

Quality Assurance Committee Standards and Guidelines



Faith In Practice

Life Changing Medical Mission

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Purpose of Quality Assurance Committee

The purpose of this document is to provide certain standards and guidelines for medical volunteers who serve on teams in Guatemala through Faith In Practice. This document is a guideline designed to assist volunteers, team leaders and in-country staff in their work when providing care to patients in Guatemala. This document is not intended to be exhaustive. The goal is to provide the best possible care to patients in Guatemala.

Role of the Quality Assurance Committee: Review of Unusual Occurrences and Quality Data

While it is recognized that because volunteers and staff do not manage the health care facilities in which they serve and patients return to their communities which often limits ability for long-term follow-up, the Quality Assurance Committee remains committed to seeking ways to identify areas for improvement and making recommendations to the local partner hospitals. Notwithstanding care limitations, the Quality Assurance Committee is committed to identifying challenges and suggesting improvements to ensure that the best patient care is provided. The Quality Assurance Committee seeks to improve care by obtaining and reviewing the following information, when possible, and asks for collaboration in the endeavor from the volunteers, in-country staff, and the facilities where patient care is provided.

Unusual Occurrences

Any event that is of concern or that compromises or directly affects patient care should be documented on an Unusual Occurrence Report form (see Surgical Protocol Appendix). This includes any unexpected event (i.e. infection, return to the OR) or outcome involving patients, volunteers, equipment malfunction or supply issue. If an unexpected event would be reported on in the US, an Unusual Occurrence Form should be completed in Guatemala. Team Leaders are responsible to work with the volunteer providers involved to ensure any unexpected outcome or unusual occurrence is documented accurately and completely. Program Directors will forward any such reports with supporting medical record documentation, including the record of operation(s), to the Quality Assurance Committee for its review and development of an action plan when appropriate.

Infections and Complications

Program Directors will work with local facilities to obtain available information about infection rates and post-operative complications. They will report these findings on a monthly basis for submission to the Quality Assurance Committee for review and comment and development of an action plan when appropriate. These reports may include supportive materials, such as medical record documentation and other pertinent information. The purpose of these submissions is to assist the volunteers and the partner hospitals to improve overall care of the patient.

Scope of Practice: Surgical Teams

Practice Privileges: Surgeons

To serve as a primary surgeon on a Faith In Practice team, the surgeon must carry active privileges at a hospital or be retired and have surrendered his or her active surgical privileges not more than one year prior to the Faith In Practice trip date. To serve as a primary surgeon, Guatemalan regulations require an active license and a proof of specialty document (i.e. board certificate, completion of residency in a specific specialty, etc.).

Surgeons who are retired, and have not carried active surgical privileges for more than one year, may participate on Faith In Practice teams, according to the following parameters:

- 1) Retired surgeon has previously served with Faith In Practice as a primary surgeon,
- 2) Retired surgeon is informed prior to serving that their role will be limited to assisting,
- 3) Team Leader and Faith In Practice are aware and accept the arrangement.

These former primary surgeons, now retired, are not required to carry an active license.

Practice Privileges: Anesthesia Professionals

To serve as an anesthesiologist, certified registered nurse anesthetist (CRNA) or other health care provider that administers anesthesia on a Faith In Practice team, this individual must carry active anesthesiology privileges at a hospital or have been retired for less than 1 year.

Scope of Practice: Credentials of Surgeons and Anesthesia Professionals

It is the responsibility of all Team Leaders to screen all medical provider applicants for the individual's scope of practice and experience and determine that their clinical expertise is appropriate for the types of procedures being planned for the team. If the Team Leader does not have the requisite experience to evaluate, they must seek a trusted professional within the specialty to do so. It is important to communicate this information to Program Directors to ensure patient recruitment aligns with surgeons' scope of practice. If there is any concern about the credentials of a potential volunteer applicant, the Chair of the Quality Assurance Committee should be contacted.

Scope of Practice: Role of Medical Residents and Medical and Nursing Students

- Only licensed surgical residents who have completed at least 2 years of clinical surgery training are permitted to assist with surgical procedures when directly supervised and the surgical field is directly visualized by the primary surgeon.
- Only anesthesia residents in their final year are allowed to administer anesthesia when under the direct supervision of an anesthesiologist.
- Nurse anesthetist students and anesthesia assistant students are not allowed to participate in the administration of anesthesia.
- Medical, nursing and physician assistant students should only practice to the level of the education they have received in their program at the time they are volunteering on a team under the direct supervision of a physician or registered nurse. Medical, nursing and physician assistant students are not allowed to scrub-in nor assist in the operating room at any time.

Role of Non-Medical Volunteers

Non-medical volunteers may not assist nor scrub into the surgical sterile field.

For any non-medical volunteer who would like to observe in the operating room during a procedure, permission must be obtained from team's OR director and circulator in the specific OR before the

beginning of the procedure. When a non-medical volunteer is being considered for observation, the OR director must make the decision based on the safety of the patient, the potential for infection and contamination of the sterile field. No more than 1 non-medical volunteers can be present in an OR at the same time. The circulator assigned to the OR will orient the non-medical volunteer about the sterile field, place him/her safely outside the parameters of the sterile field, and instruct him/her if there is anything else he/she needs to know to maintain patient safety.

Scope of Practice: Minimum Staffing Guidelines for Volunteer Surgical Team Personnel

This policy has been developed to provide a guideline for team leaders regarding the minimum number of personnel needed by surgical teams based on the type of surgery being performed. If a team does not meet the minimum staffing requirements, the Team Leader will develop a plan together with Program Director to cover all required roles. The Program Director will notify the Quality Assurance Committee Chair for discussion and assistance. If an adequate plan is not developed, Faith In Practice reserves the right to adjust the surgical volume accordingly (i.e. cancel a room).

Surgical Team Personnel

Besides the surgeon and anesthesia provider, the minimum number of experienced OR personnel are one actively practicing and licensed circulator nurse and one actively practicing and licensed or certified scrub technician or nurse per OR. Each OR must have a licensed nurse (not including the CRNA) to be able to assist the anesthesiologist in providing emergency care in the event of a cardiac or respiratory arrest. Retired nurses that have served previously with Faith In Practice, may be allowed to continue serving in the same role given approval by Team Leader and Faith In Practice. Retired nurses that have not previously served with Faith In Practice will not be eligible for these roles.

Pre-operative and Post Anesthesia Care Unit (PACU) Personnel

The minimum number of actively practicing and licensed Registered Nurses (RNs) to provide pre-operative and PACU care is 4. At both hospitals, it is recommended that 1 RN is assigned to pre-operative care and 3 RNs are assigned to the PACU area.

At both hospitals, at least 2 of the 4 RNs serving in either the pre-operative area or PACU, must be experienced PACU, ER or ICU nurses. Some teams may have physicians, physical therapists, LVNs, or medical or nursing students, assisting in this area **in addition** to the minimum four RNs.

Pediatric Surgical and Nursing Personnel

When planning personnel for surgical teams performing surgery on pediatric patients, the following guidelines should be followed.

All teams performing surgical interventions on pediatric patients **under the age of 2 years** must provide the following personnel on the team:

- Pediatric Anesthesiologist (Fellowship or at least 2 years' pediatric experience)
- Pediatric Surgeon who performs the planned procedures at least monthly
- One PACU Pediatric Nurse with Pediatric Advanced Life Support Certification (PALS)

CRNA with Pediatric Advanced Life Support Certification (PALS) is appropriate provided a Pediatric Anesthesiologist is floating and available to support in the case of emergency.

All surgical teams performing surgical interventions on pediatric patients **2 years and older** must provide the following personnel on the team:

- Anesthesiologist with experience and level of comfort with children as confirmed by the Team Leaders
- Surgeon with experience and level of comfort with children's procedures as confirmed by the Team Leaders
- PACU nurse with experience recovering children over the age of 2 years as confirmed by the Team Leaders.

Scope of Care: Obras Sociales and Hilario Galindo Hospital

Refer to Faith In Practice Scope of Care documents for each partner hospital found in the Surgical Protocol of the Leadership Manual.

Pilot Program in Urology at Hospital Hilario Galindo

TURP procedures can be performed at Hilario Galindo Hospital by teams. The following criteria need to be in place in order to perform these procedures. They include: 1) The urologist needs to perform these procedures regularly as part of practice in the United States; 2) The team needs to include a registered nurse with expertise in postoperative care of TURP patients and willing to ensure Guatemalan nurses are taught how to safely care for these patients overnight; 3) TURP procedures should be performed on Monday and Tuesday to allow enough post-operative recovery time under the supervision of the team.

Blood Products Awareness: Obras Sociales and Hilario Galindo Hospital

Refer to Faith In Practice Blood Products Awareness documents for each partner hospital found in the Surgical Protocol of the Leadership Manual. After triage on Sunday, appropriate team personnel should meet to discuss potential blood product needs that are anticipated and work collaboratively with the in-country staff to ensure a plan is in place should blood products be needed.

Scope of Practice: Surgical Procedures

The surgeon will be informed about what type(s) of procedures they may be performing in Guatemala. General standard of care is that the lead surgeon will only perform procedures that they routinely perform in their practice.

General Surgery

Laparoscopic Cholecystectomy

The standard of care for treatment of cholecystitis and cholelithiasis is cholecystectomy surgery performed by the laparoscopic procedure. The open cholecystectomy procedure is implemented when the laparoscopic procedure is contraindicated or results in the need to open the abdomen more directly. Team Leader will explain to general surgeons that gallbladder disease is more advanced and cholecystectomies in turn are more complex in Guatemala from what is normally seen in the U.S. If the team leader or the surgeon has any questions, he or she is encouraged to contact the Chair of the Quality Assurance Committee before committing to performing these surgical cases.

Gynecological Surgery

Vaginal Hysterectomy in Guatemala

Vaginal hysterectomy is a very valuable tool in the armamentarium of the volunteer gynecologist in Guatemala. A significant number of women with prolapse or other benign conditions can benefit greatly from this technique, experiencing shorter operating time, less post-operative pain, absence of abdominal incision complications, and a faster return to normal activities. Unfortunately, the common complications associated with vaginal hysterectomy can result in insurmountable issues that we must deal with in-country (need for transfusion, bladder and bowel injury sometimes resulting in fistula, and need for urgent return to surgery).

The scheduling of a vaginal hysterectomy should be carefully considered by the team leader and the operating surgeon. Surgeon experience is the most important factor in choosing this approach, second is patient selection. The primary surgeon should be proficient in vaginal surgery and performing these procedures in their hospital on a regular basis. They should also be comfortable with the limitations of anesthesia, transfusion availability, surgical instrumentation, and back-up services available in the event of a complication.

Guatemala is not a satisfactory venue for training in vaginal surgery. There may be a temptation for the primary gynecologist to allow a less experienced surgeon or resident to perform this procedure under their supervision. This is in direct conflict with agreements we have with our hospitals to not bring surgeons to Guatemala for training.

Supra-Cervical Hysterectomy

Supra-cervical hysterectomies are not appropriate in Guatemala. Team Leaders must inform all gynecologists of this prior to departure.

The incidence of cervical cancer is 7 to 8 times higher in Guatemala when compared to the U.S. Based on Faith In Practice experience, 3-5% of women screened in the VIA method have pre-cancerous lesions requiring cryotherapy. Additionally, neither the rural medical community nor the patient population understand the procedure. Due to the high incidence of cervical cancer, and very limited access to routine screening, the supra-cervical procedure is not appropriate in this setting and is not permitted on Faith In Practice teams with the exception and under the conditions noted below.

In the event that a supra-cervical hysterectomy is medically indicated at the time of surgery (unplanned), a pap smear should be ordered as soon as possible post-operatively. Additionally, the patient should receive comprehensive education to completely understand the outcome of the supra-cervical hysterectomy, that the cervix remains intact, and the need for ongoing screening. The medical staff of the hospital should be notified and participate in the education of the patient to ensure the patient fully understands and follow-up instructions can be given.

Reparative Vaginal Surgery using Permanent Mesh

The use of PROLENE® mesh in vaginal repairs has been controversial almost since its inception. The Food and Drug Administration (FDA) initially approved this product but over time, with the persistence of trial lawyers slowly withdrew their approval until, in May of 2019, they ordered the last two manufacturers of mesh kits to cease the sale of the kits. This was not a recall, as Mesh kits already in the hands of hospitals were allowed to be used until the supplies were exhausted. The manufacturing and sale of sheets of mesh was not stopped. In their advisory, the FDA said that there was no evidence that use of permanent mesh was superior to traditional procedures or use of biologic grafts.

Some experienced surgeons who believe strongly in the safety and effectiveness of mesh in vaginal repair have continued to use mesh, fashioning grafts from the still-produced mesh sheets. There may also be some mesh kits still in inventory at our two hospitals in Guatemala. Due to the controversy surrounding the use of vaginal mesh, along with the potential complications that it presents in a setting where close follow-up and treatment of complications may not be available, the Quality Committee recommends that prolene mesh be used in vaginal repair in Guatemala only when no other material or technique can be deemed adequate to accomplish satisfactory repair, and in which there is minimal risk. This does not pertain to use of prolene urethral slings and intra-abdominal placement of prolene mesh at the time of abdominal sacro-colpexy which still have FDA approval.

Practice of Prolonged Foley Catheter Placement

The Guatemalan care of Foley catheters and amount of time acceptable to remain in place is different than U.S. standards. Team leadership of surgical teams performing gynecological procedures need to discuss with surgeons that the patients need to be fully educated about their catheter, the reason it is being left in the bladder and the timeframe for placement. Leaving a catheter in too long promotes potential for infection and prolonged inability to resume normal urinary function. If the Foley catheter is removed too soon, the risk of urinary retention is increased.

Voiding Trial after Gynecologic Reconstructive Surgery

Members of the Faith In Practice team (surgeon, nurses) should support the Guatemalan medical and nursing staff in following the standard voiding trial guideline after pelvic reconstructive surgery (outlined below), creating educational opportunities to discuss the reasons and the importance of leaving the catheter in place or the procedure for testing for urinary retention.

On Post-op Day 1 or 2:

- 1) Empty Foley and disconnect Foley from bag.
- 2) Use 300mL of sterile saline to backfill the bladder while the Foley is still in the bladder.
- 3) Remove the Foley.
- 4) Have the patient void in a basin on the commode and measure the amount voided.
- 5) The patient should void a minimum of 200mL. If she voids 200mL or greater than the Foley can remain out and the patient will need to void every 2 ½ to 3 hours.
- 6) If the patient voids less than 200mL, then replace the Foley and repeat in 24 hours.

Orthopedic Surgery

Guidelines for Preoperative Optimization

- The body mass index (BMI) in most cases should be under 40 but can be up to 45 if there are no other comorbidities especially considering a major debilitating condition.
- Type two diabetes should be well controlled and ideally would have a hemoglobin A-1 C of 7.0 or less. Random blood sugars should be checked, and sugar levels should be well controlled during the perioperative.
- Albumin should be at least 3.5 or higher prior to surgery.
- Good dental hygiene and avoidance of tobacco products and excess of alcohol are other important factors.

Guidelines for Hospital Care

- Preemptive pain control, especially in the joint replacement patients. Either the use of a spinal anesthetic or regional blocks with multi modal pain control should be encouraged, which usually involves the use of Acetaminophen, Tramadol, Ketorolac, Gabapentin or Pregabalin and one or two doses of intravenous Decadron in the first 24 hours.
- Start of physical therapy is encouraged as soon as possible, as studies have shown that ambulation on the day of surgery is very helpful.
- Use of low-dose aspirin for deep venous thrombosis prophylaxis. In some cases, Lovenox should be used at least in the first few days.

Guidelines for Patient Education

- Patient education should include wound care with the use of occlusive waterproof bandages and arrangement for local follow up care with removal of staples and sutures as deemed appropriate.
- When applicable, local follow up care is encouraged where possible in consultation with Faith In Practice surgeons for any concerns or complications.

Scope of Practice: Continuity of Surgical and Nursing Care

Daily Hand-Off Policies

All surgical teams should be respectful of the stopping time at the partner hospital and plan the surgical schedule to complete the day's cases within a reasonable time, typically the last patient should be out of the PACU by 5pm. The following procedure outlines the steps to complete each day of surgery:

- An anesthesiologist and a primary surgeon need to stay until the last patient has left the recovery room and is in the convalescent ward area in stable condition based on vital signs.
- The Ward Physician/Nurse should report to the Guatemalan physician at the end of each day.
- The primary surgeons must hand-off to the Guatemalan physician, in the event of a particularly complex case, with an emphasis on special orders before leaving for the day.
- In-country staff provides the hospital staff with contact information in the case of overnight concerns or emergencies. This includes the names of two MDs, preferably someone who is bilingual, a surgeon and/or an anesthesiologist, cell phone numbers, hotel room numbers, hotel's main phone number, and in-country staff number.
- The Mission Coordinator will work with the team and Program Director to develop a plan for who will return to the hospital in case of an emergency (see Emergency Protocol in Surgery Protocol).

Referring Patients in Need of Follow-up

For patients who are in need of continued care and/or follow-up, the following guidelines should be followed:

[Further information will be inserted at a later date]

Scope of Practice: Sterilization Techniques

Sterilization guidelines have been developed and apply to both the operating suites at the Obras and Hilario Galindo. See the surgery protocol manual for specific details. It is important that the operating room director work closely with the in-country sterilization personnel to ensure equipment is being sterilized appropriately, especially specialty equipment they may not be as familiar with.

Scope of Practice: Anesthesia

Any procedures requiring IV sedation or general anesthesia should only be conducted in the operating room. Procedures can be performed with local or topical anesthesia and oral anxiolytics in a general clinic setting.

It is the Anesthesia Director's responsibility to review the Minor Procedure Clinic to ensure working function of equipment, confirm availability of supplies and medications, and ensure overall compliance with this policy.

Dental Anesthesia

All dental procedures requiring IV sedation or general anesthesia should take place in an operating room where all emergency equipment and medications are readily available. None of such procedures should be attempted in a remote dental clinic.

Regional Anesthesia

It is of utmost importance that the anesthesiologist and surgeon communicate with each other about the use of local anesthetics, as each may use them in a different capacity on the same patient. If this is the case, one must calculate the maximum dose for each medication, keeping in mind that a patient's age, weight and comorbidities, as well as the type of regional anesthesia can contribute to the development of Local Anesthetic Systemic Toxicity (LAST).

All surgical teams are encouraged to use regional anesthesia as it applies to the surgical procedures performed by their respective team and to the expertise of the anesthesiologists. It is well known that regional anesthesia reduces opioid consumption, pain, and time to discharge, while improving overall patient satisfaction. It has also been shown to decrease pulmonary complications and thromboembolic events as patients are able to ambulate and participate in physical therapy sooner.

If the anesthesia team will be performing regional blocks of any kind, they will need to ensure that the appropriate monitors, emergency drugs and resuscitation equipment are available. This includes but is not limited to the availability of standard American Society of Anesthesiologists (ASA) monitors, a crash cart and intralipid (20% liquid emulsion) to treat LAST. All anesthesia providers should be able to identify and treat complications associated with performing regional anesthetic blocks.

Scope of Practice: Operating Room Procedures

Surgical Site Identification and Pre-Procedure Time-Out

The surgeon shall identify and mark the surgical site pre-operatively.

The time-out procedure will be performed prior to the beginning of any surgical case. The procedure includes the identification of the patient, the procedure being performed and the location of the procedure, review of lab results and pregnancy testing. Please see Surgical Safety Checklist in the Surgery Protocol Appendices.

Count Sheets

A count sheet is required for all surgical cases according to the standard of care before leaving the operating room.

Record of Operation and Post-Op Orders

Proper surgical documentation in the operative note by the primary surgeon is required. The operative note should accurately describe with reasonable detail exactly what was performed including any anatomic variations, unusual occurrences or complications during the surgery so that if another team follows up on the patient, they will have all the information needed to give this patient quality care should they have a complication.

The surgeon is required to complete all documentation in the hospital's Patient Database immediately after the surgical case is completed. The surgeon must print and sign all reports and forms before the patient leaves the OR area so that the complete medical record can be transferred with the patient to the post-operative area. Residents are not allowed to be primary surgeon on record nor sign any documentation.

This documentation includes:

- **Record of Operation** describes the operation, unusual findings, complications, approximate blood loss, and any specimen sent to pathology. The surgeon must list **each planned procedure**, confirm the procedures were actually performed. Any additional procedures that are performed beyond the original planned procedures, **MUST** be added to the Record of Operation by clearly identifying the additional procedure and procedure code and describing the procedure. Because of the occasional need for additional follow-up, the completeness of the record of operation is very important.
- **Post-Op Orders Form:** These orders carry through until the following morning rounds.
- **Discharge Orders Form:** This form is completed at the end of the case, with ability to modify as needed upon discharge.
- **Pathology Form** (if applicable): This includes the form and the appropriate labels for the specimen being sent to pathology.
- **Post-op and discharge pain:** Surgeons should refer to the hospital's Pain Management Protocols when writing orders for pain medicine, and work with Team Pharmacist to identify available medicines for post-op and discharge.
- **Documentation for surgical implants:** It is required that documentation of the surgical implant including the product XXXX sticker with the implant serial number.

Medication Procedures

Dispensing of Controlled Medications

All teams that dispense narcotics to patients must follow the following procedure:

Only licensed nursing, pharmacy and medical personnel can:

- Open and package narcotics in packets for individual patient use including the medication name, dose, route and patient name.
- Dispense narcotics in packets to patients/families as ordered by the physician or advanced practice nurse and provide education about the medication.
- All narcotics in the hospital setting must be counted and documented as dispensed with any medication wasting recorded
- All narcotics must be stored in a locked and secure area with a designated licensed team member assigned the key.

Expiration Dates

Medications should be within expiration dates for distribution by teams to patients. In the event a medication is expired, the responsible team member (Anesthesia, Pharmacist or other team member) may decide on the safety and efficacy of an expired medication. According to national guidelines there are specific medications that **MUST NOT** be used after the expiration date. These include:

- Insulin
- Oral nitroglycerin (NTG)
- Vaccines, biologicals, or blood products
- Tetracycline
- Medicines that look old: degraded, powdery, cloudy, or crumbling medicine, drugs with a strong smell, or dried up medicine (as in the case of ointments or creams) should be discarded.
- Refrigerated liquids
- Eye drops with preservatives
- Injectable pens
- Specially compounded medications

The Supply Chain Management team will rotate medications in a first in first out fashion to avoid waste and assure quality of care for patients. Medications nearing expiration should be in the system so they can be used in a timely manner and can be stored in accordance with best practice and manufacturer directions.

Emergency Crash Cart Procedure

Emergency Crash Cart stocking and maintenance processes differ between Hilario Galindo and the Obras. Therefore, a drug box will be provided by FIP with the ACLS protocol drugs available at both hospitals and will be restocked and maintained by in country FIP staff. On Sunday, each team should meet after triage to review the contents of the drug box, supplement as they see fit to meet their practice standards and ensure that other emergency equipment such as defibrillator, suction, intubation equipment is located and a plan for delivery to a cardiac or respiratory emergency is discussed. If the existing emergency crash cart is opened and used, in country staff should be notified so it can be restocked according to individual hospital procedures.

Guidelines for Volunteer Issues

Procedure for Needle Stick or Blood and Body Fluid Exposure

If a team member is stuck by a needle or other sharp object or gets blood or other potentially infectious materials in their eyes, nose, mouth, or on broken skin, immediately flood the exposed area with water and clean any wound with soap and water or a skin disinfectant if available. Report the exposure immediately to the Team Physician, Mission Coordinator, and Program Director so immediate medical attention can be provided. In the case of an exposure, the patient and volunteer will be tested. Please see Emergency Protocol in General Leadership Manual for more information.

Post Exposure Prophylaxis: HIV

All Faith In Practice teams will have available in their STAT Kits HIV prophylaxis medication: Atripla (*Tenofovir disoproxil fumarate 300mg/emtricitabine 200mg/efavirenz 600mg*)

In the event that HIV prophylaxis is deemed necessary, patients are directed to take the first Atripla tablet within 72 hours of exposure (the sooner the better), followed by one tablet each day for a total of 28 days. Each STAT Kit will have 7 tablets available. This will likely provide the team member coverage

until they are able to see a physician upon return to the U.S. If more are needed, notify Program Director immediately.

Ultimately, the team member together with the Team Doctor will decide whether or not to start the Atripla.