear.⁷

Patients who need ECLS require interdisciplinary care, including attending physicians, surgeons, fellows, nurses,

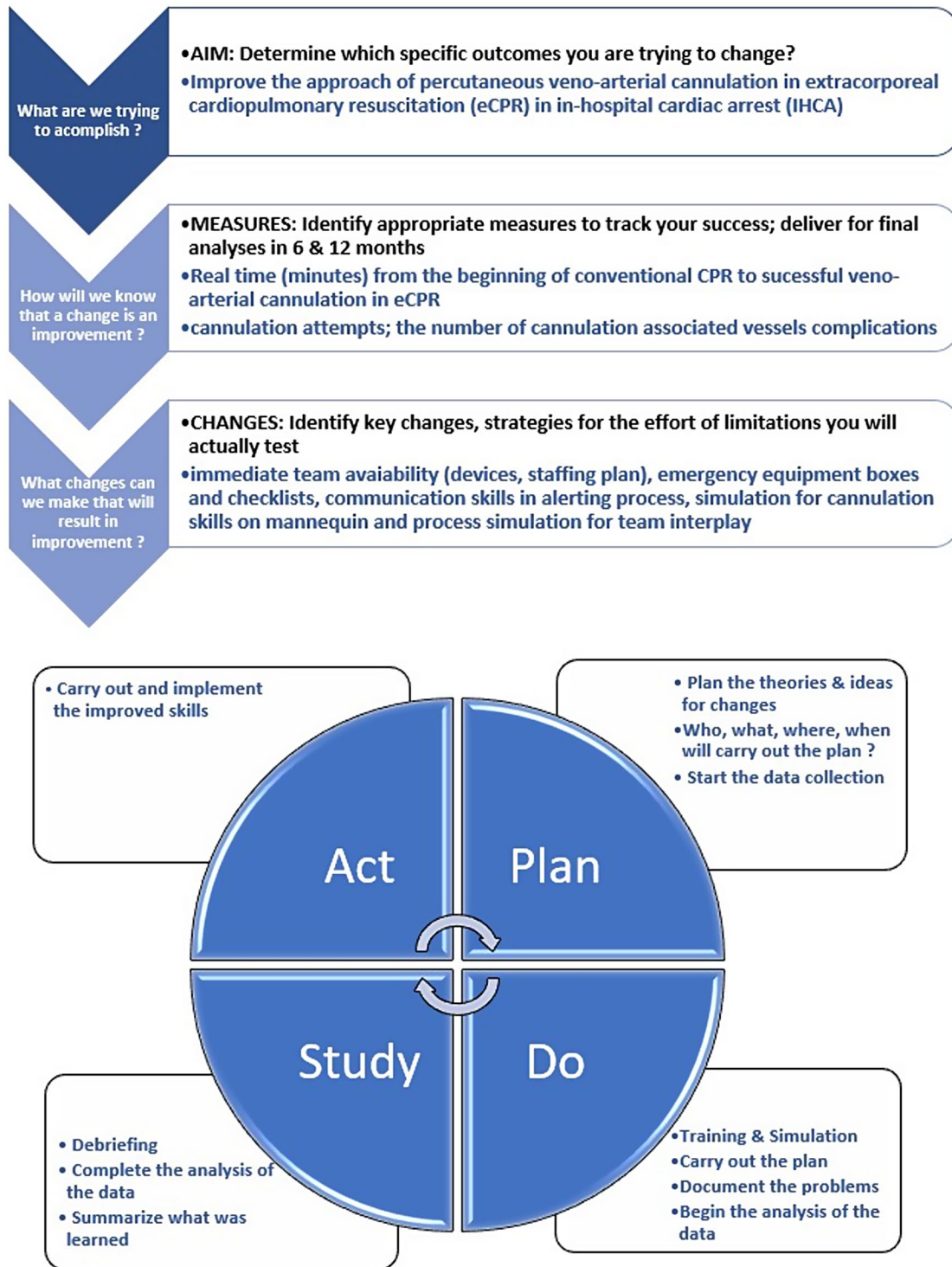


FIGURE 1 The model for improvement (structured approach) and multiple Plan-Do-Study-Act (PDSA) cycles building sequentially on a promising idea. (Adapted from Langley G, et al.⁷¹) [Color figure can be viewed at wileyonlinelibrary.com]

nurse practitioners, physician assistants, and pharmacists from the intensive care unit and others like physiotherapists, social workers, and palliative care specialists. How the team is ultimately built depends on the structure of the hospital and intensive care unit.^{46–48} The number of interventions carried out and the orientation of the department

(adult, pediatric or neonatal, cardiac, respiratory or both) also influence the size of the team and the need for training and further education. Center volume versus outcome relationship in ECLS is also controversial and there are conflicting studies on how close this relationship is. Nonetheless, it ties in with the concept of human factors,



that more ECLS training may be needed low volume center to have better the clinical outcomes.^{49–53}

4 | AN ECLS TEAMS REQUIRE A LEADER

Decision-making in ECLS is an interdisciplinary consensus between ECLS-specialized clinicians. The ECLS team is a group of professionals drawn from the specialties of emergency medicine, intensive care, surgery, anesthesiology, perfusion, nursing, and allied health and support staff who work together as a team to assess and manage the patient. Allocated roles and responsibilities are crucial for successful team performance. In the allocation of roles, as in the allocation of tasks and treatment, the overriding principle is to ensure that optimal care is always delivered to the patient. Each team member has several key tasks they are responsible for. All actions should be coordinated by the team leader, ideally one of the most experienced team members. Considering the team as an orchestra, it plays as the conductor leads.⁵⁴ Team members with less experience should also develop leadership experience while being supervised. A successful co-pilot subsequently acts as the pilot.

The need for an ECLS team leader is similar to emergency situations, such as advanced life support in trauma or resuscitation. ECLS team leaders are not necessarily the person who cannulates for ECLS. They may be also a separate member of the team. The trauma team leader is traditionally a person who coordinates the resuscitation and ensures adherence to Advanced Trauma Life Support (ATLS) guidelines.⁵⁵ The presence of a trauma team leader on the trauma team is associated with positive patient outcomes during a major trauma. In a similarly complex and multidisciplinary therapy such as ECLS, a dedicated leader to co-ordinate is needed.

5 | REQUIRED SKILLS OF AN ECLS TEAM LEADER

Human factors play a role as the primary cause of aircraft accidents in more than 80% of cases. Most aviation errors are based on psychological factors, such as overconfidence. Errors may occur even if pilots are mentally and physically fit, well-trained, and experienced. Furthermore, considering that aircraft are built by humans, it is possible that mechanical failures may also be due to human error.

During a 6-month observational period performed at 3 large institutions in an academic medical setting, adverse events occurred in 3.4% of patients undergoing heterogeneous surgical operations.⁵⁶ Analysis of human performance deficiencies associated with surgical adverse

events found that human errors were identifiable in 56.4% of the complications occurring in major cardiothoracic, vascular, abdominal transplant, surgical oncology, acute care, or general surgery.⁵⁶ Physicians who have completed their training and have accumulated habits over time are not immune to "human" failure. The more complex the process, the higher the likelihood of an error. Catchpole et al demonstrated that an average of two human errors occur even during successful surgery.⁵⁷

Additionally, it is known that the pressure of responsibility for human life and for the team, can weigh heavily on a team leader. The psychological fitness characteristics of pilots can be extended to physicians responsible for leading a team during high-risk procedures. Personality traits that ensure that stress is well tolerated without a significant decrease in performance include self-confidence, emotional stability, self-control, and appropriate risk awareness and discipline. Planning and organizational skills, as well as the motivation associated with positive thinking, characterize a good leader who raises team performance. Moreover, the perceptual and cognitive information processing are required to control complex devices, regardless of the degree of automation. The ability to avert awareness away from task-irrelevant external and internal stimuli and to focus attention at a consistently high level for prolonged times are two skills in great demand (Table 1). A truly good leader is hard to find, difficult to part with and impossible to forget. The ability to communicate with multidisciplinary team members involved in patient care can help to centralize care and to prevent errors. Active listening and discussion are two additional strategies conducive to offering constructive solutions to interpersonal conflict.^{45,55} Those mentioned skills are needed by all team members, not solely by team leader.

Although extremely far from the medical setting, the organization, structure, training, briefing and de-briefing modalities present in a "Pit-Stop Team" in Formula 1 car race, may provide a clear example of meticulous training and deployment of actions in critical moments when a dedicated team is asked to intervene quickly, effectively, and guided by a team leader.

6 | SAFETY BRIEFINGS AND ERROR REPORTING SYSTEMS

The detection and classification of procedural errors, and surrounding conditions are prerequisites for revealing the context and background of the failure and identifying associated risks. Even less dramatic events may be used to demonstrate avoidance experience if they are consciously perceived, analyzed in a timely manner and handled appropriately for future error prevention



TABLE 1 ECLS team leader-specific tasks, skills and attributes required in high-risk complex procedures, for example, extracorporeal cardiopulmonary resuscitation (ECPR)

ECLS team leader-specific tasks	Required skills, roles, and attributes
Deciding if the patient meets ECPR criteria, how to approach the cannulation and to continue resuscitation, how to manage if the patient stabilized or not; develop a plan B if the approach doesn't work and who should be involved in case of complications (e.g., cardiac surgeon in case of thoracic bleeding)	Appropriate risk awareness Prospective and future thinking Willingness to learn new things and to learn from one's own mistakes Perception and responsiveness to feedback, judgment and decision
Performing or supervise the ECPR cannulation or other procedures	Self-confidence Ability to avert awareness against task-irrelevant external and internal stimuli Multitasking skills, where attention must be focused on rapid changes and automated
Distributing information to team members if new aspects appear (lab results, changing conditions, new decisions) keeping track of and structuring various tasks and overseeing all activities within a team	Verbal and nonverbal communication skills Subconscious-minded action processes can run simultaneously with other operations Constant, focused attention at a consistently high level for a long period of time Ability to delegate Situational alertness Multitasking skills, where attention must be focused on rapid changes and automated
Resolving conflicts, for example, different opinions if ECPR should be continued or withdrawn	Integrity, emotional stability, will control Perception and responsiveness to feedback, judgment, and decision

as well as research. Team members who make mistakes may be reluctant to admit them. As such, errors are often not recognized or disclosed and the opportunity to institute appropriate countermeasures to reduce the rate of such errors is lost.

However, errors may contribute to preventing future accidents because when negative experiences are revealed, appropriate countermeasures can be taken. This strongly suggests that all errors should be analyzed, processed, and made known to all people involved. The expertise from other industries may be extrapolated to improve patient safety. In particular, team time-out procedures and operational checklists are well documented to increase safety.^{58,59} However, the checklist at the time of cannulation in some emergent situations this is not possible, but for urgent situations it might be useful. Alternatively, there should be a standard debriefing form for after cannulation. Routine team meetings and regular safety briefings also promote a culture of safety in the unit. Thus, participation in safety briefings and error reporting systems should be mandatory for every team member.

7 | ERROR AVOIDANCE

Current medical training conditions and experiences do not effectively reduce errors and mistakes. As workload increases, performance initially increases and then

decreases. Negative reactions to feeling overworked are confusion, channeled attention, resignation, frustration, and anger. This may lead to consequences such as a reduction in motor coordination, raised voice and pressured speech, which negatively affect team performance (Table 2). By way of self-reflection and mental training, these skills may be improved through a permanent change in behavior via practice and experience.^{42,60–62}

Poor decisions may escalate during procedures. This process can be diminished if stress levels are reduced, and decisions are rationally and consciously made. Available tools can be used to work through tasks one by one. The most effective type of monitoring is systematic screening where structured approach helps break a chain of erroneous decisions. As above, using checklists increases safety because operations can be systematically processed. Crisis resource management (CRM) guidelines for ECLS education are also available (www.euroelso.net).⁴¹

8 | MENTAL PRACTICE AND TRAINING

Mental practice is defined as the “cognitive rehearsal of a skill in the absence of an overt physical movement”.⁶⁰ It specifically refers to training where steps necessary to complete the procedure are mentally rehearsed prior to

TABLE 2 Factors negatively influencing team and personal performance during high-risk complex procedures, for example, extracorporeal cardiopulmonary resuscitation (ECPR)

Groups of negative factors	Detailed factors negatively influencing team performance during ECPR	Recourses to avoid, resolve and take out the negative influencing factors
Environmental stressors	Noise, unnecessary alarms on Devices and chatter Extreme temperatures High humidity Dehydration and feeling hungry Sleep deprivation	Only responsible and in the procedure involved team members are on the scene Pre-set unnecessary alarms on devices Control of room temperature if in-hospital Well-being culture, fulfilled staffing plan Limited over time and working hours
Mental stressors	Clinical training deficiencies Overwhelmed or underwhelmed Nervousness, confusion, malaise Lessening of concentration Anxiety, restlessness, resignation Frustration, anger Sleep disorders, depressive mental status	Structured training, mentoring programs Supervision, debriefing Mental training Simulation training of focusing on the tasks Simulation and mental training, supervision Supervision, mentoring, debriefing, feedback Well-being strategies, being aware excessive use of alcohol or abusive substances
Negative habits	Lack of flexibility/adaptability Lack of discipline Feeling of invulnerability Incomprehensibility Resignation Overconfidence Exaggerated ambition Desire to force something that inevitably interferes with the ability to adequately resolving problems and conflicts Ignoring rules, policies and recommendations Feeling admired and watched by others	Structured training of habits and skills Simulation and debriefing Supervision, mentoring and feedback

performance.⁶⁰ According to the randomized simulation study performed by Lorello et al the technique of mental training is a useful and inexpensive tool for improving nontechnical skills for team-based trauma care.⁶¹ Driskell et al in a meta-analysis found that mental practice has a greater influence on tasks requiring a larger mental workload (i.e., high-stakes situations) than tasks requiring strength and coordination.⁶⁰ ECLS cannulation, especially in extracorporeal resuscitation (ECPR), involves serious risk and should be regarded as a high-stakes situation like surgery and resuscitation in cardiac arrest or trauma.^{61–63} As such, we hypothesize that mental training may be a powerful tool for enhancing task performance during ECLS, ethical decision-making, decisions on escalation of care and can also be applied to leading a team. Further research in this area is warranted.

9 | THE ROLE OF SIMULATION

Most high-risk industries, such as aviation, include simulation training as a mandatory requirement. Statistically, aviation errors are due most often to psychological

factors, overconfidence, and equipment malfunction. Recommendations made by the aviation industry regarding technical and team-based training are transferable to ECLS centers and ECLS team training.^{15,64} The use of high-fidelity simulation training has become the standard for reinforcing technical skills, refining troubleshooting sequences, and enhancing team interactions.^{17,19–22,24,25,27–33,35–38,64} Modifications to mannequins to better simulate precise clinical and physiologic fidelity, support greater realism and participant buy-in.^{10,15,21,32,33}

Skills are achieved through a permanent change in behavior, itself accomplished by practice and experience. Several studies have demonstrated that simulation-based ECLS training can reduce error propagation and improve team performance, safety culture and patient-related outcomes.^{7,16,17,22,23,25,27,29,34,37,38,58,65} Furthermore, simulated scenarios have high psychological fidelity and induce stress levels like real emergency medical situations.⁶² Simulation has been accepted to complement or replace a direct patient contact hour; thus, participants can transfer their learning to real clinical settings.^{37,66} Placing an emphasis on high-quality educational learning opportunities for participants, for both initial training and continuing



TABLE 3 Recommendations

To make a difference in ECLS care, the place to start is improvements in team and leadership skills

Well-founded theory-based findings and knowledge about human psychophysiological performance and its implementation can help control critical situations in the workplace

Good communication with all people involved in planned interventions can help prevent errors and misunderstandings. Active listening are the strategies most likely to contribute to constructive solutions to interpersonal conflict

Critical mistakes or errors can serve as important learning tools if they are consciously perceived, analyzed, and appropriately handled

Team time-out procedures and checklists increase safety because operations can be systematically processed. Routine team meetings and regular safety briefings promote a safety culture in the unit

Simulation-based ECLS training improves team performance, safety culture and patient-related outcomes

professional development, provides opportunities to develop teamwork skills and expertise to decrease device- and patient-related risks.⁶⁵

Simulated scenarios should be followed by a debriefing session, during which the decision-making process and actions of the participants may be analyzed to develop a better understanding of the participant's mental framework.⁹ Additionally, pre-, and post-participation questionnaires may be used to determine the effect of a proficient transfer of knowledge, technical and behavioral skills, and confidence levels.

10 | ESTIMATED COSTS

The current literature indicates a large variation in estimated in-hospital costs for ECLS.^{67,68} The financial costs of simulation equipment limit their availability for ECLS training purposes.^{69,70} Screen-based simulators offer affordable and realistic alternatives.¹⁸ The financial impact of simulator based ECLS education is currently unknown, complex to understand, and challenging to predict. However, it is also difficult to balance the cost of education against the potential costs associated with preventable medical errors and associated morbidity.

11 | CONCLUSIONS

Analyses of the cognitive behavior of ECLS teams and individual members of these teams regarding human

error may identify additional opportunities to enhance safety in the delivery of extracorporeal life support (Table 3). Team members' activities, context, environment, and tools interact with each other and influence overall system performance. Expertise from other industries may be extrapolated to improve patient safety. Simulation and training can reduce error propagation and improve outcomes.

CONFLICT OF INTEREST

Prof. Dr. Lorusso is a consultant for Medtronic, Getinge and LivaNova and medical advisory board member for EUROSETS, all unrelated to this work; all honoraria to the university for research funding. Dr. Brodie receives research support from ALung Technologies, he was previously on their medical advisory board. He has been on the medical advisory boards for Baxter, BREETHE, Xenios and Hemovent. The remaining authors have disclosed that they do not have any conflict of interest.

AUTHOR CONTRIBUTIONS

Justyna Swol, Giles J. Peek, Zachary Shinar, Joseph Belezso, Scott D. Weingart conceived of the presented idea. Anne Willers, Roberto Lorusso, Bishoy Zakhary, Daniel Brodie, Jonathan W. Haft verified the methods. All authors devised the project, the main conceptual ideas and proof outline. Justyna Swol and Anne Willers wrote the manuscript. All authors discussed the results and contributed to the final manuscript.

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