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Embedding quality improvement and patient safety — the UCLA value analysis experience

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Despite pressure from various governmental and non-governmental groups and agencies in the US, many physicians continue to resist the need to measure and improve their clinical practices. Physicians do, however, willingly engage in the process of technology assessment so that new innovations can be introduced into their clinical activities. Technology assessment can be incorporated into a medical staff committee process called value analysis, resulting in both cost savings and cost avoidance. By including a requirement that some approved healthcare technology is monitored for safety and effectiveness within their institutions, members of a medical staff at several academic medical centers within UCLA Healthcare participated eagerly in patient safety and quality improvement programs.

Key words: embedding quality improvement; patient safety; technology assessment; value analysis.

There has been considerable pressure from medical societies, government agencies, purchasers of health services, various accrediting agencies, and consumer groups in the US to promote physician involvement in quality improvement (QI) and patient safety (PS) activities.[1–3] Recent evidence suggests, however, that physician involvement is less than optimal.[4] There is well-documented and long-standing resistance to any monitoring of medical and surgical practice and to the adoption of practice guidelines.[5] A recent survey[6] found that physicians report that they do not routinely use

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data for the assessment of their practice performance and that they are reluctant to share such data when it is collected. These findings have been reported at a time when another survey by the Estes Institute of over 700 hospitals in the US found that the top three areas of greatest concern among practitioners and administrators are: (1) improving patient safety; (2) improving relations between members of the medical staff and administrators; and (3) embracing innovations and new healthcare technologies.[7] Overall, concern about the performance of PS and QI activities by the medical profession has been heightened because of two very critical reports published by the Institute of Medicine (IOM) of the US National Academy of Sciences.[8,9]

Initially, because of a need to contain costs due to the penetration by managed care in Southern California, the UCLA (University of California at Los Angeles) Healthcare System put into place a process first to assess and then to control the adoption of expensive new or replacement healthcare technology. An additional beneficial outcome of this technology assessment process (referred to as 'value analysis') has been the embedding of QI and PS evaluations into the activities of clinical departments within the healthcare system. Because members of the medical staff were very interested in the acquisition of new technology, they were highly motivated to set up and measure the ongoing safety and effectiveness of newly acquired technology as a condition of its initial approval. The Value Analysis Program combined the processes of approval, monitoring, and measuring the effects of new technology with the goals of both performance improvement and improving patient safety within various departments at UCLA Healthcare, including the Department of Obstetrics and Gynecology.

THE CONCEPT OF THE MEDICAL STAFF

Because the majority of healthcare providers in the US are independent contractors delivering services within the hospital or other healthcare organization, and not employees of the hospital or healthcare organization, an entity called the 'medical staff' has evolved over the years. Although the governing body or administration of a healthcare organization is ultimately responsible for all of the care provided at their institution, they rely on committees established and managed by the medical staff (some institutions prefer the term 'professional staff') to guide and govern medical, surgical and other clinical activities. This governance structure has the advantage of separating the direct care of patients from administrators who could be overly influenced by budgets and other cost-cutting efforts that have the potential to adversely affect patient care. It has the possible disadvantage of insulating the professional staff from confronting necessary cost constraints and inducing potentially harmful healthcare price insensitivity. Because of the advantage of professional separation and the need for independent peer review within an institution, accrediting bodies such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) in the US require the establishment of a medical or professional staff even at healthcare organizations where some or all of the providers are employees of the organization. Accrediting agencies have been less likely to require an ongoing assessment of the cost-effectiveness of technology, and rapid adoption of new technology has been considered one of the only strengths of the overall US healthcare system by some.[10] According to the University HealthSystem Consortium (UHC), less than 40% of academic medical centers have follow-up processes in place to assess the impact of newly implemented healthcare technologies.[11]

TECHNOLOGY ASSESSMENT

The acquisition and implementation of new healthcare technology is responsible for a significant portion of the cost growth of healthcare services in the US.[12,13] Attempts to control this growth have been only moderately successful. Up until the past 5–10 years the process for the introduction of new technology (including surgical and monitoring equipment, and other medical devices) was largely based upon a request from members of the medical staff who wished to use the new technology. This involved a simple process in the form of a request to an administrative department within the organization, such as Purchasing. Before the era of prospective payment for hospital services and a contractually arranged set payment made on the basis of an admission diagnosis (the diagnosis-related group or DRG-based prospective payment system) virtually all requests for new technology were granted with little or no 'in-house' technology assessment or concern about cost containment. As long as the instrument or device had United States Food and Drug Administration (FDA) approval and the institution could bill and expect to be paid for its use, there was little reason to deny any request made by a member in good standing of the medical staff. Recently it has been pointed out that FDA approval of medical equipment and devices is primarily based upon its safety and effectiveness for measuring or creating a specific physiologic function or event, and not necessarily its clinical effectiveness in terms of a desired health outcome.[14] By example, for a pulse oximeter (further discussed later), FDA approval simply established that the device can safely measure oxygen saturation in blood and not that the results are necessarily useful clinically.

This loose process of technology assessment resulted in poor standardization of instrumentation and devices, needless duplication, and excess inventory costs. The recent explosion in new and expensive technology presented a challenge to healthcare organizations, particularly academic medical centers, such as exist within UCLA Healthcare. Their leadership and professional staff wished to continue a reputation of 'cutting edge' introduction and use of the newest healthcare technology, but were subject to the same cost constraints that all healthcare organizations now have. In some instances academic institutions are more challenged because they tend to treat the most severe cases of disease with little if any additional reimbursement.

ESTABLISHMENT OF VALUE ANALYSIS (VA) AT UCLA HEALTHCARE

The establishment of pharmacy and therapeutics (P&T) committees at many healthcare organizations several decades ago was prompted by a rapid growth in the cost of pharmaceuticals and in the availability of multiple products used to provide the same therapeutic benefit. The concept was that an organization could evaluate several products on the basis of effectiveness and cost, and then make available only the approved products. The success of such committees[15] inspired the leadership of several institutions, including UCLA, to apply a similar process for the evaluation and acquisition of other new non-pharmaceutical technology. Establishing a committee within the structure of the medical or professional staff rather than as part of hospital administration allowed the providers of clinical care to assess directly and then adopt or reject new technology (e.g. surgical instruments, orthopedic devices and monitoring equipment) based upon adequate in-house technology assessment followed by a binding voting process. The name and purpose of the proposed technology

assessment committee was 'value analysis' instead of 'quality analysis' so as to emphasize the difference between improved clinical outcomes at any cost (maximized healthcare) versus improving outcomes optimally by considering available resources and net benefits.[16,17] In other words, a major challenge of the new committee on technology assessment would be to adopt and promote newer technologies that improve outcomes and are efficient, while rejecting technologies that only add expense without significant measurable clinical benefit. The success of course depended on the active participation of members of the medical staff and the acceptance of the VA committee as the dominant authority on technology assessment within the institution.

MEMBERSHIP ON THE VALUE ANALYSIS COMMITTEE

In 1998, the administration of UCLA Healthcare approached the medical staff at UCLA Medical Center and proposed the establishment of a value analysis committee for technology assessment. Administration agreed to provide financial support for technology assessment, including funds for a full-time employee focused on gathering quantitative data concerning the technologies being evaluated (the value analysis facilitator, VAF). Subscription fees for outside objective technology assessment from well-established not-for-profit healthcare technology evaluation firms such as ECRI (formerly the Emergency Care Research Institute) were also provided. ECRI now studies and evaluates the full range of healthcare technology and is designated as an evidence-based practice center (EPC) by the US Agency for Healthcare Research and Quality and a Collaborating Center of the World Health Organization (WHO). The stated focus of ECRI is healthcare technology, healthcare risk and quality management, and patient safety. Subscribers to their services have access to an unbiased review of the latest healthcare technology. Subscribers can also request that an assessment of new technology be undertaken. The VA committee used other healthcare technology assessment firms on an 'as needed' basis.

Initially the committee was chaired by one member of the medical staff (an obstetrician/gynecologist and co-author [jcg] of this article), but eventually, due to the success of the committee and increasing workload, two co-chairs were appointed. The leadership of the VA committee now includes the chief medical officer of UCLA Healthcare, and continues to have a member of a surgical department as co-chair. Membership on the committee is based upon a wide cross-section of clinical and non-clinical departments (Table 1). Medical staff involvement and support is considered key to the success of this method of technology assessment. Without support of key members of the medical staff, physicians and other clinicians would be less likely to comply with whatever requests and policies emerge from the VA committee. The process also addresses the need for better relations between the medical staff and administration and for more proactive assessment of new and replacement technologies which, as has been previously mentioned, have become areas of major concern at many US healthcare organizations.[7]

THE VALUE ANALYSIS PROCESS

Once mandatory oversight by the VA committee was established by the leadership of the medical staff and administration as a condition for the adoption of new technologies within UCLA Healthcare, members of the medical staff became very interested in participation on the VA committee. Appointment by chairs tended to indicate trust

Table 1. New technology committee.

Physician representation	Administrative and nursing representation
• Anesthesia	• Chief Operating Officer
• Urology	• Value Analysis Coordinator
• Main operating room	• Controller
• Cardiothoracic surgery	• Director, Quality
• Orthopedic surgery	• Director, Managed Care
• Neurosurgery	• Radiologic Sciences Administrator
• Radiological sciences	• Chief Medical Officer
• Pathology & Laboratory Medicine	• Directors of Main Operating Room & Surgery Center
• Cardiology	• Director, Financial Services
• Pulmonary & Critical Care Medicine	• Director, Pharmacy
• Medical Group	• Director, Purchasing
• General Surgery	
• Pediatric Surgery	
• Obstetrics & Gynecology	

and confer prestige on physicians and other clinicians who served on or presented to the committee.[18] A standardized request form was developed to begin the VA process (Figure 1). This request form has evolved over the years and now includes a question about conflict of interest. Not infrequently, a member of the medical staff who is requesting a new or replacement technology is also involved in the design and development of the technology, and could stand to gain financially if and when it was adopted. Full disclosure allows for this possibility to be addressed as part of the VA committee process. Once the new or replacement technology request form is received, a technology assessment and financial analysis is completed. The member of the medical staff who is requesting the technology is advised that the VA process will take about 6 weeks. Following this stage of analysis the request is scheduled with the VA committee for review and decision. The medical staff requester must attend the VA meeting to defend the request and answer any questions that the committee members may have.

Each physician member of the VA committee is periodically assigned new technology to review with the assistance of the VAF. Clinical and financial data are gathered from a variety of sources, including medical and surgical literature, and from technology assessment firms such as ECRI. A financial analysis is also performed by the VAF with assistance from the medical center finance department. This key step involves the extraction of financial data on patients or diagnoses similar to those that would be affected by the new or replacement technology. Without these cost data, the process would be difficult, if not impossible, to conduct because 'value analysis' implies that some consideration is given to the cost of new technologies as well as their benefits. The VAF and physician reviewer, along with one or both of the committee co-chairs, then meet with the member of the medical staff who is proposing the adoption of new (or replacement) technology several weeks prior to the full VA committee meeting. This is done to be certain that enough clinical and financial data have been gathered for an adequate presentation to occur. Full committee meetings occur monthly. Agenda packages are assembled and mailed to committee members at least 1 week in advance of the monthly meetings. About four to six proposals are presented at each monthly meeting. The committee chair at each meeting is responsible to move the agenda efficiently. Final decisions about adoption or rejection of new or

UCLA Healthcare
Value Analysis Committee

CONTROL#:
(Purchasing Use Only)

New/Replacement Technology Request Form

1. **All questions must be answered completely and signatures obtained from Department Chair and Budget-Responsible Manager for Value Analysis Committee consideration.**

2. **Return completed form to:**
   ValueAnalysis Coordinator
   c/o Purchasing

3. **Once your request is received, an analysis will be completed to include clinical and financial information. When the analysis is completed, a copy will be sent to you and the Value Analysis Committee. The requestor MUST attend the Value Analysis Committee meeting to discuss the request and supply any further information to the Committee. If you have any further questions, please contact John Yeretsian, or one of the Committee Co-Chairs as listed on the last page of this request.**

Name of Product:

Manufacturer: **Mfr. Catalog#:**

Sales Representative's Name: **Phone Number:**

Value Analysis Committee requires the Hospital Budget-Responsible Manager be informed of your initiative and your Department Chair/Chief review and approve your request prior to Committee consideration.
All initiatives that are approved and >$5,000 will require Value Analysis Committee review for final decision.

Budget-Responsible Manager's Review: Signature: Date:
[ ] Informed of initiative
Comments:

Department Chair/Chief Review: Signature: Date:
[ ] Approved [ ] Denied
Comments:

Approved or Denied, return form to Value Analysis Coordinator

Briefly describe this product and clinical impact (also, describe other required components/accessories, if applicable):

Is there a product in-house now performing the samefunction? [ ] Yes [ ] No
If YES, what product(s) perform the same function as the requested product? (Empac#, description, manufacturer, catalog#)

Will there quested product [ ]replace or [ ]supplement current in-house products now performing the same function? [ ] Yes [ ] No
If NO, why is it necessary to introduce and use this new technology?

Figure 1. UCLA Healthcare Value Analysis Committee standardized new/replacement technology request form.

replacement technologies are made in closed-door session once all presenters have left the meeting. The focus of these discussions is a careful consideration of the relative costs and benefits of the technology, possible alternatives, and processes that may be needed to monitor quality and cost if approval is granted. Presenters of new technology are informed in writing about VA committee decisions, with reasons for the

What improvements to patient care and/or cost reductions are anticipated?

What other department(s) will use and/or be affected by this technology? Are other departments aware of this technology and your request?

What is the projected annual usage volume of this technology?

What is the approximate price of this product?

Do you expect the projected annual dollars for this technology will exceed $50,000?

Will there be additional implementation costs, such as installation, service agreements, cost of education, impact on equipment?
[ ] Yes [ ] No
If YES, please describe:

Is the requested product(s):
Patient chargeable? [ ] Yes [ ] No
Urgently Required? [ ] Yes [ ] No If Yes, why and how soon?
Under a current contract? [ ] Yes [ ] No
If YES, please specify: Novation UC Other

Will the requested product(s):
Need evaluation? [ ] Yes [ ] No If YES, would you be willing to lead the evaluation? [ ] Yes [ ] No
If product needs to be evaluated, who needs to be involved in the evaluation?
Name: Dept: Phone:
Name: Dept: Phone:
Name: Dept: Phone:

Need Medical Staff notification? [ ] Yes [ ] No
Will this involve a procedure / process requiring Physician training? [ ] Yes [ ] No

How did you find out about this product? (mark all that apply)
[ ] Prior experience with product [ ] Trade Show [ ] Contract Review
[ ] Sales Rep came to department [ ] Other (specify)

Conflict of Interest Statement

Physicians requesting products be admitted to the formulary must complete this conflict of interest section.

The University's overall policy on conflict of interest is that none of its faculty, staff, managers or officials shall engage in any activities that place them in conflict of interest between their official activities and any other interest or obligation. The University's Conflict of Interest Code requires that all University employees and officers disqualify themselves from participating in a University decision when a financial conflict of interest is present.

A potential conflict of interest does not, however, disqualify a physician from requesting a product be added to the formulary. The Committee recognizes that many members of the Medical Staff may have relationships with manufacturing companies. For example, physicians with expertise in a certain area often have received research grants orother support from these companies. Nevertheless, it is critical to the Committee's deliberations that the physician making the request discloses any such relationships up front.

Figure 1. (*continued*)

decision listed. When a denial occurs they are permitted one rebuttal session if they request it. Although rebuttal requests were fairly frequent during the first several years of committee activity, they have become less common as the quality of the initial presentation improved. Interestingly, attendance at VA committee meetings is much

A. List companies involved in developing, producing and/or distributing the requested product:

B. List companies with products that may be major competitors with the requested product:

Do you/your Department have a proprietary interest in any of the companies listed above?
[ ] Yes [ ] No

If YES, which company(ies):

Please check all that apply:
[ ] Own stock in one of the above companies (excluding mutualfunds)
[ ] Serve on the board of directors for one of these companies
[ ] Expect to receive (or currently receive) ≥$500 in royalties from one of these companies
[ ] Other

C. Have you/your Department received any financial support from the any of the companies listed above?
[ ]Yes [ ] No
If YES, which company(ies):

Please check all that apply:
[ ] Received funding for research
[ ] Received support for presenting continuing medical education or other professional education programs supported by the company
[ ] Received an educational grant
[ ] Received travel support
[ ] Other

D. Additional Comments:

Name of Requesting Party (Please Print):

Department: **Date:**

Facility: **Phone:**

Signature:

Please attach supporting documentation that can assist the Value Analysis Committee in its review of this technology (manufacturer's specification, research articles, sales literature and representative's business card).

Figure 1. (*continued*)

better than most other medical staff committee meetings, and interest in the proceedings and outcomes is intense.

MANDATORY MONITORING OF NEW HEALTHCARE TECHNOLOGIES

As the VA process evolved, it was not always clear that some new and replacement technologies were beneficial or cost-effective based upon outside objective criteria

and internal review. Many articles about new technology, even in the peer-reviewed medical and surgical literature, may be influenced by manufacturers and other potentially biased parties.[19] Even when randomized controlled trials (RCTs) are reported, the problem of acceptance of effectiveness and safety based upon reported results from these well-designed studies can be problematic. These trials are conducted under ideal conditions (so called off-line research), and the fact that all subjects studied must volunteer to be included needs to be considered when generalizing the results for some technologies to a possibly less cooperative or compliant non-study population. The effectiveness of a technology may be significantly different once 'on-line' observational studies and monitoring is performed. When the available data suggest that a technology is probably cost-effective and should be adopted, but questions still remain about the effectiveness and/or safety within UCLA Healthcare, a provisional approval may be granted by the VA committee. At this point the medical center and departmental QI and PS committees are asked to assist those who proposed the new technology in setting up a mandatory monitoring process for a defined period of time, usually 6–12 months. After this conditional period the technology is assessed 'in-house', and those who proposed the technology are required to report back to the VA committee with the findings of the PS or QI evaluation study for a decision about final approval or denial. This process of coupling an interesting and clinically rewarding activity, such as applying new technology, with a less popular process of ongoing monitoring and measuring for performance improvement has resulted in improved physician participation in departmental and medical center PS and QI activities.

RESULTS OF THE VA PROCESS AT UCLA HEALTHCARE

Table 2 lists the total number of new and replacement technologies that were evaluated by the VA committee for a 5-year period from 1998 through 2003. The number denied, approved and approved conditionally with PS and QI evaluation studies required is listed. Table 3 contains the estimated financial savings annually over the 5-year period in terms of cost savings and cost avoidance. Cost avoidance is more difficult to estimate because it requires the estimation of the savings derived from technologies that were not requested because of the likelihood that they would be rejected. This was possible to estimate because a record was kept of contacts with the VAF and members of the medical staff who were considering submitting an application for approval for a new or replacement technology, but were never filed after a discussion about the process and requirements for approval took place. These were always reviewed by the leadership of the committee to make sure that needed technology was not being suppressed by the VA process.

THE CASE OF FETAL PULSE OXIMETRY

Pulse oximetry (arterial oxygen saturation monitoring) is a technology which has improved the quality and safety of patient care in many fields, including anesthesiology and both newborn and adult intensive care. After US FDA approval in 2000 of the Nellcor N-400 fetal oxygen saturation monitoring system, a fetal pulse oximeter became available for the assessment of fetal well-being during labor. This approval does not necessarily verify clinical effectiveness, however.[14] A study sponsored by the manufacturer reported that fetal pulse oximetry combined with fetal heart rate (FHR) monitoring resulted in a significant reduction in cesarean delivery rates for

Table 2. Value analysis – 5-year totals.

	Approved	Approved conditionally	Denied or tabled and withrawn
1998	22	10	5
1999	18	11	3
2000	21	12	6
2001	23	12	5
2002	26	10	3
Totals	110	55	22

non-reassuring electronic FHR tracings.[20] An additional finding of this study was that the overall cesarean delivery rate was unchanged. This may mean that only the indication for the operative delivery changed due to the use of this technology. Electronic FHR monitoring has been used routinely in labor to screen for fetal well-being for more than three decades, and was widely adopted as the standard of care before adequate unbiased evaluation of the technology was performed.[21] Although FHR has a high predictive value for fetal well-being (99%) when it is reassuring, it has only a 50% positive predictive value for fetal compromise. This could potentially lead to twice as many cesarean deliveries as needed for this patient population, along with possibly preventable maternal and even fetal morbidity.[22,23]

There is a well-documented increase in cesarean delivery rate in the US and elsewhere, in part due to the routine use of electronic FHR monitoring.[24,25] Over the years, other technologies – such as fetal scalp pH sampling and fetal scalp and acoustic stimulation – have been introduced to refine the interpretation of FHR. None of these technologies has been routinely adopted by clinicians because of a consistent lack of demonstrated value. Fetal pulse oximetry (FPO) holds the promise, according to some experts, of representing a reliable technology that can differentiate between false and true positive electronic FHR tracings and reduce the need for preventable cesarean deliveries and improve patient safety. Prior to FDA approval, a request was submitted by the Obstetrics and Gynecology Department at the UCLA Medical Center to the VA Committee at UCLA Healthcare for the adoption of fetal pulse oximetry technology in two of the four hospital labor and delivery units with a combined annual delivery rate of about 6000. Because of the preliminary data in published abstracts, the technology was approved by the committee on the conditional basis that an ongoing QI and PS evaluation program be initiated to measure the safety

Table 3. Value-analysis financial results.

	Estimated costs saved ($)	Estimated costs avoided ($)
1998	350,000	650,000
1999	725,000	575,000
2000	625,000	275,000
2001	750,000	450,000
2002	605,000	395,000

and effectiveness of FPO before final approval for all hospitals in the UCLA Healthcare system. The cost of FPO monitoring (about $250 per monitored patient) represented a substantial cost increase when used on the estimated 20–25% of monitored labor patients. An average annual cost increase for labor and delivery services of $375,000 could increase to nearly $1 million dollars annually if and when FPO was approved throughout the entire UCLA health system.

Shortly after conditional approval of the FPO by the VA committee, the UCLA Department of Obstetrics and Gynecology QI coordinator assisted several staff obstetricians to design and implement an evaluation process for fetal monitoring assessment, including electronic FHR monitoring, fetal scalp pH measurement, and FPO use when a non-reassuring electronic FHR tracing occurred. On several occasions prior to the conditional approval of FPO, medical center and departmental QI and PS committees had made several attempts to implement such an evaluation process, but these efforts failed due to a lack of interest and participation by the medical staff. Thus, the VA process was instrumental in encouraging departmental participation in quality improvement. After a 6-month process of monitoring FPO, as a part of the overall QI and PS fetal-monitoring program, results at the two centers within UCLA Healthcare showed that overall cesarean delivery rate was not decreased and fetal outcomes were not improved.

In September of 2001, the Committee on Obstetric Practice of the American College of Obstetricians and Gynecologist (ACOG) published a Committee Opinion (Number 258) on Fetal Pulse Oximetry.[14] It stated in part that ACOG 'currently cannot endorse the adoption of this device in clinical practice. The committee is particularly concerned that the introduction of this technology to clinical practice could further escalate the cost of medical care without necessarily improving clinical outcome.' The department and medical center had decided to discontinue the use of FPO prior to the ACOG policy statement release.

SUMMARY

Physicians are not keen to design and implement patient safety (PS) and quality improvement (QI) processes within their departments in the absence of incentives that may include making them a mandatory part of some clinical activity that they enjoy. Acquiring and implementing new healthcare technology is an activity that clinicians enjoy and willingly embrace. Before the widespread practice of DRG-based reimbursement, the process of acquiring new healthcare technology was a simple matter of requesting that it be purchased. This process was managed administratively, and members of the medical or professional staff usually had their requests granted eagerly and with little if any monitoring of approved technology. In the US, governance of clinical activities in healthcare organizations occurs through a structure called the medical or professional staff. Although the administrative governing body of an institution is ultimately responsible for clinical care, the management of these activities is delegated to the medical staff. Clinical functions such as credentialing, privileging, approval of clinical protocols and disciplinary matters are carried out and guided by the medical staff committee system. When technology assessment, referred to as value analysis at UCLA Healthcare, is performed as an official function of a medical staff committee, members of the medical staff were more likely to participate in this activity and were also motivated to monitor healthcare technology as part of a PS or QI evaluation process. This allowed PS and QI committees to embed their

activities by working with members of the medical staff to measure and improve outcomes as part of UCLA's value analysis process.

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