

# Quick Reference Guide: How To Enter Data in the SUI Surgery Module

#### Important Information to Start:

- Before you can begin the entry of cases, you must be set up in the system by your site's ACQUIRE Administrator.
- All patients having surgery for stress urinary incontinence (SUI) or mixed urinary incontinence are eligible for inclusion in the SUI Surgery Module. Please see the full manual for complete inclusion/exclusion criteria.
- If the patient has a midurethral sling or periurethral bulking agent surgery, you will be asked for information about the device you used: you **must** retain device packaging with UDI/barcode info for entry into the database!
- Patients are **not** required to sign informed consent forms, but they should be informed of the purpose of the program and that they will receive a questionnaire at 6 weeks and annually thereafter (unless they opt out).

## To Add A New Patient:

- 1. From <u>acquire.augs.org</u>, click on the Provider portal. Choose the Patient Records tab on the left side of the screen.
- 2. Click on the "New Patient" button on the right-hand side of either page.
- 3. First name, last name, and birthdate are required fields.
- 4. If an email address is entered, the patient will receive questionnaires. If the patient doesn't want to receive questionnaires, please click the "opt out" selection below the email field.
- 5. For visit date, either use the calendar date finder function or enter date in MM/DD/YYYY format. Do not use only two digits for the year.
- 6. A visit type should be added if the patient was seen. The three options are **Consultation Visit**, **Surgery Visit**, and **Unscheduled Visit**.
  - The Consultation Visit has 3 associated questionnaires:
    - Demographics and History
    - ICIQ
    - Preoperative Information
  - The Surgery Visit has 4 (5 if the device information questionnaire is triggered) questionnaires:
    - Demographics and History
    - ICIQ
    - Index Procedure
    - Preoperative Information
    - Device Information
  - The Unscheduled Visit has 1 questionnaire:

- Unscheduled Visit
- 7. When a provider adds a patient, the patient will automatically be assigned to the provider that created the record. However, if a patient is created by a data manager, a provider field will be present and will include a list of all the providers at their site. Please choose the appropriate provider that will be associated with that patient, who will then receive all follow-up questionnaires for that patient. At this time, this field cannot be edited once a provider is chosen. If you mistakenly add the wrong provider, please contact AUGS for assistance at acquire@augs.org.

#### **Consultation Visit**

- 8. Typically, a Consultation Visit is the patient's first visit, where demographic and history information are collected.
- 9. There are 3 questionnaires: Demographics and History, ICIQ, and Preoperative Information. ICIQ questions are to be asked of the patient during their visit.
- 10. Once all the information has been entered into a form, click Review and Submit on the bottom right. If necessary, edit any data fields that are incorrect. Once everything is correct, scroll down and click the Submit Form.
- 11. Note: The four questions in the ICIQ are intended to be answered by the patient but entered by the provider/data manager.

## Surgery Visit

- 1. To enter the Surgery Visit, click Add Visit in the upper right of the patient's page. Choose Surgery Visit in this field.
- 2. When creating a Surgery Visit, a surgery date must be assigned.
- 3. The demographics and history tab in the Surgery Visit forms will automatically populate data from the information in the Consultation Visit information (if completed) but should be reviewed and updated as needed. To do so, click on Review and Submit (even if the autopopulated information is correct) and then click Submit.
- 4. Next enter information into the Index Procedure tab and click review and submit as noted previously.
  - a. Note that the Device Information questionnaire will appear in the patient's list of forms in their Surgery Visit if a Midurethral Sling or Periurethral Bulking Agent Injection is selected.
- 5. If applicable, complete the Device Information by entering the UDI Number and LOT Number. Once that information is entered, you can click Retrieve FDA Information and finish the form. Review and Submit as with all the other forms. Only UDI and/or LOT number are required fields. Once the device is found by the system, no other fields are required to be completed.
- 6. Be sure to give the patient her Patient Information Card and the Follow Up Reminder Card after her surgery so that she knows both the importance of the project as well as when to expect her follow-up questionnaire.

## Unscheduled Visit:

- 1. If the patient returns any time after her first follow-up visit for an unscheduled visit, click Add Visit in the upper right of the patient's page and choose Unscheduled Visit.
- 2. There will be one form to complete asking for details of the visit.

## Follow Up Visits:

#### Six-week Follow-Up for Patients:

- 1. Six weeks after the surgery date, the patient will receive an email with instructions on how to make an account in the ACQUIRE portal to complete her questionnaire. This account will be accessed through the Patient portal on the registry homepage (acquire.augs.org).
- 2. Once a patient completes a questionnaire, it will then appear in the Questionnaires section of the Provider portal for the patient's provider to review.
- 3. Note: Providers not assigned to a patient will not see these completed patient questionnaires unless they are also the Site Administrator or Data Manger for their site. Site Administrators and Data Managers are able to see all of the completed questionnaires. For more information on user roles, please see the full provider manual.

#### Six-week Follow-Up for Providers:

- 1. Six weeks after a surgery date, a provider questionnaire will be available for the provider to complete in the patient's Surgery Visit section. The questionnaire will also show up in the Questionnaires tab of the provider portal so that you know the survey is due.
  - a. Complete the questionnaire after the patient has returned for her first follow-up (even if it is later than six weeks).
  - b. If the patient does not return for a follow up visit, questions can be asked over the phone.
  - c. Note: Once the questionnaire has been opened and closed in the Questionnaire tab, it will disappear from this section of the registry. However, the questionnaire will still be available for completion, review, and/or editing in the patient's Surgery Visit tab within Patient Records.

#### Annual Follow Up Questionnaires for Patients and Providers:

- 1. Patients and providers will also have yearly follow-up questionnaires to complete (through the portal) over the next three years based on the date of their surgery.
- 2. For Patients: A patient reminder/link to the patient portal/questionnaire will be automatically generated by the system. Providers or their staff should attempt to follow up with patients that have not completed their questionnaires.
- 3. For Providers: The annual provider follow-up questionnaire will automatically appear in their list of outstanding questionnaires in the Questionnaires tab at the appropriate time.

For questions or help logging in, please reach out to your site's ACQUIRE administrator.