Wrong-Site Surgery
Staff Training Handbook

Your Guide to the
JCAHO’s Universal Protocol
About the expert

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Della M. Lin, MD, was an inaugural Health Forums Patient Safety fellow—a joint collaboration between the American Hospital Association and the National Patient Safety Foundation (NPSF). She is coeditor of the book, *The JCAHO 2003 and 2004 National Patient Safety Goals: Successful Strategies for Compliance*, has participated in several HCPro, Inc., audioconferences related to patient safety, and is a member of the Estes Park (CO) Institute Faculty. She has also been on the speaking faculty for the 5th and 6th annual NPSF Annenberg Patient Safety Conferences.

Lin is a practicing anesthesiologist and has served on the American Society of Anesthesiologists Patient Safety Committee. She is also executive director of continuing medical education at Queen’s Medical Center in Honolulu. Lin has more than 15 years of physician-leadership experience, having served as department chief of anesthesiology, on hospital medical executive committees (MEC), and peer-review and credentialing committees. She is currently a board member for various healthcare entities. Lin is a consultant, lecturer, author, and facilitator for organizations and hospitals for MEC and credentialing-committee retreats, external peer-review activities, integrating patient-safety initiatives, disruptive-physician interventions, developing postgraduate-education programs, multidisciplinary performance-improvement programs, and physician-leadership development.
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Intended audience

• Physicians
• Physician leaders
• Residents
• Nurses
• Directors of nursing
• Operating room/radiology technicians

Intended for the education of medical and nursing staff in healthcare organizations and facilities, this booklet provides essential information about how to prevent surgery on the wrong body site, body part, or person when performing a procedure in an operating room, emergency department, intensive care unit, special procedures unit, endoscopy unit, and interventional radiology suite.

This training handbook covers JCAHO requirements and best-practice advice that physicians and nurses should follow to ensure patient safety during operations and invasive procedures.
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Introduction

No physician or nurse goes into surgery preparing to operate on the wrong person, body part, or site. But good intentions aside, these errors do occur and their effects are disastrous. Wrong-site surgery is emotionally devastating for the patient and the surgical team. It’s also a prime trigger for lawsuits and a public-relations nightmare for the hospital.

The horrors of wrong-site surgery captured the nation’s attention in 1995 when the media reported that Willie King went to a Tampa, FL, hospital to have one gangrene-infected foot amputated, but the surgeon removed his other gangrene-infected foot. The media soon picked up on other stories, such as one New York surgeon who operated on the wrong side of a patient’s brain and another surgeon who confused two patients and performed a mastectomy on the wrong woman.

Despite increased awareness and public outrage, the number of these types of errors continues to rise. The JCAHO reports that wrong-site surgery is the third-leading type of sentinel event experienced by accredited organizations. Since 1995, the JCAHO has received information about 300 of these incidents, but because the accreditor doesn’t mandate sentinel-event reporting, the actual number of wrong-site surgeries likely surpasses the number reported.

This problem is so significant that the JCAHO has published
two *Sentinel Event Alerts* on the topic, targeted the issue with a National Patient Safety Goal, and approved the Universal Protocol for Preventing Wrong-Site, Wrong-Procedure, and Wrong-Person Surgery™, which all accredited organizations must follow to prevent these errors.

The American Academy of Orthopaedic Surgeons (AAOS) is one of 40 professional organizations that endorse the protocol, which mandates standardized presurgery procedures to verify the correct patient, correct procedure, and correct surgical site. The AAOS believes that wrong-site surgery is a system problem that originates in three common issues:

- Poor preoperative planning
- Lack of institutional controls
- A breakdown in communication among the surgeon and the patient or staff

Don’t think you can’t make these mistakes or that they can’t happen at your facility. At one time or another, you may be involved in a surgery with multiple surgeons, which is one risk factor for wrong-site surgery. Other risk factors include time pressures, multiple procedures performed during a single operating-room visit, new or unfamiliar procedures and equipment, and a patient who presents with unusual characteristics.

The most common types of wrong-site surgery vary by setting and specialty—and no specialty is immune. The JCAHO’s sentinel-event database lists the knee (arthroscopy and other)
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as the site with the highest incident rate of wrong-site surgery. Extraction of the wrong tooth is the most common wrong-site procedure reported to the medical-misadventure unit of the Accident Compensation Corporation, which administers accident compensation in New Zealand. Surveys of hand surgeons indicate that surgeries involving multiple digits are also vulnerable to error. In addition, research conducted by the AAOS indicates that the two most common wrong-site operations in its field are arthroscopic surgery of the lower extremity and spine surgery. During the latter, errors most commonly occur when a surgeon performs the procedure one level above the intended site.

To address these concerns, the JCAHO has created the following requirements to help facilities prevent these types of surgeries.

**The National Patient Safety Goals**

Eliminating wrong-site surgery is one of the JCAHO’s National Patient Safety Goals. Since January 1, 2003, the JCAHO has required accredited hospitals to

- use a preoperative-verification process, such as a checklist, to confirm that appropriate documents are available
- follow a process to mark the surgical site and involve the patient in the process
- conduct a time out before beginning a surgical or invasive procedure to confirm that the team is about
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Surveyors will continue to evaluate and score compliance with these goals until July 1, 2004, when the Universal Protocol takes effect. As of that date, the JCAHO will no longer separately score the goals associated with wrong-site surgery.

**The Universal Protocol**
The Universal Protocol will replace the wrong-site surgery National Patient Safety Goal on July 1, 2004. Although similar to the goal requirements, its three main components expand upon them by calling for surgeons and other surgical team members to follow a system that verifies the patient, site, and procedure.

The Universal Protocol also involves the scheduling office in the preoperative-verification process and emphasizes that verification should include patient position, correct implants, and any special equipment. It also attempts to clear up any ambiguity about the goals, such as what patient involvement in the site-marking process actually means.

The three components of the Universal Protocol are the:

1. preoperative-verification process
2. site-marking process
3. time-out process immediately before starting the procedure
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The protocol requires accredited organizations to follow these processes—and not only in the operating room setting. The protocol also applies to nonsurgical invasive procedures that expose patients to more than minimal risk, such as catheterization or radiological procedures. If you are unsure which procedures qualify for the protocol, include any procedure that requires documented informed consent.

Although some of these procedures don’t require site-marking, you must still follow the other protocol requirements. In fact, if you perform a procedure that doesn’t require site-marking, the other components become more important because you lose the safety net that the site-marking provides.

The JCAHO’s new protocol is endorsed by 40 major professional organizations, including the American Medical Association, American Nurses Association, American Hospital Association, American College of Physicians, American College of Surgeons, American Dental Association, and American Organization of Nurse Executives.

The following processes build double-checks into your procedures to help eliminate wrong-site surgery and ensure that your patients receive the high-quality care they deserve in a safe setting.
Preoperative-verification process

Before you perform any invasive procedure, it is your responsibility to verify the following:

- Correct procedure
- Correct site
- Correct patient

This verification must take place four times:

1. When the surgery/procedure is scheduled
2. At the time of admission/entry
3. Whenever another caregiver takes over responsibility for the care of the patient
4. Before the patient leaves the preoperative area or enters the surgical/procedure room

Your organization should have a policy that specifies which two pieces of information to use to identify a patient. Under no circumstances should a room number identify a patient. Acceptable pieces of information include the patient’s name, birth date, Social Security number, address, medical-record number, assigned identification number, and telephone number.

Tip: As part of this process, consider using a preoperative checklist with a box to check or initial at each point of verification to document that you verified the correct patient, site, and procedure. Although the JCAHO doesn’t require a check-
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Key pieces of documentation
Types of documentation that you should have readily available as part of the preoperative verification include the following:

- History and physical
- Physician’s orders
- Physician’s office notes
- Physician’s progress notes
- Lab reports (e.g., pathology reports referring to sites)
- Signed consent form that lists all written references to the site and the exact laterality or anatomical location written out in full
- Supporting images or films, if applicable
- Required implants and special equipment
- Surgery schedule or procedure schedule

Case #1: Mistaken identity
A few hours after admission for surgery, Mrs. Jones trades beds with her roommate to be closer to the window. When the transporter arrives to take Mrs. Jones to surgery, he uses bed location as a patient identifier and brings Mrs. Jones’ roommate, instead of Mrs. Jones, to the preoperative area for surgery.

How could the surgical team have avoided operating on the wrong person in this case?
Protocol requires that members of the surgical team use two patient identifiers to verify that they are about to operate on the correct person.

Verification should also take place before the patient leaves the preoperative area.

*Note:* The JCAHO allows the preoperative nurse to serve as a member of the surgical team and mark the site if the surgeon is unable. However, the preoperative nurse is not present when the team performs the time out in the operating room. (Some states prohibit nurses from marking the surgical site, so it’s important to check your state’s laws.)

If the surgical team follows the protocol, the patient will reveal that she is not in fact Mrs. Jones, and the team will stop plans to conduct the surgery until the correct patient is transported to the area and prepped.

**Site-marking process**

It’s important that the surgical team identifies the intended site of incision or insertion before the surgery takes place. The protocol applies to all operative and invasive procedures that take place in the operating room, special-procedures unit, endoscopy unit, or interventional radiology suite. Although there are exceptions, the site-marking process applies to procedures that involve the puncture or incision of the skin or insertion of an instrument or foreign material into the body.
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**Who should mark the site?**

- The surgeon—the protocol suggests that the person who performs the procedure mark the site.
- A surgical team member—when it's not possible for the surgeon to mark the site, a surgical team member who is fully informed about the patient and the procedure should mark the site.

*Tip:* Involve patients in this process. Although the protocol doesn’t state that patients actually mark the site, ask them to state their names, scheduled procedure, and location of the procedure. Some hospitals do allow patients to mark the site (a process they put in place as the result of the National Patient Safety Goal). If yours is one of them, it’s good practice to add another safety measure in which a surgical team member also marks this site. This practice is especially helpful if there is an order for the patient to receive medication one to two hours prior to surgery and before anyone on the surgical team has arrived. For example, if a patient is heavily sedated between the floor and the preoperative area, he or she cannot be consciously involved with the signing in the preoperative area.

**When do you mark the site?**

- Before sedating the patient
- Before moving the patient into the procedure room

**What do you mark?**

- The intended operative site
- Right/left distinctions
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• Multiple structures (e.g., fingers and toes—individually mark every finger and toe that you will operate on; don’t just mark the right hand if you plan to operate only on the long finger and index finger)
• Multiple levels (e.g., spine)

Tip: Spinal surgeries require a two-part approach to site-marking:

1. Prior to surgery, mark the general level of the procedure (i.e., cervical, thoracic, or lumbar) and indicate whether it’s anterior or posterior by marking a line where the incision will be—in the front if it’s the anterior, or in back if it’s the posterior—and whether it’s right or left
2. During surgery, mark the exact interspace using standard intraoperative radiographic marking techniques

How do you mark the site?

• Use an indelible marker so you can see the mark even after the patient is prepped and draped (which also indicates that the signing is close to the incision site)
• Writing the word “yes,” using initials, or drawing a line to represent the incision site

Tips:

• Don’t use stickers to mark the site. They can come off or move. If you do use stickers, make sure they aren’t the only form of site-marking.
• Never use the word “No” or an “X” to mark operative or nonoperative sites—it’s too confusing.
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• If you are operating on more than one site, mark one location with the number 1 and the other location with the number 2.
• Mark drawings with right/left distinctions when operating on natural body orifices (e.g., if you are performing a right ureteroscopy, mark near the urethra opening to indicate the site after placement of the scope).

Are there any exceptions to the rules?
Yes. Under the Universal Protocol, you don’t have to mark the following:

• Single-organ cases (e.g., cesarean sections or cardiac surgery), although you aren’t prohibited from marking them as an extra safety measure.
• Cardiac catheterization or other cases in which the surgeon hasn’t predetermined the catheter/instrument-insertion site.
• Teeth. Instead, mark the operative site on documents, the dental radiographs, or a diagram.
• Premature infants, as the mark may cause a permanent tattoo.
• Routine or minor procedures (e.g., venipuncture, peripheral IV-line placement, insertion of NG tube, or Foley-catheter insertion). These procedures would not require a signed informed consent.

Tip: If you are conducting a procedure at the patient’s bedside and you never leave the patient from the moment you
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decide to do the procedure and obtain consent up to the
time of procedure, then you do not have to mark the site.
Remember, if you leave the person at any time, you must
mark the site beforehand.

Case #2: Ambiguous site-markings
Dr. Reed was about to perform arthroscopic surgery. The cor-
rect knee was marked with an X. However, Dr. Reed thought
the X meant the nonoperative site so he operated on the
other knee.

What is wrong with this scenario?
Several aspects of the Universal Protocol were
violated:

- First, the person who performed the procedure should
  have marked the site while the patient was awake and
  aware. Note that some procedures don’t allow this
  action to take place (e.g., if the patient requires heavy
  medication prior to arriving to surgery).
- If the surgeon was unable to mark the site, a member
  of the surgical team should have done the site-marking.
- The protocol prohibits marking the nonoperative site,
  unless it is necessary to do so for some other aspect
  of care.
- An “X” is too ambiguous a mark. In this case, the
  surgeon interpreted the X to mean, “This is the wrong
  knee so don’t operate here,” although it actually
meant it was the right location. The protocol requires an unambiguous mark at or near the incision site.

**Case #3: Patient refusal**

Despite receiving education from staff on the importance of site-marking for patient safety, Mr. Johnson refuses to allow the surgeon to mark the site of his surgery.

**How should the surgeon and surgical team handle this situation?**

You cannot force a patient to accept surgical site-marking, but it is important to explain why the policy is in place and document that you had the discussion with the patient. The lack of site-marking means that one of the safety nets required by the Universal Protocol is not in place. Therefore, it's crucial that staff carefully follow all other procedures (i.e., preoperative verification and time out) to make sure they perform the correct procedure on the correct patient and site.

**Time outs**

Time outs allow the entire surgical team to take a moment immediately before the surgery to confirm they are about to

- operate on the correct site
- perform the correct procedure
- operate on the correct patient
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- use the correct implants
- use the correct patient position
- have the correct equipment they may need during the procedure

The entire surgical team is responsible for making sure that the time out occurs before the surgery.

**What you need to know**

- Make sure the entire team is involved in the time out
- Use active communication (some sort of signal, such as a nod or other gesture, or a brief oral acknowledgement)
- Document the time out in the medical record or on a checklist
- Have a system in place in the event that staff disagree with the information provided during the time out

**Case #4: Improper time outs**

A surgical team is about to operate on Mr. Garber, who needs his right hernia repaired. Everyone except the scrub nurse verbally indicates that the right hernia is the correct site. The surgeon takes the scrub nurse’s silence as affirmation. In reality, however, the nurse doesn’t agree but is afraid to speak up because the surgeon has a quick temper and doesn’t like to be corrected.

*What is wrong with this scenario?*
Never interpret silence or absence of response as agreement. The protocol is clear that surgery must be stopped until everyone on the team provides verbal confirmation—or even a nod of the head—that they agree with the information. But there is another issue at play here as well: In this scenario, the nurse didn’t feel comfortable speaking up or correcting the surgeon. Hospitals must provide cultures that stress the importance of the final check before surgery. They also must foster an environment where staff feel free to speak up if something appears wrong with a patient’s care, which means that everyone must work as a team and not simply agree with others in the room. Until everyone on the surgical team confirms the information, the scrub nurse should not pass the scalpel to the surgeon.

Case #5: Solo time outs
An anesthesiologist is about to perform a block on a patient. Since the doctor is the only person in the room performing the procedure, she doesn’t believe it’s necessary to perform a time out.

Is a time out necessary if there is only one person in the room performing the procedure?

The time out serves as a moment to stop yourself to make sure that you are about to perform the right procedure on the right patient.
Because there are so many distractions, it’s good practice to take the time—even if you are the only other practitioner in the room—to say to yourself, ‘This is Mr. Jones, and I’m about to perform _____,” as an extra safety measure.

**Case #6: Critical patients**

An ambulance arrives with a patient in critical condition. It is a life-and-death situation, and there is no time to follow the guidelines outlined in the Universal Protocol.

**What should you do in this situation?**

There may be circumstances that prevent you from following all the Universal Protocols. Certainly, timeliness of care comes first. In these rare exceptions, the situation must be critical—for example, a patient has been in a car accident, is near cardiac arrest, and needs a chest tube put in. But the fact that there can be exceptions should never be used as an excuse to take a short cut or avoid the process.

**Overcoming compliance barriers**

The greatest barriers to compliance with the Universal Protocol are resistance and old habits. It’s easy to feel invulnerable to wrong-site surgery if it’s never happened to you, so you may believe you don’t have to follow these processes. But this feeling and approach make a facility more vulnerable to errors.
The Universal Protocol means a change to your regular routine. Physicians may not be in the preoperative area as a patient is being prepped for surgery because they are busy with another case; sometimes they see patients in their offices, but don’t see them right before they undergo anesthesia. This is no longer acceptable.

Physicians must make the time to see the patient prior to surgery. Remember, as the surgeon, you are accountable for making sure that you are operating on the correct patient and site and conducting the correct procedure. As the perioperative nurse, it is your responsibility to act as a patient advocate to prevent wrong-site surgery. The anesthesiologist has a responsibility to check and be part of the team accountability.

**Five reasons to follow the protocol**

1. It’s a liability issue.

Studies by the AAOS indicate that wrong-site surgery cases almost always win a claim. In fact, the Physician Insurers Association of America found that from 1985–1995, 225 cases of wrong-site orthopedic surgery occurred in the United States, and 84% of those cases resulted in judgments for the plaintiff.

Now that the Universal Protocol is a mandate, it will be more difficult to defend a wrong-site case if it appears that a physician didn’t comply with the requirements. Some professional liability companies are considering increasing premiums or
dropping coverage of physicians who don’t comply with the
time-out and site-verification processes.

2. Your professional society endorses the protocol.
Forty professional organizations participated in the summit
to support the Universal Protocol. Chances are, you are mem-
ber of one of these prestigious associations, which include

- Accreditation Council for Graduate Medical
  Education
- Agency for Healthcare Research & Quality
- American Academy of Ambulatory Care Nursing
- American Academy of Cosmetic Surgery
- American Academy of Facial Plastic and
  Reconstructive Surgery
- American Academy of Family Physicians
- American Academy of Ophthalmology
- American Academy of Orthopaedic Surgeons
- American Academy of Otolaryngology-Head & Neck
  Surgery
- American Academy of Pediatrics
- American Association of Ambulatory Surgery Centers
- American Association of Eye & Ear Hospitals
- American Association of Nurse Anesthetists
- American Association of Oral & Maxillofacial
  Surgeons
- American College of Cardiology
- American College of Chest Physicians
- American College of Emergency Physicians
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- American College of Foot and Ankle Surgeons
- American College of Obstetricians & Gynecologists
- American College of Physicians
- American College of Radiology
- American College of Surgeons
- American Dental Association
- American Hospital Association
- American Medical Association
- American Medical Group Association
- American Nurses Association
- American Organization of Nurse Executives
- American Pediatric Surgical Association
- American Society for Surgery of the Hand
- American Society of Anesthesiologists
- American Society of General Surgeons
- American Society of Ophthalmic Registered Nurses
- American Society of PeriAnesthesia Nurses
- American Society of Plastic Surgeons
- American Society of Plastic Surgical Nurses
- American Urological Association
- Association of American Medical Colleges
- Association of periOperative Registered Nurses
- Association of Surgical Technologists
- Federated Ambulatory Surgery Association
- Federation of American Hospitals
- Medical Group Management Association
- National Association Medical Staff Services
- National Patient Safety Foundation
3. It’s the right thing to do.
Beyond meeting protocol requirements, there is tremendous value to conducting a time out. During surgery, you must often wait while a team member finds an x-ray or piece of equipment or repositions a patient. In addition to ensuring that you are about to conduct the correct procedure on the correct person and site, the time out also provides a moment for the entire surgical team to understand what is about to happen and to make sure that they have everything they need for the surgery.

4. A football team wouldn’t make an important play without a huddle.
Just as a quarterback wouldn’t proceed with an important pass play without discussing it with the rest of the team first, surgeons shouldn’t go ahead with a surgery without talking to their entire team.

5. It will boost morale.
Studies show that hospitals that have put a time-out strategy in place have greater overall efficiency and improved nursing morale. In fact, Kaiser Permanente in Anaheim, CA, reported a drop in its nursing turnover rate from 23% to 7% after it scripted a time-out briefing. Kaiser’s time-out process calls for the following:
Surgeons are responsible for indicating the type of surgery, time estimate, desired patient procedure, standard procedure, special needs, any special intraoperative requests, and script for the surgical/scrub technician.

Circulators must identify the patient site and marking, and verify back-table medications, whether blood is available, and whether x-rays are available.

Anesthesiologists must identify the special patient risks involving anesthesia, special positioning concerns, special medication needs, and any airway concerns.

If anyone fails to conduct the time out, the entire surgical team is suspended.

## Nine compliance tips

Keep the following tips in mind when following the Universal Protocol:

1. The preoperative-verification process begins when scheduling the surgery.
2. Initial verification of the surgery and site begins upon first contact with the patient. This should occur prior to admission, during a preoperative phone call or contact.
3. As verification, let the patient state his or her name, other identifying information, and the site and reason for the surgery.
4. Remember to write all words out on the operative permit. Don’t use abbreviations.
5. Mark the surgical site with the word “yes” or a line. Some hospitals use the surgeon’s initials to mark the site. This acts as verification that the surgeon actually signed the site.
6. Involve the patient or the patient’s significant other in this process.
7. Use a verification checklist to remind you of all the requirements.
8. Conduct a time out in the operating suite, prior to surgery.
9. Make sure that your processes for verification, site-marking, and time out are consistent throughout the organization.
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Final exam

Note: The quiz and certificate of completion printed within the handbook are not applicable for nursing contact hours. Please see your instructor for the quiz and evaluation specific to this nursing activity.

1. Which patients need to have the surgical site/side marked?
   a. a patient undergoing spinal surgery
   b. a patient undergoing carpal-tunnel surgery
   c. a patient undergoing ureteroscopy surgery
   d. all of the above

2. Which patients do not require surgical site-marking?
   a. a patient undergoing heart surgery
   b. a patient undergoing arthroscopic surgery
   c. a patient undergoing hernia repair
   d. none of the above

3. True or false: The JCAHO prohibits the patient from marking the site.

4. What is the final step to the site-verification process?
   a. patient identification
   b. time out
   c. site marking
   d. preoperative-verification checklist
5. True or false: The universal protocol only applies to procedures that take place in the operating room.

6. At which point must you follow the preoperative-verification process?
   a. when the procedure is scheduled
   b. when the patient first arrives in the preoperative area
   c. when the patient is sedated
   d. none of the above

7. Which of the following are acceptable marks for the site-marking process?
   a. initials
   b. the word “yes”
   c. a line
   d. all of the above

8. True or false: A surgeon does not have to mark the site as long as he or she stays at the patient’s bedside from the moment the decision is made to do the procedure through to the completion of the surgery.

9. Which of these elements is not necessary when conducting a time out?
   a. verification of who is actually conducting the surgery
   b. verification of the correct patient position
   c. verification of the patient’s identity
   d. verification of the correct side and site

10. True or false: As long as you conduct a verbal time out, there is no need to document that it took place.
Answers to the final exam

1. d  6. a
2. a  7. d
3. False  8. True
4. b  9. a
5. False  10. False

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Suzanne Perney
Vice President/Publisher

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