ASCA Application Scenarios (DRAFT)

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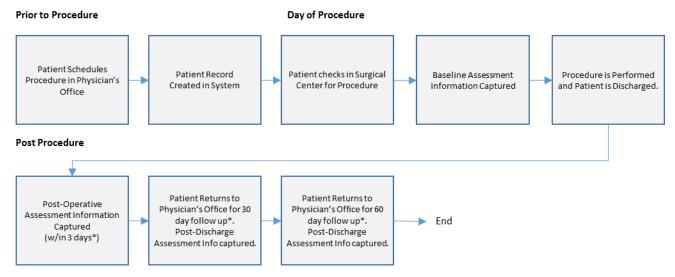
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Business Objective

The Application we are building will be used to track outcomes information for certain surgical procedures performed at outpatient surgical centers. Information collected will be used to support a planned research project, as well as to help clinicians in managing their patients.

Overall Process Description

The Application captures information prior to the surgical procedure, shortly after the procedure is done, and then at various points after the procedure has been done. High level process description follows.



^{*} Time period for follow up is TBD.

Prior to Procedure:

- 1. **Patient** and **Physician** have initial consultation, which results in Patient decision to have the procedure. At this time, Patient is given the option to opt-out of the study.
- Physician's Office Staff schedules the procedure with the Surgical Center using their existing process.
- 3. Patient record is created in ASCA Application. We create records for all Patients, regardless of their opt-in status, but only track study information for Patients that do not opt-out. Patient Record is created in one of three ways:
 - a. In the Physician's Office, by Physician's Office Staff, at time of scheduling appointment.
 - b. In the Surgical Center, by Surgical Center Staff, at time of scheduling appointment.
 - c. By automated **File Upload**, on a regularly scheduled basis.

Day of Procedure:

- 4. On the day of the procedure, when Patient arrives at Surgical Center, Surgical Center Staff uses ASCA Application to complete any missing demographic information and to capture data in the Pre-Op Baseline Assessment.
- 5. After procedure, Surgical Center Staff captures any **Discharge Assessment** questions from either Patient or **Medical Record**. Patient is then discharged to home.

Post-Procedure:

- 6. Post-Discharge Assessments are captured at three points (time frames are TBD)
 - a. A Follow-Up Post-Discharge Assessment performed shortly after discharge (e.g. 3 days).
 Most likely done by phone.
 - A 30 Day Post-Discharge Assessment performed during follow-up visit in Physician's Office.
 - c. A **60 Day Post-Discharge Assessment** also performed during follow-up visit in Physician's Office.
- 7. At any point, users can view dashboards and/or reports summarizing collected information. These are still to be determined.
- 8. At any point an **ASCA Research Representative** can review the completeness of data entered for all of the Surgical Centers.

- We will provide Patients a way to opt-out of tracking. We will still create records for Patients
 who opt-out in the ASCA application but we will not track any study information for them. To be
 determined whether we will track any patient identifying information for them.
- We will provide ability to maintain different sets of questions for different types of procedures –
 e.g. one set of questions for a hip replacement and another set of questions for a knee
 replacement.
- We will track both Patients and Patient Observations. A Patient Observation covers all of the information gathered from the time a procedure is scheduled to the last post-procedure assessment. One Patient can have multiple observations patient "John Smith" might have his right knee replaced on January 1st, and his left knee replaced 6 months later. The ASCA Application would have one Patient Record with demographic information for John Smith, and two related Patient Observation records for each knee replacement.
- Patient Observation records will be assigned to individual Physicians, Surgeons and Surgical Centers.

Detailed Process Descriptions (data capture)

I. Patient Schedules Procedure

- 1. After consultation with **Clinician** in the Physician's Office, **Patient** schedules the procedure with **Physician's Office Staff**. At this time Patient may be screened to determine their eligibility to participate in the study. If so, and if Patient is eligible, Patient is given option to opt-out of study.
- 2. Physician's Office Staff schedules the procedure using their existing appointment scheduling process/software.
- 3. When procedure is scheduled, either Physician's Office Staff or Surgical Center Staff opens the ASCA Application, creates a new Patient Record and/or Patient Observation Record and enters Patient Demographic information. Alternately, Patient Record and Patient Observation Record may be created by means of an automated File Upload process (described later).
- 4. Physician's Office Staff gives Patient a printed **Pre-Op Baseline Assessment**. Assessment can be completed in one of several ways:
 - a. Physician's Office Staff may interview the Patient and enter the information directly into the ASCA Application (this is the preferred way) Or,
 - b. Patient can be provided with a device (iPad, Tablet, Laptop, etc.) he or she can use to complete the assessment in the office. Or,
 - c. Physician's Office Staff may give Patient a printed Assessment to complete at home, with instructions to bring the completed assessment with them to the **Surgical Center** on the day of the procedure.

End

Assumptions:

- Scheduling the procedure is done using Physician's current scheduling software, and is outside
 of the scope of ASCA Application.
- Physician's Office Staff will need some way of identifying what procedures are to be tracked in ASCA Application. This is likely a "manual" reminder (printed "cheat sheet", etc.)
- Printed copies of the Pre-Op Assessment will need to be available in the Physician's office.

Ia. Automated File Upload

- 1. On a regularly scheduled basis, **Surgical Center Scheduling Application** produces a **Patient Record Export File** (CSV or XML). Patient Record Export File is saved to a reserved directory.
- 2. On a regularly scheduled basis, ASC Application will retrieve Patient Record Export File via FTP. File will be validated by the Application and the contents will be imported into the ASCA Application Database.
- 3. ASC Application will maintain a record of validation attempts. Records may be viewed by an authorized user within the ASC Application via dashboards and/or reports.
 - Records that fail authorization will not be imported into the ASCA Application. Failed Records will be retained in the application and may be retrieved, corrected and resubmitted by an authorized user.

b. Records that contain issues but still pass validation will be imported. Application will maintain list of issues associated with the record. Issues will be viewable to authorized users along with record of validation attempts.

End

Assumptions

• We will define specifications for generating an import CSV/XML file, but it will be the responsibility of the Surgical Center's scheduling application to generate the file.

II. Patient Check-in for Procedure

- 1. **Patient** arrives at **Surgical Center** on the day of the procedure.
- 2. During check-in process, **Surgical Center Staff** identifies patient as having a procedure that will need to be tracked in the ASCA Application. Surgical Center Staff opens **ASCA Application** and determines whether or not Patient has opted out of data collection.
- 3. If Patient has not opted out
 - a. Surgical Center Staff selects Patient Demographic record and enters any required missing data.
 - b. If Patient has completed a paper **Pre-Op Baseline Assessment** at home, Surgical Center Staff opens appropriate Patient Observation record and enters that information.
- 4. If Patient fails to show up for the procedure, Surgical Center Staff notes this in appropriate Patient Observation record. If Patient procedure is subsequently rescheduled we will need to determine whether to treat this as a new observation, or just re-activate the current one.

End

Assumptions:

• Surgical Center Staff will have some way of identifying what procedures are to be tracked in ASCA Application.

III. Patient Discharge following Procedure

- 1. After the procedure, **Surgical Center Staff** completes a **Discharge Assessment**.
- 2. If there are assessment questions that need to be answered by the Patient:
 - a. Surgical Center Staff may interview the Patient and enter the information directly into the **ASCA Application** (this is the preferred way) Or,
 - b. Patient can be provided with a device (iPad, Tablet, Laptop, etc.) he or she can use to complete the assessment in the Surgical Center. Or,
 - a. Surgical Center Staff may give Patient a printed Assessment to complete at home, with instructions to mail (or fax) the completed assessment to the Surgical Center.
- 3. If there are assessment questions that need to be gathered from other sources (such as the medical record) then Surgical Center Staff retrieves the information from the relevant source and enters into ASCA Application.

End

Assumptions:

• None

V. Office Staff performs Follow-up Post-Discharge Assessment

- 1. On a regular basis, **Physician's Office Staff** or **Surgical Center Staff** will use the ASCA Application to access a work list of Patients with incomplete Follow-Up Post-Discharge Assessments.
- 2. Staff will contact Patient by phone and will enter assessment information directly in the Application.
- 3. If Staff is not able to reach Patient, Staff may enter information about the call attempt (time and date call was attempted, notes about the attempt, etc.)
- 4. If Staff determines that Patient is unreachable, or that too much time has elapsed to warrant completing the Assessment, Staff may close the Assessment and note reason for closing.

 Assessment will no longer appear on work list.

End

Assumptions:

VI. Clinician collects Post-Discharge Assessment Information

- 1. Following discharge, **Patient** will see a **Clinician** for 30 day and 90 day follow up exams. These exams will happen in the Physician's Office.
- 2. When Patient checks in for appointment, **Physician's Office Staff** determines that follow-up visit is for a procedure that we are tracking. Staff accesses Patient in ASCA Application and reviews list of outstanding Assessments.
- 3. Staff will collect appropriate **Post-Discharge Assessment** information in the same manner as described above; by interviewing the patient and entering information directly into ASCA Application, by the Patient using a provided device, or by means of a printed assessment completed by the Patient either in the office or at home.

End

- Patient is seeing Clinician in the same Physician's office that the procedure was originally scheduled in.
- Clinician (or Physician's Office Staff) needs a way to recognized that the Patient is being seen for a procedure we are tracking.
- 30 day and 90 day time periods are "TBD". However, system will support 2 post-discharge assessments, and we will use the same time period for all procedures.

VII. Post-Discharge Assessment links sent through Email

- On a regular basis Physician's Office Staff or Surgical Center Staff can use ASCA Application to review work lists of outstanding Post-Discharge Assessments. Staff may select Assessments and generate Assessment Emails. Only Patients who have provided emails will be included in this process.
- 2. Content for emails is specific to a procedure. It is pre-defined, but can contain light personalization for example salutation might include the patient's name, body might include physician's name, etc.
- 3. In addition to pre-defined content, emails might contain links to patient educational materials, or online assessments that the Patient can complete from home.

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Assumptions:

None

II. Patient Completes an Assessment through an Email link

- 1. **Patient** opens the **Assessment Email** from their email program at home. The email contains a URL which takes patient to a login form within the **ASCA Application**. The URL contains Patient Identifier, Observation Identifier and Assessment Identifiers, so Patient is automatically authenticated with the system and is brought to the proper assessment.
- 2. Patient completes Assessment and marks it as "complete".
- 3. ASCA Application sends an email to the patient verifying that the assessment was completed, then changes the status of the Pre-Op Assessment to "Complete".

End

- Assessment will be completed in one session. Patient does not need to save partially completed assessment and return at a later point.
- Assuming that there is no information in the assessment that is sensitive enough to prohibit us from auto-authenticating the patient.
- Once marked as complete, Patient cannot review answers through this link. Selecting a link to a completed assessment shows a generic "This assessment has already been completed" screen.
- For additional security we may also "expire" email links after a certain amount of time has passed.

VII. Removing Patients from ASCA Application

- 1. **Physician's Office Staff** and **Surgical Center Staff** may remove individual Patient / Patient Observations from the **ASCA Application**.
- 2. Patient/Observation information remains in the ASCA Application, but no longer appears on any User work lists or reports.

End

Detailed Process Descriptions (administrative)

I. Viewing ASCA Application Dashboards & Reports

- 1. **User** (Clinician, Physician Office Staff, Surgical Center Staff or ASCA Research Representative) logs into **ASCA Application**.
- 2. ASCA Application presents User with access to Reports and/or Dashboards based on their assigned Role. Reports/Dashboards fall into the following groups:
 - a. Quality quality of care, outcomes, etc.
 - b. Efficiency how efficiently care is delivered (time, cost, etc.)
 - c. Participation Completion rates for assessments
 - d. User Access who has accessed the ASCA Application and what they have done

End

- In order to encourage participation, Dashboards and Reports should be defined that are useful to Clinicians, Physician's Office Staff, and Surgical Center Staff.
- Permissions are defined by Role. ASCA Application will contain an additional Super User
 Administrator role, who will have access to everything in the Application. There will be some permissions that are only available to the Super User Administrator, and only a Super User Administrator can create another Super User Administrator.
- Users will be assigned to one or more Surgical Centers and/or Physician's Offices (collectively referred to as **Facilities**). Uses can only see information for Facilities that they are assigned to.
- In addition to Facilities, we will be able to define **Facility Groups** that will reflect Facilities organizational structures. For example we might create a Facility Group for AMSURG, which would contain the various facilities that belong to it. In this instance, a facility could only belong to one facility group.

II. Managing User Access

- ASCA Application Administrator receives user access request from Designated Party (Not sure who this should be). Users may be Added, Removed and Suspended within the ASCA Application.
- 2. If request is to Add User
 - a. Request will include First and Last Name of user to be added, email address, which Surgical Center or Centers the user is to have access to, and what role they are to be assigned.
 - b. ASCA Application Administrator adds user to system.
 - c. ASCA Application generates email to new user with login credentials and links to online documentation.
- 3. If request is to Remove User
 - a. ASCA Application Administrator will access list of Registered Users.
 - b. ASCA Application Administrator will remove user.
 - c. User record will be retained within ASCA Application, but Removed User will no longer appear in the list of Registered Users.
- 4. If request is to Suspend User
 - a. ASCA Application Administrator will select the User from a list of Registered Users
 - b. ASCA Application Administrator will Suspend User.
 - c. User will still appear in the list of Registered Users, but user may no longer be authenticated with the ASCA Application. User may be "un-suspended" at any time.

End

Assumptions:

• Each Surgical Center or Surgical Center Group has at least one designated ASCA Application Administrator, who may be an employee of the Surgical Center or Physician's Office.

III. Forgotten Password

Users will have the ability to reset their passwords in the event of a forgotten password.

IV. Manage Study Data

ASCA Research Representatives will have ability to review records and make decisions about which records/assessments to include or exclude from the study (this may take form of some kind of custom reporting).

Example Assessment Measures

The following illustrates the types of measures we will capture throughout the process.

List of Assessments

Demographics	Captured when Patient record is first collected in ASCA Application, at the time the procedure is scheduled.	AgeGenderMorbid obesity
Pre-Op Baseline Assessment.	Captured when procedure is scheduled, or when received in Surgical Center.	Severity of painActivities of daily livingRange of motion
Discharge Assessment	Captured after procedure has been completed, and prior to Patient's being discharged from Surgical Center.	 Transfer to inpatient facility Death Acute myocardial infarction
Post-Discharge Assessments	Captured w/in first few days of discharge, and again during 30 day and 90 day follow up visits to the Physician's Office.	 Patient Satisfaction Measures Severity of pain Activities of daily living Range of motion Surgical site bleeding

Glossary

30 day and 90 day follow up visits - Follow up exams scheduled 30 days and 90 days after discharge for a procedure we are tracking. There will be assessments tied to each of these - potentially different assessments for each procedure we are tracking.

Administrators - Users responsible for business processes (Finance, Billing, etc.) at a management level.

ASCA Application - the application we are developing.

ASCA Application Administrator - User who is responsible for administrative functions within the ASCA Application (adding/removing users, changing passwords, etc.)

ASCA Research Representative - ASCA or KNG employee responsible for monitoring use of the system, especially in regards to ensuring that sufficient data is gathered to support the final study.

Assessment Email - Post-Discharge emails generated by the ASCA Application and sent to Patients.

Clinician - Surgical Center or Physician's Office employee responsible for clinical care of the patient.

Discharge Assessment - Data collected at time of Patient discharge from the Surgical Center.

Medical Record - Medical Record of the Patient. May refer to record maintained either at Surgical Center or Physician's Office. Outside of the scope of the ASCA Application.

Patient - Person who is having a procedure that we are tracking. A Patient is defined uniquely within the ASCA Application.

Patient Demographic - Information that identifies the patient.

Patient Observation Record - Information that is specific to the procedure that is being tracked. All of the assessments associated with a given procedure are assigned to the same observation.

Physician's Office Staff - Employee of the Physician's Office.

Post-Discharge Assessment - Information gathered after the Patient is discharged from the Surgical Center. There may be multiple Post-Discharge Assessments associated with a single observation.

Pre-Op Baseline Assessment - Information gathered before the Patient has the procedure. There will only be one Pre-Op Baseline Assessment for an observation.

Surgical Center - the facility where the procedure is done.

Surgical Center Staff - Employee of the Surgical Center.

User - User of the ASCA Application.