Value Analysis
Best Practices for Navigating the Evidence Maze
Current Clinical Issues and Key Question Development
Value Analysis
Best Practices for Navigating the Evidence Maze

Value analysis brought a paradigm shift in the way supply chain professionals need to approach procurement and engage with clinical staff as they face the pressures of the current healthcare climate. These pressures arose from healthcare and payment reforms that require careful balancing of the cost, quality, and safety equation of healthcare.

With many balls to juggle in assessing technologies across dozens of clinical service lines, supply chain and value analysis professionals are often challenged by the clinical evidence piece of the equation. Part of the challenge involves engaging clinicians in the equation. While many factors affect the ability to engage clinicians, one important factor is being able to bridge the divide by conversing in a meaningful way about clinical evidence of a technology’s efficacy and safety.

This crucial conversation can be politically charged and provoke anxiety. However, using an objective, analytic framework that will resonate with clinicians when discussing the body of evidence can demonstrate that the value analysis team is thinking thoroughly and thoughtfully about factors that matter to clinicians and their patients. An objective evidence framework de-emphasizes cost, emphasizes clinical outcomes and clinical concerns, and brings transparency into the process.

As one of 13 Evidence-based Practice Centers (EPCs) designated by the U.S. Agency for Healthcare Research and Quality (AHRQ), ECRI Institute uses a framework that is now emerging as a useful tool for value analysis professionals. The framework, discussed in a Methods Guide (2014) developed by the EPCs, is known by the acronym “PICOTS”:

- **PATIENTS**
- **INTERVENTION**
- **COMPARATORS**
- **OUTCOMES**
- **TIMEFRAME**
- **SETTING OF CARE**
The PICOTS framework is a fairly new concept to healthcare value analysis, as suggested by a recent national poll of about 100 value analysis professionals. The poll, conducted by ECRI Institute in June 2017, found that 86 of 100 respondents were unfamiliar with the PICOTS analytic framework. Only 5 of 14 who were familiar with PICOTS indicated using it as part of their value analysis processes, but all were interested in learning about it and how to apply it.

**Value analysis: An overview**

A typical value analysis project starts with someone submitting a request for a new or different product or a new use of a product. When considering a product in value analysis, understanding the full context around how it will be used, the populations in which it will be used, by whom it will be used, the desired outcomes for the patient and hospital, and where it will be used is imperative to the health system’s cost, quality, and outcomes equation.

Applying the PICOTS framework can bring a useful order, systematic approach, objectivity, and consistency to considerations of any clinical technology or intervention. The approach can uncover and raise important key questions that both sides may not have realized need to be addressed. Each element of PICOTS drills into the clinical concerns and issues. It raises key questions and helps define the search strategies to identify appropriate clinical evidence to answer key questions.

**Patient- versus hospital-oriented measures**

The framework can also help differentiate between patient-oriented and hospital-oriented outcome measures. Patient-oriented outcomes are directly experienced by the patient, such as pain, complications, functional ability, survival time, and quality of life. Hospital-oriented outcomes are critical to the value analysis process, but should be recognized as predominantly hospital-focused (e.g., length of stay and bed/room turnover time, costs, operating room/procedure time, clinician training time).

In working with hundreds of health systems in both the United States and abroad, ECRI Institute has used this framework to develop key questions, identify evidence and evidence gaps, and help bring more transparency to value analysis decision making about healthcare technologies and procedures.
Benefits of Using the PICOTS Analytic Framework for Value Analysis

— Brings an objective, systematic, consistent, and transparent approach to clinical evidence assessment
— Clearly fleshes out and documents issues and concerns
— Guides key question formulation and type of evidence required to address key questions
— Guides search strategy for clinical evidence to avoid pitfalls of cherry picking data
— Clarifies questions some may not have thought to ask or realized were important to consider
— Guides conversation between supply chain/value analysis and clinical staff
— Builds credibility with clinical staff because of focus on patient outcomes
— Demonstrates to C-suite the importance of a value analysis approach to large and small issues
— The transparency and documentation provided through use of the framework enables a “look back” in the future to assess the impact of the value analysis decision

Case Studies Using PICOTS

The following three case studies illustrate how the PICOTS framework can be used to effectively address diverse questions in an objective, consistent, systematic manner that fleshes out important issues that were not immediately apparent. These cases also illustrate why embarking on value analysis with no more than a product name is insufficient for performing high-quality value analysis.
The value analysis director at a three-hospital health system in the Mid-Atlantic area serving rural and urban areas contacted ECRI Institute’s Health Technology Assessment group for assistance with the following issue. When females of child-bearing age present to their emergency department (ED), these patients are given a urine-based, rapid, point-of-care (POC) pregnancy test to get a qualitative (yes/no) result quickly so appropriate treatment planning can be accomplished to avoid tests and treatments that might harm a fetus. The ED also orders a confirmatory quantitative hCG pregnancy test from the lab using the patient’s blood sample. The value analysis team questioned whether POC testing was duplicative and unnecessary because POC testing in the ED costs tens of thousands of dollars annually. The value analysis director wanted to know when it is appropriate and cost-effective to require both tests and when only the quantitative hCG test from the hospital lab is needed.

In applying the PICOTS framework, at first blush, many elements seemed to be defined:

— **Patients**: Females of child-bearing age
— **Intervention**: Urine-based POC qualitative hCG testing
— **Comparator**: Blood-based laboratory quantitative hCG testing
— **Outcomes of interest**: Determining pregnancy status quickly, ensuring patient/fetus safety; saving costs by avoiding unnecessary testing
— **Timeframe for follow-up**: Not defined
— **Setting of care**: ED

Upon further discussion about the clinical concerns of the requesting physicians, additional issues came to light. The ED physicians justified their request for POC testing by explaining that lab results took too long and therefore jeopardized patient care. This important
clinical concern raised some new key questions: What was the efficiency of their laboratory operation in completing a stat pregnancy test? Were results being communicated to the ED physician in a timely manner? Thus, investigating the evidence on how long it should take to conduct laboratory-based pregnancy testing and communicate results versus how long it actually took in this health system might show whether improvements were needed in these processes. An additional key question that emerged was whether having a qualitative versus quantitative test result made a difference in decision making about treatment and patient outcomes. In other words, is a yes/no pregnancy result sufficient to inform patient management, or are there situations in which a clinician needs to know what the hCG level is to make appropriate treatment decisions?

Fleshing out these clinical issues and key questions allowed the medical librarian to search for the right kind of evidence to address each question. Certain questions needed controlled comparison studies to answer, while others did not. After evidence for each of the key questions was aggregated and analyzed, the value analysis director was able to engage the ED and laboratory clinical staff in discussions to create a protocol for best practices for pregnancy testing in the ED. This involved reviewing how the laboratory handled the ED’s stat requests for pregnancy testing and determining which clinical conditions required a quantitative versus qualitative result. During our searches for data and information about these issues, the medical librarian also identified the first quantitative hCG POC pregnancy test that would soon enter the market. This new technology could possibly disrupt existing qualitative hCG POC testing and quantitative hCG laboratory testing.

What our analysts found

Key conclusions from our literature review of available studies on the issues defined by using the PICOTS framework to engage the value analysis professionals and clinicians were as follows:

- While qualitative POC hCG tests typically yield faster results than quantitative serum hCG testing in the hospital laboratory, quantitative hCG testing can detect pregnancy five to seven days earlier than urine-based qualitative hCG testing. Detecting very early pregnancy is especially important in females presenting with abdominal symptoms suggestive of ectopic pregnancy. For further consideration, the first commercial quantitative beta-hCG serum POC test has recently entered the U.S. market, which could potentially displace existing methods of qualitative POC and quantitative laboratory hCG test use in the ED.

- Studies have reported unsatisfactory performance for qualitative POC hCG urine tests for detecting very early pregnancies and have demonstrated that quantitative serum hCG testing remains the gold standard for determining pregnancy status.
■ Qualitative POC hCG tests have been validated for use with both urine and serum, but not whole blood. The reported sensitivity of urine and whole blood in the POC hCG test yielded similar results (95.3% versus 95.8%).

■ Hospitals wishing to use only one of these tests in the ED should examine their process and time required to deliver stat quantitative hCG test results to the ED or consider the new POC quantitative serum beta-hCG test in the ED. Some studies of elapsed time from quantitative hCG test ordering to results delivery have noted that processes often can be improved to provide adequately fast results for appropriate patient management. Clinical practice guidelines did not provide recommendations about which tests to use.
PICOTS Use Case #2: Novel use of demineralized bone matrix

A physician leader of a value analysis team for a large health system in the Western United States with both rural and urban care settings contacted ECRI Institute with a question about the health system’s use of a costly product typically used in orthopedic and spine procedures: OsteoSponge® demineralized bone matrix (DBM). Something jumped out at him during his utilization review: 40% of one brand-name DBM product was being used by a single physician who was not an orthopedic or spine surgeon, but rather a cardiothoracic surgeon performing open-heart surgeries. The initial question was: What is the efficacy of this DBM product when used during open-heart surgery? It adds a lot of cost to the bundled payment for open-heart surgery.

A few PICOTS elements seemed to be evident initially:

— **Patients**: Those undergoing open-heart surgery
— **Intervention**: DBM (OsteoSponge) use during open-heart surgery
— **Comparator**: None defined
— **Outcomes of interest**: Efficacy of OsteoSponge for open-heart surgery
— **Timeframe for follow-up**: None defined
— **Setting**: Inpatient

As the framework was applied to define the remaining PICOTS, several new considerations emerged. Initial investigation into the DBM showed that the company making the product did not mention its use for open-heart surgery anywhere in its product literature or website. In addition, because FDA classifies the product as a human tissue/cell product (as are many DBMs), the agency required no regulatory clearance or approval, so no labeled indications were available and no clinical data had been required to market the product.

We raised additional questions about the “P” portion of the framework because defining the population further would affect the rest of the analytic framework,
key question formulation, and evidence searches. DBM use typically pertains to filling bone voids during orthopedic or spine surgery and aiding union of bones that have not healed/fused properly over time after surgery. We hypothesized that perhaps the cardiothoracic surgeon was using DBM to aid healing of sternal complications—cases in which the sternum had not fused after surgery. Typically, surgeons use some type of mechanical device (wires, cage) to close the sternum and aid its fusion after initial open-heart surgery. If infection occurs or the sternum does not fuse, mechanical approaches are again the standard practice. However, we hypothesized that perhaps the surgeon used DBM to aid fusion for patients who had experienced complications. Thus, the “P” would be patients with sternal complications following open-heart surgery. Would this explain utilization of 40% of the health system’s OsteoSponge supply?

However, the amount of DBM product attributed to this surgeon’s use suggested a broader patient population than just those with complications or a high complication rate. If the surgeon used DBM in all open-heart-surgery patients to aid sternal healing, this prophylactic use would mean the “P” is any patient undergoing open-heart surgery. The patient population and intervention inform the “C” part of the framework. Comparators would differ in first-time open-heart surgery patient population versus a population with postsurgical complications.

If DBM was being used in all open-heart-surgery patients, then the appropriate comparator would be first-time open-heart surgery with and without use of DBM, and searches would seek to identify comparative studies. For the “O,” the important outcome to measure would be sternal nonunion complication rates between groups. For the “T,” follow-up time would need to be weeks to several months to determine and compare complication rates. On the other hand, if the “P” consisted only of patients with postsurgical complications, then the comparators would need to be other means of addressing sternal nonunion complications. The value analysis physician leader did not have answers to these questions but realized they were important to explore.

Thus, with some of the PICOTS framework not well defined, ECRI Institute’s medical librarians undertook broad searches to cover any open-heart-surgery patient populations reporting on use of the product.

- Searches about the brand-name DBM product yielded no results. Searches were broadened to include any DBM product used during open-heart surgery. This yielded a single case report on a different DBM used to treat a sternal complication and no published studies or meeting abstracts. Searches were further broadened to identify studies of any type of bone putty or bone cement for open-heart surgery. Broadening the search to include bone cement yielded a single case series on use of Kryptonite™ bone cement to aid sternal healing after open-heart surgery.

- We concluded that use of DBM during open-heart surgery appears to be a novel use. Results on its use for orthopedic and spine bone healing cannot be extrapolated to sternal
wound healing. Data from controlled trials are needed on this clinical application to elucidate safety and efficacy.

Given the absence of supporting evidence for use of DBM for sternal wound healing or preventing sternal nonunion after cardiothoracic surgery, we recommended its use for these clinical applications be confined to a controlled trial setting in which structured data are captured on patient characteristics and patient outcomes, with a goal of comparing outcomes and publishing results, given the paucity of published evidence on the topic.
PICOTS Use Case #3:
Trialing a new virtual reality device in a pediatric hospital

Sometimes evidence is not available on a new device, but a cutting-edge healthcare facility wants to use the device to develop its own evidence before adopting and implementing the technology system-wide. PICOTS can be critical to structuring a successful trial that collects data on relevant outcomes in a robust way. A value analysis team that uses the PICOTS framework to help develop a robust trial can position itself as an important “go-to” resource for leadership.

A nonclinical technology analysis team and clinician at a leading national children’s hospital recently faced this situation. They wanted to trial a prototype virtual reality headset intended to enhance chronically ill children’s experiences during the frequent needlesticks they endure when having their blood tested or in receiving chemotherapy. The device consists of a headset that delivers an immersive virtual reality (IVR) experience of novel games developed for this clinical situation. The group also wanted to reduce parent anxiety about their children’s doctor visits and lessen the dread associated with outpatient therapy and checkups. The team and physician wanted to understand how the device would be assessed by others performing a value analysis (including potential granters of funding) so they could collect appropriate safety and efficacy data. They also noted that the device would involve a significant cost with no revenue stream through traditional payment models. Generating compelling data of its clinical value would be critical, but they wanted to be sure they collected data with the least possible bias and examined meaningful outcomes.

The PICOTS initially revealed the following:

— **Patients:** Children who require frequent needlesticks while under care for a serious chronic illness

— **Intervention:** Use of IMR during visits involving a needlestick

— **Comparator:** No IMR during visits requiring a needlestick

— **Outcomes of interest:** Pain and anxiety

— **Timeframe for follow-up:** Immediately before and during the procedure

— **Setting:** Outpatient hematology and oncology pediatric clinic
Further discussion revealed that the “P” needed more refinement because “children” is a broad population spanning infants to adolescents. Age and the type of IVR delivered to age groups could elicit different responses. The illness, its duration, and disease stage could also affect IVR response. Also, the clinicians noted that since children’s care depends on their parents’ or main caregiver’s commitment, adult behavior affects children’s responses. Thus, parents/caregivers are also a “P” of interest that merits separate consideration.

When a technology is intended to measure patient experience, the “O” measures are, by definition, subjective. Finding additional objective measures is also important if possible. In this case, clinicians indicated that parental anxiety and pain experience sometimes led to cancelled visits for therapy or follow-up. Thus, adherence to scheduled appointments could be an objective, though surrogate, outcome measure. Because illness symptoms can vary over time and affect response to a technology, controlling for variables by using techniques such as randomly assigning patients and parents to use IVR would yield stronger data for determining value.

With regard to “T,” the team initially considered immediate pre- and post-IVR experience over an initial brief timeframe of a few visits. Discussion led to the realization that longer-term follow-up would be more informative of the value of the IVR technology to determine whether effects are sustained over the course of the illness or whether they become less effective over time. At the conclusion of the PICOTS framework discussion, this team understood how to organize its trial and collect data that would demonstrate whether its device provided value. The results included the following action items:

- Stratify data measurement and collection by population (parent and child), children’s age, type and degree/stage of chronic illness.
- Choose validated outcome measures for the subjective measures (e.g., pain, anxiety) of the children and anxiety of parents.
- Choose objective measure of adherence to therapy (showing up for appointments, completing recommended regimens).
- Use a randomized crossover design to control for known and unknown variables.
- Conduct longer follow-up.
Conclusions

Understanding PICOTS basics helps to navigate the value analysis maze by introducing a systematic, consistent, objective, and transparent analytic approach. This can bridge divides between administrative and clinical interests. The framework’s flexibility is illustrated by the three case studies presented here. Thus, no matter the technology or intervention, the PICOTS framework helps elucidate the context around the technology’s use to ensure the necessary questions are being raised. Asking the right questions enables one to understand the types of studies and data (e.g., comparative data from randomized controlled trials, case series data, registry data) that are needed to address each question so that searches are aimed at identifying the appropriate evidence as well as evidence gaps. In this way, outcomes can be assessed question by question so that value analysis teams and clinical leaders can have fruitful discussions about the evidence, which is one important input to the cost, quality, and outcomes value analysis equation.
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