

August 11, 2016

TOM HAMELIN  
Senior Director, SAMNIS  
7756

**Subject:        *Surgical & Perioperative Services (Epic OpTime)  
Report 2016-15***

The final report for Surgical & Perioperative Services (Epic OpTime) Report 2016-15, is attached. An earlier version of this final report was previously sent on August 3, however several pages were inadvertently omitted. The complete final report is attached to this letter.

We would like to thank all members of the department for their cooperation and assistance during the review.

Because we were able to reach agreement regarding management action plans in response to the audit recommendations, a formal response to the report is not requested. The findings included in this report will be added to our follow-up system. We will contact you at the appropriate time to evaluate the status of the management action plans.

UC wide policy requires that all draft reports be destroyed after the final report is issued. We also request that draft reports not be photocopied or otherwise redistributed.

David Meier  
Director  
Audit & Management Advisory Services

Attachment

cc:	Margarita Baggett	Patty Maysent
	David Brenner	Roman Martinez
	Judith Bruner	Pierre Ouillet
	Lori Donaldson	Cheryl Ross
	Brendan Kremer	Blake Stock
	Andrew Lamb	Madelyn Uy
	Christopher Longhurst	Sheryl Vacca

August 2, 2016

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***Report 2016-15***

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# UC San Diego

## AUDIT & MANAGEMENT ADVISORY SERVICES

Surgical & Perioperative Services (Epic OpTime)  
Report No. 2016-15  
August 2016

**Performed By:**

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**Approved By:**

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ATTACHMENT A – Summary of Preference Cards to Actual Usage

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## I. EXECUTIVE SUMMARY

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Audit & Management Advisory Services (AMAS) has completed a review of Surgical & Perioperative Services (Epic OpTime) as part of the approved audit plan for Fiscal Year 2015-16. The objective of our review was to evaluate whether use of the OpTime system within Surgery Operating Rooms (ORs), in conjunction with manual procedures, supported effective operations, complete documentation, and accurate charges.

We concluded that controls provided reasonable assurance that the use of OpTime and other manual procedures were adequate to ensure effective operations, complete documentation, and accuracy of charges. Management is continuously developing methods of monitoring and managing operations and this process appeared to provide the necessary analytics to ensure effective use of resources.

In evaluating a sample of OR cases, we determined that there was some inconsistency in charging certain supply items and improvement was needed to ensure that routine supply costs, specifically gowns and gloves, were not billed to the patient. It also appeared that preference cards were outdated in some cases. The sample of cases we reviewed had variances in the preference cards to actual items and quantities. We also determined each OR site may benefit from evaluating current case picking processes to identify enhancements and opportunities for standardization. Also, the implementation of the Epic Tissue Tracker integration is necessary to replace the current documentation paper processes and maintain accreditation. Management Action Plans to address these findings are summarized below:

### A. Charging for Routine Costs

SAMNIS management will:

1. Consult with Revenue Integrity to further define and identify routine supply costs that may be separately identified.
2. Perform data analysis on routine costs that have been billed and adjust or reimburse accounts for these costs.
3. Continue to work with the Aperek Interface Team and Information Services to develop a rule or other process within Aperek, OpTime or Epic Enterprise to prevent routine costs from being billed.

### B. Preference Card Accuracy

SAMNIS management will:

1. Ensure that the most frequently utilized preference cards and procedure codes are evaluated for accuracy.
2. Develop data analytics to assist with evaluation to ensure that preference cards are necessary, available, accurate, and maintained.
3. Evaluate options for providing additional resources and/or implementing improved processes to ensure that preference cards are adequately maintained by responsible staff.
4. Work with surgeons, schedulers, and/or other surgical staff to develop a process to ensure that planned procedure card variances are communicated to case pickers and surgical staff to ensure that items are not wasted due these variances.

**C. Process Improvements for Picking Cases**

SAMNIS management will evaluate current case picking processes at all locations to reduce inefficiencies, standardize processes to the extent possible, implement best practices, and continue to refine and/or automate processes with future system enhancements. Consideration should also be performed on whether OpTime access and printing capability would be beneficial for the Thornton case pickers to provide efficient notification of case and/or schedule changes.

**D. Tissue Tracking**

SAMNIS management has been working with Epic Team to implement a tissue tracking integration, TrackCore Implant Interface, which will contain the controls to ensure required tissue tracking documentation is performed.

Observations and related management actions are described in greater detail in section V. of this report.

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## II. BACKGROUND

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Audit & Management Advisory Services (AMAS) has completed a review of Surgical & Perioperative Services (Epic OpTime) as part of the approved audit plan for Fiscal Year 2015-16. This report summarizes the results of our review.

Surgical & Perioperative Services, within Surgery, Anesthesiology, Musculoskeletal, Neurology, and Imaging Services (SAMNIS), provides services for Anesthesia Monitoring, Interventional Neurophysiology, Operating Rooms, Post-Anesthesia Care Unit (PACU), the Shiley Eye Center, and Sterile Processing Department (SPD) & Central Service. The focus of our review was primarily activity related to the Operating Rooms (ORs).

In November 2013, the UC San Diego Health (UCSDH) implemented the Epic OpTime system (OpTime) to replace the Operating Room Scheduling Office System (ORSOS) as the OR management system. OpTime is used primarily for surgery scheduling, preference card management, and perioperative documentation. UCSDH is dedicated to delivering the highest quality, safest care for every patient, every time, in a five-star environment. Currently, there are over 2,000 cases performed in the ORs each month.

In order to ensure that the proper instruments and supplies are on hand for OR surgeries, the system automatically selects a preference card based on the Current Procedural Terminology (CPT®) code for the procedure scheduled. The preference card may be modified by the physician or scheduler for a better fit of instrument and supplies needed for each individual case. In the OpTime system each preference card is associated with a CPT code, and surgeons may have customized preference cards to suit their individual needs. At the time of our review 6,586 preference cards were in use.

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## III. AUDIT OBJECTIVE, SCOPE, AND PROCEDURES

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The objective of our review was to evaluate whether use of the OpTime system within Surgery ORs, in conjunction with manual procedures, supported effective operations, complete documentation, and accurate charges. In order to achieve our objective, we performed the following:

- Reviewed relevant UC and UCSD policies and federal regulations;
- Reviewed prior AMAS audit report 2011-15 *Major Supply Inventory Management – Operating Rooms*;
- Reviewed Epic OR100 OpTime Fundamentals manual;
- Interviewed:
  - SAMNIS key administrators, surgical staff, scheduling, billing, buying, and information systems
  - Clinical Systems Manager, Information Systems;
- Observed the picking of instruments and supplies for cases at the Thornton and Hillcrest main ORs;
- Analyzed OpTime preference card data and maintenance;
- Evaluated the accuracy of preference cards based on a sample of actual cases; and
- Evaluated supply usage to billing on a sample of actual cases.

### Sample Selection

As part of our testing, we judgmentally selected 15 cases from the OR schedule between April 4, 2016 and May 12, 2016. Cases were selected across the Hillcrest (HC) and Thornton (TH) Main OR sites with the intention of obtaining a broad mix of complexity of cases, dates, times, surgeons, and services.

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## **IV. CONCLUSION**

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Based on our review, we concluded that controls provided reasonable assurance that the use of OpTime and other manual procedures were adequate to ensure effective operations, complete documentation, and accuracy of charges. SAMNIS management is continuously developing methods of monitoring and managing operations, and this process appeared to provide the necessary analytics to ensure effective use of resources.

In evaluating a sample of OR cases, we determined that there was some inconsistency in charging certain supply items and determined improvement was needed to ensure that routine supply costs, specifically gowns and gloves, were not billed to the patient. We determined that some routine costs, specifically gowns and gloves, were charged on 11 out of the 15 cases we reviewed, for a total of 19 items or \$226. Although the dollar value impact is low, the billing of routine costs is unallowable per the *Centers for Medicare and Medicaid Services (CMS) Provider Reimbursement Manual, Part 1, Chapter 22, Section 2202.6*.

We performed some data analytics on the complete OpTime preference card and base procedure card population of 6,586 cards, and determined 4,882 (74%) had not been utilized in the past three months, indicating that there may be outdated preference cards that should be inactivated. Also, 1,216 (19%) of the total preference card population had not been updated in over 180 days. We also identified a significant variance in the range of costs for the most used cards across multiple surgeons which may be an indication of the need to perform maintenance on these related preference cards.

Through our review of preference cards to actual case usage, we determined that all of the cases had variances in the preference cards to actual items and quantities. As a result, the experience and processes of the surgical staff dictate whether additional supply costs are incurred and whether additional supply items and/or quantities are on hand during the case. The additional supply costs associated with one case tested represented \$305 or 50% of the total case supply cost.

We also determined each site may benefit from evaluating current case picking processes to identify enhancements and opportunities for standardization. Also, the implementation of the Epic Tissue Tracker integration is necessary to replace the current documentation paper processes and maintain accreditation.

Additional information on these observations is provided in the balance of the report.



## V. OBSERVATIONS REQUIRING MANAGEMENT ACTION

<b>A.</b>	<b>Charging for Routine Costs</b>
Gowns and gloves, representing unallowable routine costs, were charged on 11 out of 15 cases tested for a total of 19 items or \$226.	
<b>Risk Statement/Effect</b>	
Separately billing routine supply costs may not be compliant with <i>CMS Provider Reimbursement Manual, Part 1, Chapter 22, Section 2202.6</i> and may be subject to False Claims Act (31 U.S.C. 3729(b)) provisions and penalties.	
<b>Management Action Plans</b>	
A.1	SAMNIS management will consult with Revenue Integrity to further define and identify routine supply costs that may be separately identified.
A.2	SAMNIS management will perform data analysis on routine costs that have been billed and adjust or reimburse accounts for these costs.
A.3	SAMNIS management will continue to work with the Aperek Interface Team and Information Services to develop a rule or other process within Aperek, OpTime or Epic Enterprise to prevent routine costs from being billed.

### A. Charging for Routine Costs – Detailed Discussion

Routine supplies are items used during the normal course of treatment, which are directly related to and/or integral to the performance of separately payable therapy, treatments, procedures, or services. These supplies are normally found in the floor stock, which are generally used for all patients in that specific area/or location. Examples of routine supplies include towels, gowns, gloves, lap sponges, scalpels/blades, and blankets.

Non-routine supplies are also known as ancillary supplies. These are those medical/surgical items that due to their therapeutic or diagnostic characteristics are essential to patient care. Non-routine supplies are separately billable supplies. To be billed as a non-routine supply, the item must be:

- Directly identifiable to a specific patient;
- Furnished at the direction of a physician because of a specific medical need (excluding gowns, gloves, drapes etc.) and must be documented in the patient's medical record; and
- Either non-reusable or represent a cost for each preparation.<sup>1</sup>

As part of our testing of 15 Surgery cases, we evaluated whether supplies indicated on the preference card were used and charged to the patient. We determined that gowns and gloves were charged on 11 out of the 15 cases we testing for a total of 19 items or \$226. We noted that SAMNIS had made some

<sup>1</sup> Nave, Shelley. (2011, December). Hospital Supplies – To Bill or Not to Bill? *Coding & Compliance Focus News*, 3. Retrieved from <http://medassets.com>.

efforts to write rules within OpTime to prevent the billing of these routine supply costs, however these efforts have not been successful to date in ensuring that these costs do not continue to bill when adjustments are made to the supplies based on an interface with Aperek, UCSD's inventory management and purchasing system. AMAS did not evaluate all supplies to determine if additional items meet the definition of routine supplies. Further review should be conducted to ensure that routine supplies are not charged as these charges may not be compliant with *CMS Provider Reimbursement Manual, Part 1, Chapter 22, Section 2202.6* and may be subject to *False Claims Act (31 U.S.C. 3729(b))* provisions and penalties.

<b>B.</b>	<b>Preference Card Accuracy</b>
Preference cards were not adequately maintained and/or inactivated, based on the results of data analytics and evaluation of a sample of actual case supply usage to preference card supplies.	
<b>Risk Statement/Effect</b>	
Outdated preference cards may reduce efficiencies in case picking, performance, and restocking and may increase case costs; the potential for delay; and/or patient's risk of infection.	
<b>Management Action Plans</b>	
B.1	SAMNIS management will ensure that the most frequently utilized preference cards and procedure codes are evaluated for accuracy.
B.2	SAMNIS management will develop data analytics to assist with evaluation to ensure that preference cards are necessary, available, accurate, and maintained.
B.3	SAMNIS management will evaluate options for providing additional resources and/or implementing improved processes to ensure that preference cards are adequately maintained by responsible staff.
B.4	SAMNIS management will work with surgeons, schedulers, and/or other surgical staff to develop a process to ensure that planned procedure card variances are communicated to case pickers and surgical staff to ensure that items are not wasted due these variances.

### **B. Preference Card Accuracy – Detailed Discussion**

The preference card specifies the surgical supplies that are anticipated to be used for a particular case, including the supply ID, name, type, catalogue number, the quantity to be opened during the case (open), the quantity to be available (prn), and latex indicator.

#### Data Analysis of Preference Cards

AMAS received a file containing all preference cards for the OpTime system from Surgery. We performed data analytics and determined that of the 6,586 cards evaluated, 4,882 (74%) had not been used in the last three months. Therefore, it appears that preference cards may need to be updated to ensure that only necessary cards are available for selection. This also promotes efficiency in maintaining preference cards, as only active cards would need to be maintained.

We also analyzed the preference card file to determine length of time since the card was edited. Based on this review, approximately 19% of were not updated in the past six months.

Days Since Last Edit	Cards	Percentage
0 to 30	532	8%
31 to 90	4,646	71%
91 to 180	192	3%
181 to 360	637	10%
361+	579	9%
	6,586	

We also evaluated supply costs of preference cards by procedure codes where there are greater than 25 procedure codes (927 preference cards met this criteria across 24 procedures). More than one preference card means that more than one surgeon is performing that procedure code using a customized preference card. The Minimum Cost contains the supply cost specified as needed (open) on the preference card for the case. The Total Cost includes all supply costs (open and prn) that are anticipated as potentially used for a case. We noted significant variation in the range of Minimum and Total Costs for these preference cards.

PROCEDURE CODE	COUNT OF PREFERENCE CARDS	LOWEST MINIMUM COST	HIGHEST MINIMUM COST	RANGE MINIMUM COST <sup>2</sup>	RANGE MINIMUM COST % <sup>3</sup>	LOWEST TOTAL COST	HIGHEST TOTAL COST	RANGE TOTAL COST <sup>4</sup>	RANGE TOTAL COST % <sup>5</sup>
1004950500	28	\$ 64.13	\$ 147.32	\$ 83.19	130%	223.38	\$ 2,394.69	\$ 2,171.31	972%
1006006122	55	\$ 32.70	\$ 158.84	\$ 126.14	386%	96.75	\$ 844.63	\$ 747.88	773%
200002150111	36	\$ 75.23	\$ 207.35	\$ 132.12	176%	92.01	\$ 4,043.03	\$ 3,951.02	4294%
2101511	40	\$ 61.91	\$ 99.24	\$ 37.33	60%	95.24	\$ 621.97	\$ 526.73	553%
229922	38	\$ 32.18	\$ 121.55	\$ 89.37	278%	33.1	\$ 540.35	\$ 507.25	1532%
239302502833	34	\$ 69.36	\$ 123.64	\$ 54.28	78%	156.36	\$ 890.95	\$ 734.59	470%
2393033	33	\$ 77.32	\$ 181.42	\$ 104.10	135%	96.13	\$ 620.76	\$ 524.63	546%
26992	31	\$ 70.65	\$ 100.92	\$ 30.27	43%	109.96	\$ 806.32	\$ 696.36	633%
2731012760344	51	\$ 57.67	\$ 119.22	\$ 61.55	107%	104.14	\$ 1,373.19	\$ 1,269.05	1219%
27600607	36	\$ 29.03	\$ 256.24	\$ 227.21	783%	35.42	\$ 5,179.10	\$ 5,143.68	14522%
3161000	40	\$ 79.72	\$ 481.58	\$ 401.86	504%	152.45	\$ 690.16	\$ 537.71	353%
4414000	28	\$ 157.40	\$ 886.38	\$ 728.98	463%	1004.03	\$ 3,732.50	\$ 2,728.47	272%
47560579	32	\$ 225.89	\$ 496.76	\$ 270.87	120%	687.59	\$ 4,337.46	\$ 3,649.87	531%
49000000	84	\$ 33.20	\$ 776.01	\$ 742.81	2237%	214	\$ 4,635.45	\$ 4,421.45	2066%
4932000	74	\$ 95.23	\$ 505.31	\$ 410.08	431%	135.38	\$ 5,953.13	\$ 5,817.75	4297%
49520525	37	\$ 52.24	\$ 147.32	\$ 95.08	182%	101.99	\$ 2,394.69	\$ 2,292.70	2248%
49560566	28	\$ 84.42	\$ 2,079.56	\$ 1,995.14	2363%	136.43	\$ 3,282.36	\$ 3,145.93	2306%

<sup>2</sup> Range Minimum Cost = Highest Minimum Cost – Lowest Minimum Cost

<sup>3</sup> Range Minimum Cost % = Range Minimum Cost/Lowest Minimum Cost

<sup>4</sup> Range Total Cost = Highest Total Cost – Lowest Total Cost

<sup>5</sup> Range Total Cost % = Range Total Cost/Lowest Total Cost

PROCEDURE CODE	COUNT OF PREFERENCE CARDS	LOWEST MINIMUM COST	HIGHEST MINIMUM COST	RANGE MINIMUM COST <sup>2</sup>	RANGE MINIMUM COST % <sup>3</sup>	LOWEST TOTAL COST	HIGHEST TOTAL COST	RANGE TOTAL COST <sup>4</sup>	RANGE TOTAL COST % <sup>5</sup>
49580587	29	\$ 79.03	\$ 282.12	\$ 203.09	257%	114.32	\$ 1,535.24	\$ 1,420.92	1243%
5200010	29	\$ 15.51	\$ 93.02	\$ 77.51	500%	16.18	\$ 196.18	\$ 180.00	1112%
5741000	26	\$ 90.67	\$ 147.62	\$ 56.95	63%	91.93	\$ 161.07	\$ 69.14	75%
58555563	26	\$ 89.57	\$ 1,111.07	\$ 1,021.50	1140%	1541.87	\$ 4,522.94	\$ 2,981.07	193%
5866100	42	\$ 88.88	\$ 988.97	\$ 900.09	1013%	129.03	\$ 3,241.62	\$ 3,112.59	2412%
5872000	28	\$ 133.52	\$ 875.61	\$ 742.09	556%	156.47	\$ 1,461.87	\$ 1,305.40	834%
59812841	42	\$ 97.80	\$ 143.75	\$ 45.95	47%	100.57	\$ 149.31	\$ 48.74	48%

We were advised that all preference cards from the prior information system were imported into OpTime upon implementation of the system. With the exception of global updates, SAMNIS operational procedures exclude updating preference cards that have not been used in the past two years. Therefore, the legacy data may impact the number of inactive preference cards and reflect outdated pricing. There also may be reasonable differences (e.g. complexity of cases for an individual physician, etc.) between the range of Minimum and range of Total preference card supply costs for procedure codes across surgeons. However, this may also indicate that these preference cards should be updated to ensure accuracy of these preference cards.

#### Preference Card to Actual Supplies

As part of our testing of 15 Surgery cases, we evaluated the supplies indicated on the preference card to the actual supplies used and wasted. A table of the actual cases selected for review and results is provided in **Attachment A**. In analyzing cases, we considered whether:

- Supply item quantities specified as open were used and/or wasted (**Column A**),
- The quantities used of a supply item exceeded the combined total of open and prn (**Column B**),
- Additional supply items were used and not indicated on the preference card as prn (**Columns C and D**),
- Supply items were being used based on the preference card or added as additional supply items (**Column E**), and
- It appeared that the preference card was adequately maintained based on the above criteria.

In all of the cases tested (100%), we identified variances in preferences cards to actual usage, which could result in:

- Picking supplies for cases and loading the supply cart with unneeded items, reducing efficiency;
- Supply items being opened that are not needed, increasing the case cost (since only unused, unopened items can be restocked); and
- Additional movement within and into and out of the surgical suite by not having supply items or quantities on hand, potential increasing delay and the patient's risk of infection by airborne contamination.

Some variances in preference card supplies to usage were explained by anticipated variances in the planned procedure versus the preference card selected (**Attachment A, Column F**). For example, we selected a case for an open revision of gastric band port, upper endoscopy. However, the preference

card used was a placement gastric banding laparoscopic. We were advised that there was not a more accurate preference card available. We did not identify any comments on the case that would have let the surgical staff know that all items specified as open on the preference card should not have been opened. However, based on the process or the experience of the surgical staff, the items marked as open on the preference card were not opened unless used. We determined based on the surgical receipt that the items that were indicated as open on the preference card, but were not opened, represented \$305 in cost and would have represented an additional 50% of total cost to the case.

We also evaluated a sinus surgery endoscopic bilateral case. We were advised that this service utilizes a limited number of preference cards and, therefore, should have variances among the cases for items utilized. We determined based on the surgical receipt that the items that were indicated as open on the preference card, but were not opened, represented an additional \$23 or 20% of the total cost to the case. We also evaluated an arthroplasty right total hip- right case for open item variances and determined that the surgical receipt did not contain the cost of all items that were not used. Therefore, we were unable to evaluate the preference card cost of items that were not opened would have represented.

Management has been proactive and has developed innovative techniques to evaluate and manage case costs. An example of this innovation includes the generation and distribution of a surgical receipt within days of a case being performed. The surgical receipt provides information to the surgeon on the time associated with the case and the cost and quantities of case supply items. These receipts may be used by surgeons to evaluate the case cost and discuss case supply items and practices with surgical staff.

Responsibility for maintaining preference cards has recently shifted from one individual to collectively among surgical staff. SAMNIS management has been working to set aside time for surgical staff to perform maintenance on preference cards. However, additional focus is still required to ensure preference cards are updated and accurate. Additional suggestions may be to:

- Further refine the surgical receipt or develop an additional report to evaluate preference cards to actual cases;
- Include evaluation of preference card supply items in the case audits being performed in the charge area; and
- Develop additional analytics to evaluate the maintenance and accuracy of preference cards.

C.	Process Improvements for Picking Cases
	The “picking” of supplies and instruments for cases was a very manual process dependent on the quality of the preference cards, experience of the case picker (picker), and varied in practice between OR location and individuals, and could be further standardized and refined to optimize efficiencies.
	<b>Risk Statement/Effect</b>
	Variations in the experience and practices of pickers and preference cards directly effects the quality in the availability of supplies and the efficiency of the process. Therefore, highly experienced pickers and accurate preference cards are required. Inefficient processes increases the potential that the complete case will not be picked, additional resources will be required, and/or delay may occur.

### Management Action Plan

C.1	SAMNIS management will evaluate current case picking processes at all locations to reduce inefficiencies, standardize processes to the extent possible, implement best practices, and continue to refine and/or automate processes with future system enhancements. Consideration should also be performed on whether OpTime access and printing capability would be beneficial for the Thornton case pickers to provide efficient notification of case and/or schedule changes.
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### C. Process Improvements for Picking Cases – Detailed Discussion

We observed the picking of cases at the Thornton and Hillcrest main ORs. Pickers relied on the OR front desk to communicate with them regarding changes to cases or the schedule, and provide them with the schedule and the Supply PickLists. The Supply PickLists are case specific, providing notes called “special needs.” The Supply PickList contains similar information to the preference card, and combines preference card information if more than one preference card is associated with the case. At times, preference cards are also evaluated by pickers to modify the Supply PickList based on the procedure being performed. We found the pickers to be very diligent in their work and utilized their knowledge of the cases and surgeons to tailor the items on the Supply PickList to the needs of the case. We identified that improvements in the accuracy of preferences cards could minimize these modifications and potential variance by individual pickers.

We made the following observations:

- The process for picking is very manual. The Supply PickLists are manually annotated based on the supplies picked;
- There may be variations in the supply items that are picked based on the picker. For example, a picker may have a different level of experience with the case/surgeon/restocks and make modifications to the items picked based on this experience; and
- There is variation in the method of documenting what has been picked based on the individual at the Hillcrest site.

We also observed that the Thornton site uses a comprehensive process of documenting the case cart number, and missing items on multiple forms (wall schedule, handoff schedule, Supply PickList, and Case Cart Quality Assurance Form). The Hillcrest site utilizes only a wall schedule and Supply PickList, and does not identify the case cart or cart location. We determined additional efficiencies may be realized by evaluating processes at both sites:

- Eliminating unnecessary documents and/or forms;
- Considering design of the location;
- Considering providing picker access to OpTime to review and/or print the schedule and evaluate preference card supplies;
- Maintaining preference cards to reflect actual usage;
- Standardizing processes among personnel and possibly sites;
- Implementing best practices; and
- Continuing to refine and/or automate processes as further system enhancements are available.

<b>D.</b>	<b>Tissue Tracking</b>
The OpTime system did not have controls in place to ensure required tissue tracking documentation was obtained and the chain of custody was maintained, therefore manual paper-based processes were required.	
<b>Risk Statement/Effect</b>	
Tissue tracking documentation processes must be in place to maintain accreditation.	
<b>Management Action Plan</b>	
D.1	SAMNIS management has been working with Epic Team to implement a tissue tracking integration, TrackCore Implant Interface, which will contain the controls to ensure required tissue tracking documentation is performed.

#### **D. Tissue Tracking – Detailed Discussion**

We were advised that the current OpTime system does not have controls in place to ensure that documentation required to track biologic tissue implants used in surgical patients is collected, and that reporting on the chain of custody is performed. A recent accreditation review required re-implementation of a prior paper process to ensure mandatory data is documented to maintain accreditation to satisfy regulatory compliance for The Joint Commission, the California Department of Public Health (CDPH), and the American Burn Association. The prior paper process utilizes completion of Graft Receipt Inspection Forms (GRIF) at the point of care, and biologic implant validation and implantation information is also obtained by Materials Management and entered manually into TrackCore database to complete the chain of custody.

SAMNIS management is currently working with Epic to implement a tissue tracking integration, the TrackCore Implant Interface, in July 2016 to update the interface to maximize OpTime's functionality. Under the interface, Materials Management would affix a TrackCore barcode to biologic products. The circulating nurse would scan TrackCore items into OpTime which would auto-populate all required fields. At predetermined intervals, OpTime would send a flat file extract to the TrackCore Remote Interface, closing the chain of custody. However, until the integration is implemented the OpTime system alone does not contain the necessary controls to ensure this documentation is collected and the chain of custody is performed to maintain accreditation.

## Summary of Preference Cards to Actual Usage Testing - Attachment A

Case Sample #	Preference Card	(Column A) Items Listed on the Preference Card to be Opened that in the Actual Case were not Opened and Used	(Column B) Actual Quantity of Some Supplies Exceeded the Combined Open and Prn Quantity on the Preference Card	(Column C) Additional Items Not Included on Preference Card	(Column D) Items Should be Indicated as PRN on Preference Card	(Column E) Items Listed in Additional Items that are on the Preference Card*	(Column F) Planned Procedure Different than Preference Card Selected
1	CYSTOSCOPY DIRECT VISUALIZATION INTERNAL URETHROTOMY	X	X	X	X	X	
2	RESURFACING HIP	X	X	X	X		
3	Discectomy Anterior Cervical Inst Ortho	X	X	X	X	X	
4	PLACEMENT GASTRIC BANDING LAPAROSCOPIC	X	X	X	X		X
5	Psp Endobronchial Ultrasound (Ebus)	X			X		
6	ARTHROPLASTY HIP	X	X	X	X		
7	ESOPHAGOSCOPY WITH DILATION	X	X	X	X		
8	CRANIOTOMY WITH OR WITHOUT IMAGE GUIDED SYSTEM	X	X	X	X		
9	LAPAROTOMY EXPLORATORY	X	X	X	X	X	
10	SINUS SURGERY ENDOSCOPIC	X	X	X	X		
11	HYSTERECTOMY ABDOMINAL LAPAROSCOPIC	X	X	X	X		
12	BIOPSY BREAST NEEDLE/SENTINEL NODE BIOPSY	X	X	X	X		
13	PROSTATECTOMY SIMPLE ROBOTIC ASSISTED DAVINCI SI	X	X	X	X	X	
14	HERNIA REPAIR INGUINAL BILATERAL	X	X	X	X		
15	RESECTION LIVER	X	X	X	X	X	

\*This indicates that quantities were entered by scanning or looking up the supply item rather than entering the quantity from the case supply list.