

Breast Interventions e-Consent

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As part of a Lean Six-Sigma Green belt course, a project was identified and approved to solve the problems and waste associated with paper consent forms

This quality improvement report describes the process and result of the e-consent project

Informed consent is a legal and ethical process during which a competent patient is informed about the risk and benefits of a procedure, and the patient gives permission to proceed without coercion

Paper consent forms are ubiquitous, however are associated with waste and have associated safety risks with potential medical-legal implications

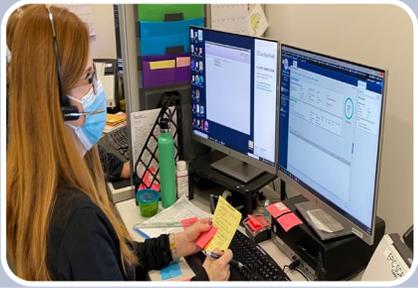
Background

- At a single academic institution, at least 2,438 paper consent forms were used in 2021 for pre-procedure consent in a breast imaging center with three separate locations
- Paper consent forms resulted in unnecessary cost and effort since e-consent forms are free and available in EPIC electronic medical records (EMR) institution-wide
- The current condition is a complex, multistep, multilocation, high-waste (waiting, transportation) process of utilizing paper consent forms that are transported to an outside location for scanning into EMR and then shredded for disposal

Types of waste are shown, all were identified during this project

D	• Defects
O	• Over production
W	• Waiting
N	• Non-utilized talent
T	• Transportation
I	• Inventory
M	• Motion
E	• Extra process

Current process.



Forms are ordered every 2 weeks and stored in file room



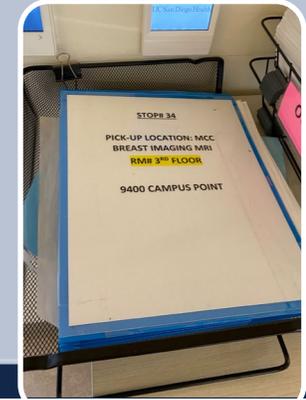
Packets are assembled and stored until procedure date



Nurse picks up packet and prepares for procedure



Consent form is used, handed from the nurse to the MD to the patient and back



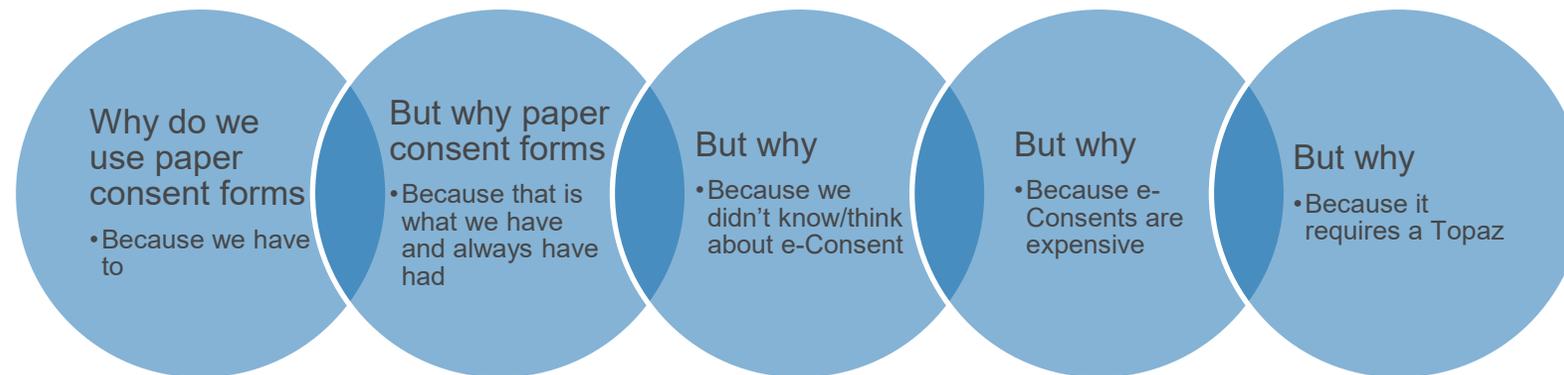
Consent form is taken to off site location for scanning in EMR and shredding

- Number of procedures performed in 2021: 2,438
- Cost/form: \$0.17, Annual cost \$414.46
- Cost per label \$0.01 x 2 labels/form, Annual cost \$48.76
- Coordinators, nurse, courier, shredding and disposal of consent and “time-out”
- Total: \$463.22 + personnel costs, Intangibles: environmental effect

Problem statement: At least 2,438 paper consent forms were used in 2021, which results in unnecessary cost and effort since e-consent forms are free.

Methods

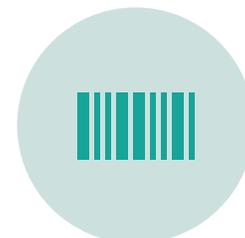
- A gap analysis was performed as part of a lean sigma six green belt project to identify the root cause and guide improvement
- We performed a “5 Whys” and completed a fishbone diagram. Why is there a problem (use of paper consent forms)?: Not aware that EPIC has a solution and that we could do e-Consents.



Target condition identified:

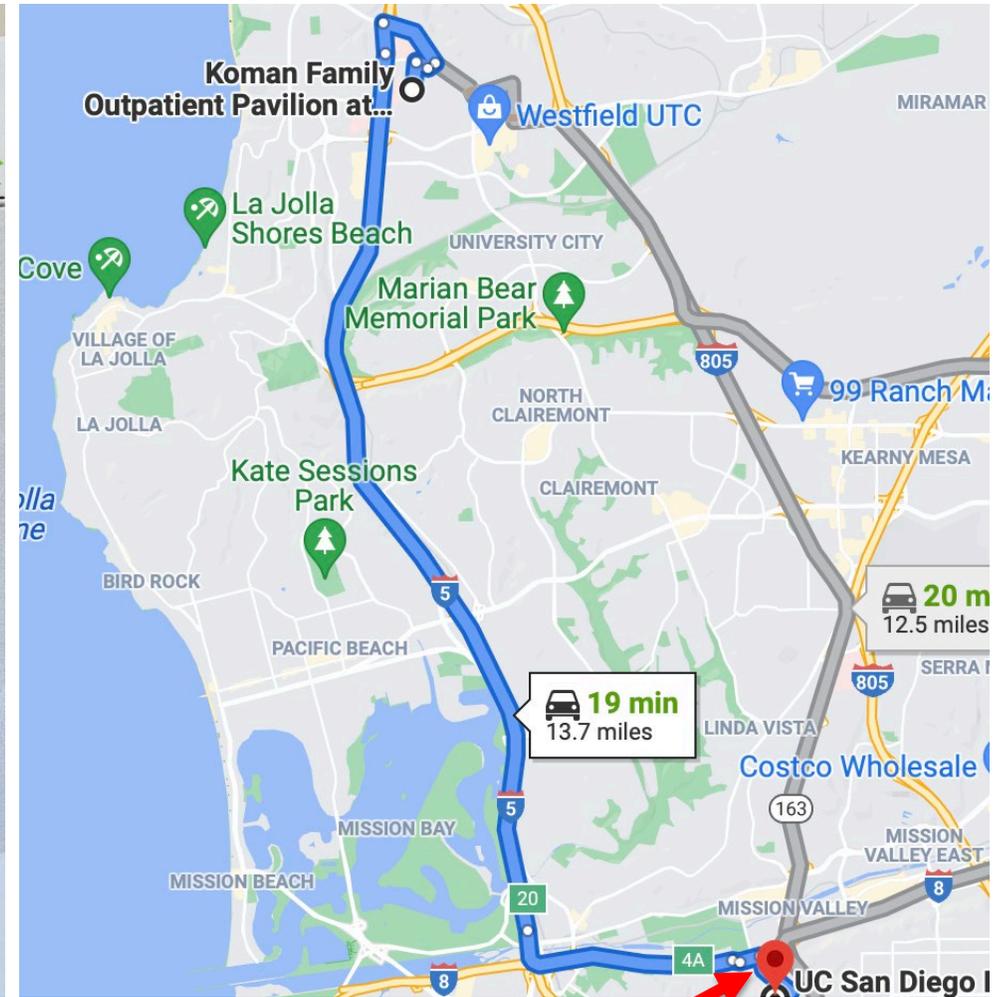
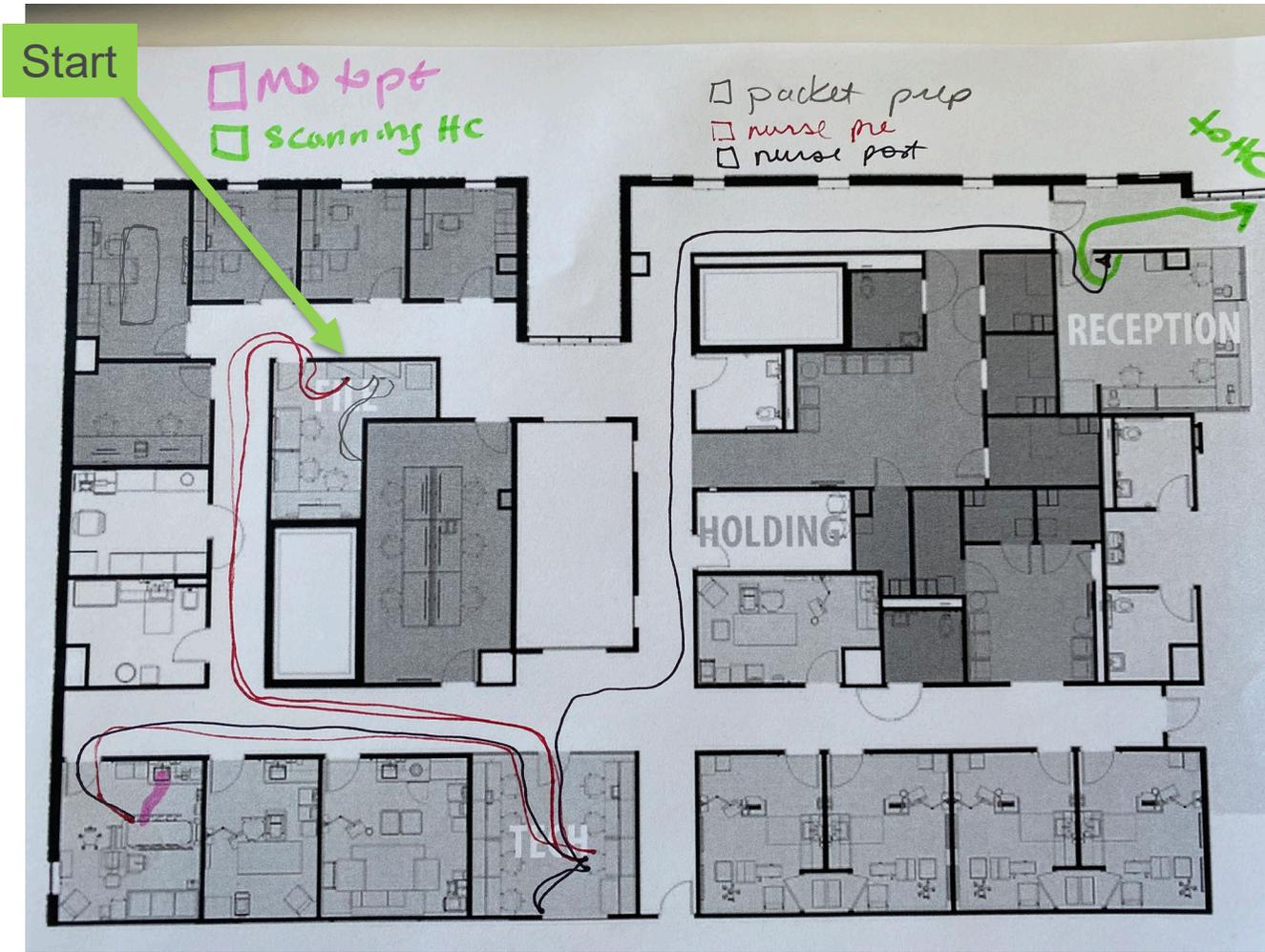


ZERO PAPER



ZERO SCANS

Minor procedure paper consent form- Spaghetti Diagram*

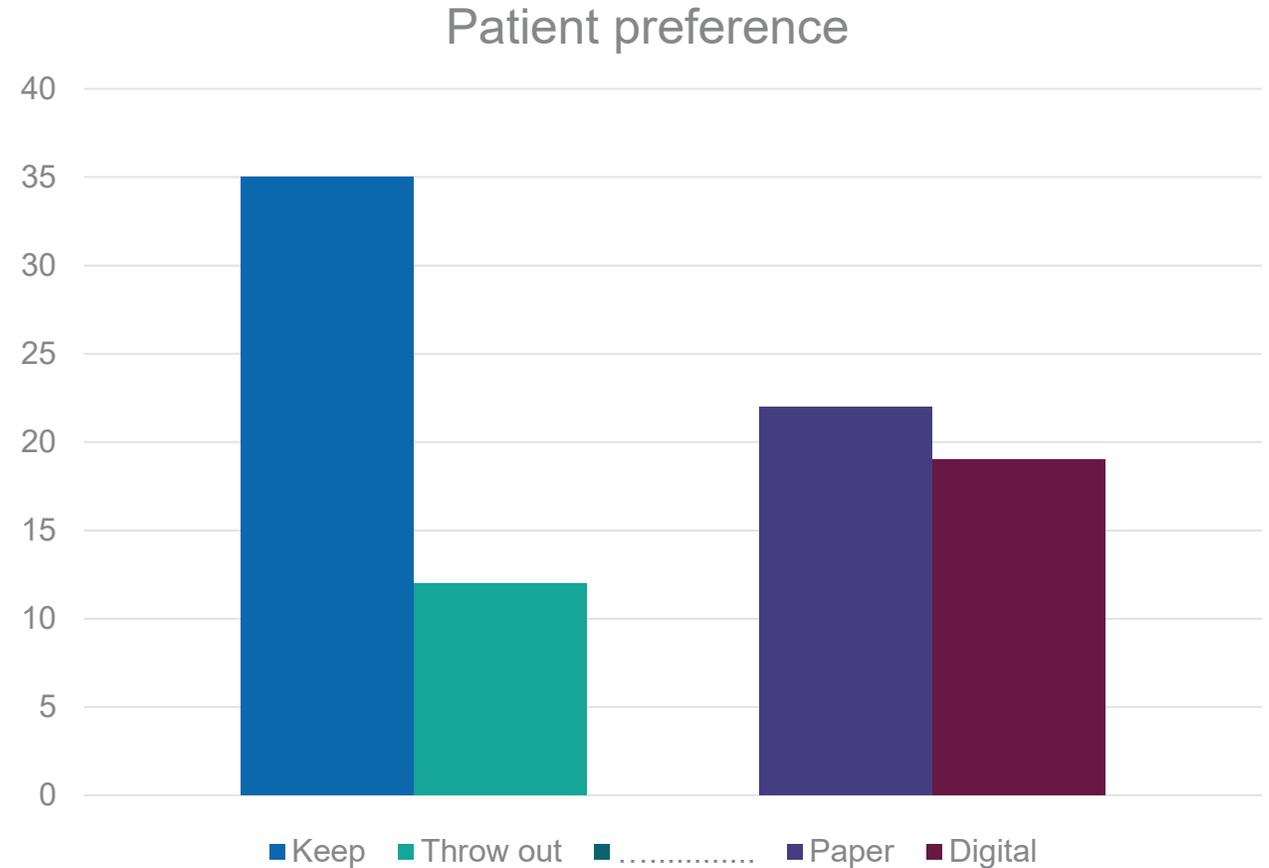


*Lean tool to help eliminate or decrease waste
Visual representation of flow

Finish

Voice of Customer- proactive source

- Informal survey of procedure patients during a one-week period
- Asked the following questions:
 - What do you do with the consent form (keep or throw out)
 - Do you prefer paper or electronic copy



Countermeasures proposed

- Using e- Consent and documenting brief procedure notes in Epic. Purchase of Topaz for ease of obtaining the patient's signature. No further purchasing of duplicate paper consent forms or paper progress notes. Not involving six team members to achieve one task and removing the courier service, shredding service, scanning, storage of paper forms. Investing in training in the use of e- Consent and Epic documenting. Creation of “standard work” documents for e- Consent and EPIC progress notes.
- The plan included: visiting divisions that were currently using e-Consent. Meet with information technology representative specializing in EPIC to learn how to use e-Consent and to make sure it is available to breast radiologists. Purchase and set up of Topaz. Made sure all radiologists were trained on e-Consent EPIC. Additional training of technologists and RNs in creating and bringing up e-Consent. Discussion with risk management to confirm the process for signature. Creation of template for brief procedure note in EPIC. Coordinate with EPIC topaz.

A3 Problem-Solving Report

Title: Breast Interventions e-Consent
 Owner: H. Ojeda-Fournier
 Team Members: Joe Savoi, Susana Carmona, Irina Kalyan, Fabiola Vazquez, Becca Wokuluk

Date/Revision(s): 1/14/2022
 Location: Breast Imaging Division, Department of Radiology

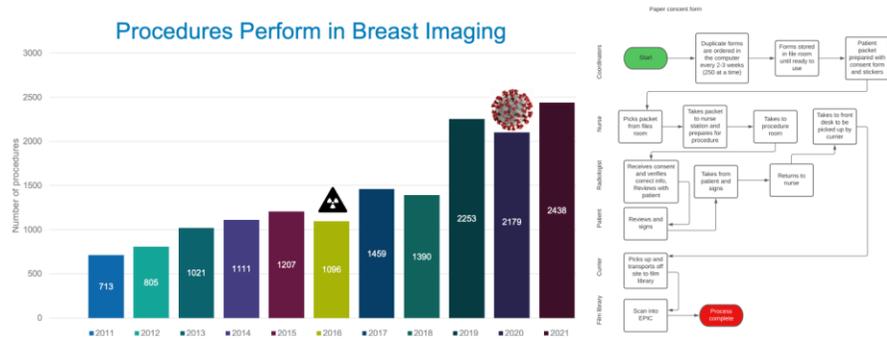
A3 problem solving reports

1. Problem Statement:

At least 2,438 paper consent forms were used in 2021, which results in unnecessary cost and effort since e-consent forms are free.

2. Current Condition:

Complex, multistep, multilocation, high-waste process (waiting, transportation) process of creating paper consent forms which then have to be transported to outside location for scanning into EPIC and shredding.

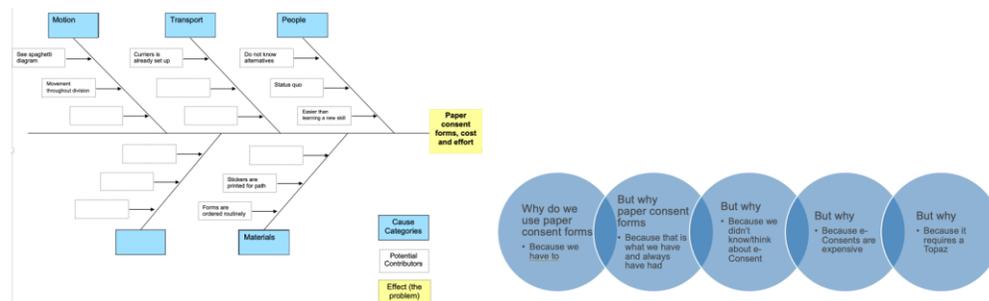


3. Target Condition:

Zero paper. Zero scan. (SMART goal: It is Specific (paper to no paper). It can be Measured (thousands of consent forms and scans → zero). It is Attainable (infrastructure is in place: EPIC e-Consent). It is Relevant (we perform at least 10 procedures every day). It is Time bound (March 15 go live to achieve the target condition).

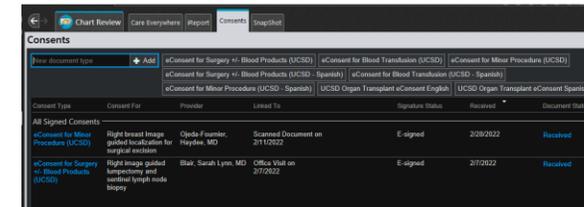
4. Gap Analysis:

To identify the root cause, we performed a "5 Whys" and completed a fishbone diagram. Why is there a problem (use of paper consent forms): Not aware that EPIC has a solution and that we could do e-Consent.



5. Countermeasures Proposed:

- Propose using e-Consent and documenting brief procedure note in Epic.
- Required to change from paper brief procedure note to EPIC note to truly be paperless
- Purchase of Topaz for ease of obtaining patient signature
- No further purchasing of duplicate paper consent forms or paper progress note. No involving 6 team members to achieve one task. Removing the courier service, shredding service, scanning, storage of paper forms.
- Investing in training in the use of e-Consent and Epic documenting.
- Creation of "standard work" documents for e-Consent and for EPIC progress note.



6. Plan:

- Evaluate resources, visit sites that are using e-Consent (HO, Julie)
- Meet with EPIC to learn how to use e-Consent and to make sure is available to breast radiologists (HO, IK, SC)
- Purchase and set up Topaz (SC, RW)
- Making sure all radiologists are trained on e-Consent EPIC, demonstrate how to, observed other radiologist doing procedure, create standard work (HO, ME, RRP, WL, VL)
- Training of technologists and RN in creating and bringing up e-Consent (Julie and Fabi)
- Risk management to confirm process for signature
- Test run: February 28, 2022 (HO and Julie)
- Creation of template for brief procedure note in EPIC
- Coordinate with EPIC topaz install March 5, 2022 (HO, RW)
- Go-live date March 15, 2022 (HO) (it actually happened one week earlier!)

7. Results (Check) Next steps (Act):

- Safely changed to e-Consents
- Cost of Topaz signature pad: \$1,000/unit
- Culture changed rather quickly as the radiologist saw the value once the swim lane diagram was presented to them
- The target condition was achieved for all three locations that perform procedures
- No longer ordering paper consent forms or assembling packages for biopsy

Next steps:

- Audit to make sure that consent forms are being signed
- Follow up with IR regarding best practice and lessons learned
- Alternative to Topaz: tablet for e-Consent, also looking into doing consent on iPhone

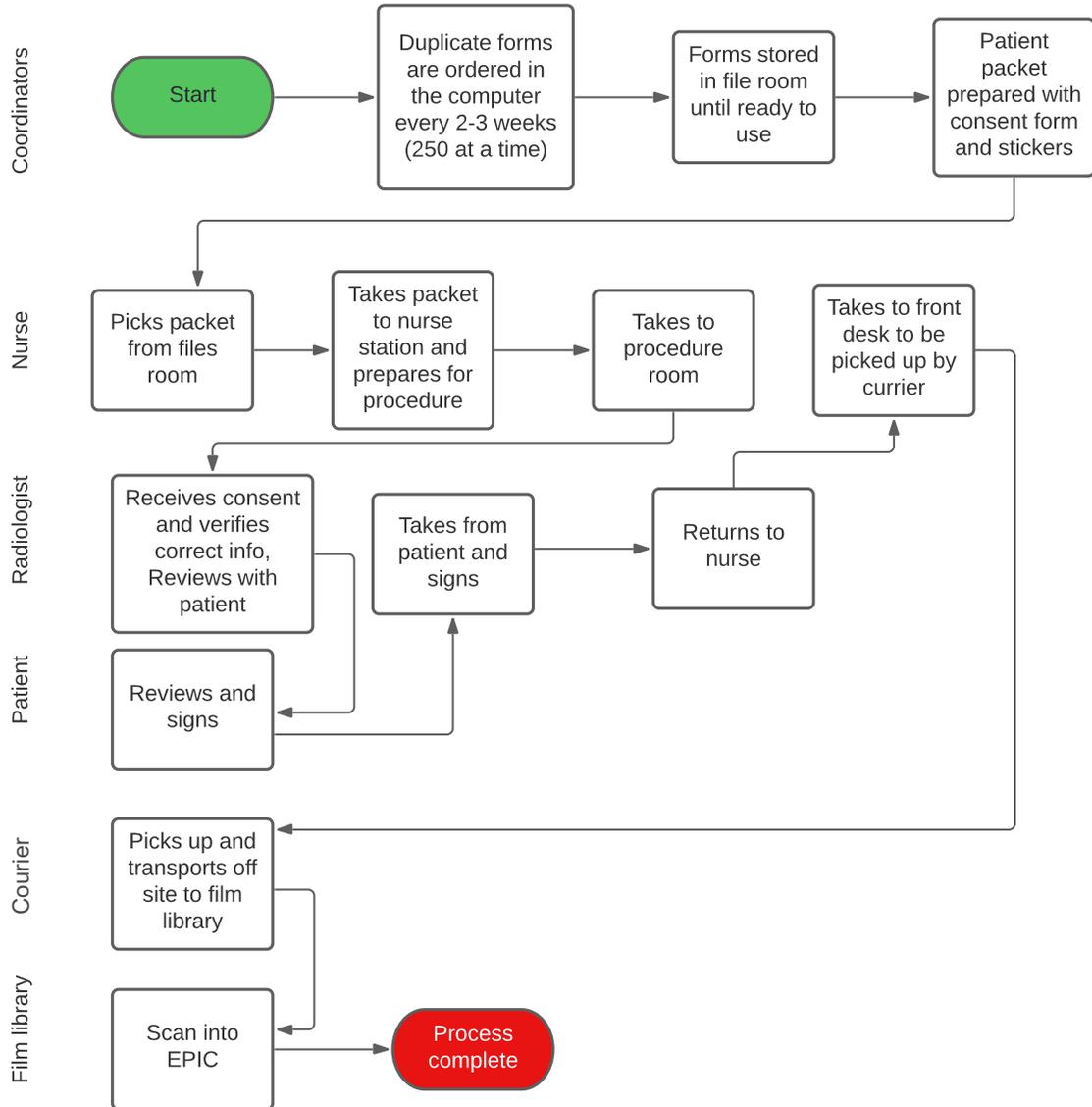


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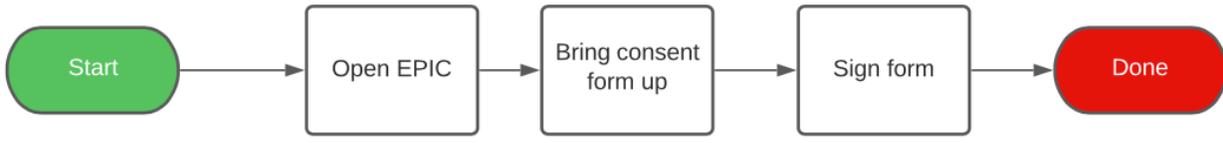


ZERO SCANS

Before (using paper consent forms)



After (implementation of e-Consent)



Swim lane diagram

- Shows process from start to finish and who is responsible for each step of process

Results

- Safely changed to e-Consents. Cost of Topaz signature pad \$1,000/unit. Culture changed rather quickly as the radiologist saw the value once a completed swim lane and spaghetti diagram were presented to them. The target condition was achieved. No longer ordering paper consent forms or assembling packages for biopsy. No longer utilizing courier service.

Discussion

- Breast imaging centers at institutions that utilize EPIC EMR can leverage the e-Consent features to reduce waste and streamline operations. Future steps include an audit to ensure that consent forms are being signed. Also, convening with other procedural divisions in radiology to share best practices and lessons learned and considering an alternative to Topaz signature capture device: tablet for e-Consent or utilizing iPhone to capture signatures.