A Prospective Randomized Evaluation of Two Perioperative Active Warming Techniques for Maintenance of Normothermia in Colorectal Surgeries

PROTOCOL TITLE:

A Prospective Randomized Evaluation of Two Perioperative Active Warming Techniques in Maintenance of Normothermia in Colorectal Surgeries

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1.0 Objectives

We propose a study in which we compare two intraoperative active warming devices for maintenance of normothermia in patients undergoing colorectal surgery. A novel underbody resistive warming mattress (VitaHeat Medical) will be compared to the forced air warming blanket (3M Bair Hugger) that is currently used in our institution.

Our hypothesis is that the underbody resistive warming mattress will be equally effective as forced air warming in maintaining normothermia in colorectal surgery.

2.0 Background

In humans, maintenance of core temperature is tightly regulated by the thermoregulatory center in the hypothalamus. However, skin temperature varies in differing ambient temperatures due to continuous heat transfer. Heat transfer from the body to the environment occurs by convection, conduction, radiation and evaporation. (1)

Upon induction of anesthesia thermoregulatory control is impaired which results in a significant redistribution of core body heat to the periphery resulting in hypothermia. During anesthesia, skin surface is responsible for majority of heat loss. This occurs mainly by radiation and convection (90%) and to a lesser degree by evaporation and conduction (5% each). (2)

Hypothermia is recognized as an important risk factor in the development of various perioperative complications. Hypothermia induced coagulation abnormality increases perioperative blood loss, leading to increased need for blood transfusions. Other important complications are surgical site infections, myocardial injury, and longer length of hospital stay. In fact, perioperative hypothermia has been identified as an independent risk factor for surgical site infections (SSI). (2)

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Colorectal surgery is associated with higher risk of SSI's than most other surgeries. In these surgeries, maintenance of intraoperative normothermia, defined as temperature above 36°C, may be particularly challenging. Contributing factors to hypothermia include long duration of surgery, extensive surgical exploration, and patient positioning. Despite the availability of many warming techniques, many surgical patients still exit the operating room hypothermic. Reducing perioperative hypothermia could greatly reduce morbidity and mortality in colorectal surgery.

Devices and methods that are available for prevention of intraoperative hypothermia can be grouped into passive and active warming.

Passive warming with insulating blankets (cotton or reflective) reduce heat loss by only 30% (2) and obviously cannot be used alone to maintain normothermia.

Active warming methods that are most effective are convective and conductive warming. Forced air warming has been the standard of care for skin surface warming with many studies showing its effectiveness. It is convective heat transfer that relies on the amount of exposed skin surface. The efficacy of forced air is decreased when skin surface area is limited due to surgical reasons and positioning. Temperature gradient from the hose to the periphery exists makes distribution of heat uneven. Burn injuries have been reported when the hose was used alone against manufacturer's guidelines (4).

Another group of warming devices are circulating–water garments. These are devices that have warm water circulating through a conductive-heating garment that is wrapped around the patient. It has been shown to be more effective in heat transfer than forced air warming (5) and more effective in patients undergoing abdominal surgery. (6) However, potential for leakage, difficulty with handling and higher maintenance costs are limiting factors.

Circulating water and electrical mattresses placed under the patient have been ineffective in maintaining normothermia. (7)

Radiant heaters such as incubators for neonates are used most commonly in neonates. Radiators may be used at a safe fixed distance. At this distance the efficacy of radiant heat is less than forced air warming. (8) Also a high risk of burn injury exists if this safe distance is not maintained.

Fluid warming (to near 37^{o} C) alone is not effective in maintaining normothermia. However, in patients undergoing major surgeries where more than 1 L/hour of fluid is administered intraoperatively the combination with other warming techniques have been shown to be more effective than the warming device alone. (9)

Resistive heating devices have been shown to be comparable to forced air in preventing intraoperative hypothermia. They are multi-part devices controlled by a

central unit making them bulky. Due to their size, cleaning and maintenance may be costly. (10)

VitaHeat is an FDA approved novel underbody conductive heating mattress that uses resistive heating technology. This device overcomes some of the deficiencies of the older resistive devices. Some of the improved features include silent operation, ease of cleaning, reusability and low maintenance.

In this study, we will compare the efficacy of this new warming device to the standard warming technique in patients undergoing colorectal surgery under general anesthesia.

References:

1. Sessler DI Perioperative thermoregulation and heat balance. Lancet 2016; published online on Jan16, 2016
2. Torosian A Thermal management during anaesthesia and thermoregulation standards for the prevention of inadvertent perioperative hypothermia. Best Pract Research Clin Anaesth 2008; 22: 659-668.
3. Sessler DI, Schroeder M. Heat loss in humans covered with cotton hospital blankets. Anesth and Analg 1993; 77: 73-77.
4. Cheney FW, Posner KL, Caplan RA, Gild WM. Burns from warming devices in anesthesia. A closed claims analysis. Anesthesiol. 1994; 80: 806-810.
5. Taguchi A, Ratnaraj J, Kabon B et al. Effects of circulating-water garment and forcedair warming on body heat content and core temperature. Anesthesiol. 2004; 100: 10581064.
6. Janicki PK, Higgins MS, Janssen J et al. Comparison of two different temperature maintenance strategies during open abdominal surgery: upper body forced-air warming versus whole body water garment. Anesthesiol. 2001; 95: 868-874.
7. Hynson JM, Sessler DI. Intraoperative warming therapies: a comparison of three devices. J Clin Anesth 1992; 4: 194-199.
8. Bauer, A Weyland W. Kazmaier S et al. Efficacy of postoperative rewarming after cardiac surgery. Ann Thorac Cardiovasc Surg 2004; 10: 171-177.
9. Smith CE, Desai R, Glorioso V et al. Preventing hypothermia: convective and intravenous fluid warming versus convective warming alone. J Clin Anesth 1998; 10: 380-385.
10. Negishi C, Hasegawa K, Mukai S et al. Resistive heating and forced-air warming are comparably effective. Anesth & Analg 2003; 96: 1693-1687.
11. Melton GB, Vogel JD, Swenson BR et al. Continuous intraoperative temperature measurement and surgical site infection risk Ann Surg 2013;258: 606-613

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3.0 Inclusion and Exclusion Criteria

3.1 All patients' ≥18 years of age who are scheduled to undergo laparoscopic or open colorectal surgical procedures under general anesthesia are eligible to participate.

3.2 **Inclusion:** Eligible subjects will include patients 18 years of age undergoing laparoscopic or open colorectal surgical procedures under general anesthesia.

Exclusion: Patients less than 18 years of age, emergent surgery, thyroid problems, preoperative fever and pregnant patients.

- Adults unable to consent: *Exclude*
- Individuals who are not yet adults (infants, children, teenagers): *Exclude*
- Pregnant women: *Exclude*
- Prisoners: *Exclude*

4.0 Study-Wide Number of Subjects: N/A

5.0 Study-Wide Recruitment Methods: N/A

6.0 Multi-Site Research: N/A

7.0 Study Timelines

7.1 Describe:

- The duration of an individual subject's participation in the study: 30 days
- The duration anticipated to enroll all study subjects.12/31/2018
  - *The estimated date for the investigators to complete this study (complete primary analyses).03/01/2019.*

8.0 Study Endpoints

8.1 The primary outcome measure will be the percentage of intraoperative time above a body temperature of 36ºC.

8.2 The secondary outcomes will be the amount of blood or blood product transfusion, surgical site infections as defined by National surgical quality improvement project (NSQIP) and other infections such as urinary tract infections, pneumonias, cardiac events such as cardiac arrest and myocardial infarction, thromboembolic complications (DVT/PE). Length of hospital stay will be recorded as will length of stay, time to return of bowel function (time to first flatus) will be recorded. At 30 days following

the surgery readmissions to the hospital, the reason for the admission and the length of stay during this additional hospitalization will be recorded.

9.0 Procedures Involved

9.1 Study design: A prospective randomized controlled trial.

Stratified randomization will be performed using a computerized randomization table where the strata will be type of surgery (open vs closed) and the treatment will be forced air blanket or underbody mattress warming device. This will allow equal groups of both warming devices in both types of surgery.

Group 1: Patients will receive active warming via a heating mattress (VitaHEAT Medical) placed on the OR table with two thin sheets between the patient and the device; one covering the mattress and the other used as the draw sheet as usual practice. The device will be turned on 10 minutes prior to the patients' arrival to the operating room table. Patients' upper body will be covered with blankets. To increase skin surface contact with the mattress any blankets remaining under the patients' chest or head will be removed after intubation and replaced with a donut.

Group 2: Patients will receive standard forced air warming applied to the upper body and turned on after the patient is prepped and draped. These warmers will be placed directly in contact with the skin without any intervening insulation.

Both groups will have IV fluid warmer initiated on arrival to the operating room. The operating room temperatures will be adjusted to 21° C.

Participation in the study is voluntary. The patients may choose not to enroll in the research. Patients who choose not to enroll will use the standard forced air warmer.

Preoperative and postoperative temperatures will be measured orally. Intraoperative core and skin temperatures will be monitored continuously at 1 minute intervals using an esophageal probe and skin temperature probe using a skin temp probe placed on the great toe and covered to prevent any contact with the warming devices.

The total amount of gas flows will be maintained at 2 L/min. Total and fractional inspired concentration of oxygen (FiO_2) will be maintained 60% in both groups except for the periods of induction and emergence.

A heating mattress (VitaHEAT Medical) will be used as the research device in this study. The mattress has regulatory approval. This heating mattress (VitaHEAT Medical) is a reusable underbody conductive warming mattress which heats to a maximum of 41°C. This device will be compared to the forced air warming which heats to a maximum of 43°C. It meets all FDA safety guidelines.

Temperatures that will be record are:

Operating room temperatures will be collected at three different times:

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1. upon arrival of the patient to the operating room using a calibrated thermometer
2. at incision
3. at extubation.

Patient temperatures will be recorded at:

1. In the preoperative area (orally)
2. Skin temperature of the great toe of one hand will be monitored starting upon on arrival to the operating room at 1 minute intervals until the extubation. This will be performed using a skin temperature probe.
3. Immediately after intubation following placement of an esophageal temperature probe core temperature will be monitored at 1-minute intervals. The esophageal temperature probe will be placed by measuring the distance from the mouth to the earlobe plus the distance from the ear lobe to the manubrium of the sternum-2 finger widths below the sternal notch approximately 32-38 cm. (4) Both esophageal and skin temperatures will be measured using a band thermometer.
4. Temperatures will be measured orally and recorded upon arrival and at departure from the recovery room.

At the end of surgery, prior to leaving the operating room, patients' posterior skin surfaces will be inspected for thermal injury and recorded. If at extubation, the patient's temperature is below 36^{o}C, active warming and fluid warmer will be reinstituted in the recovery room and modes of active warming recorded.

Data points collected include: patient demographics, the amount of blood and blood product transfusion, blood loss, surgical site infections, along with other infections such as urinary tract infections, pneumonias will be recorded. Cardiac events such as cardiac arrest and myocardial infarction, thromboembolic complications (DVT/PE), any posterior skin surface burn injury, time to first flatus, and length of hospital stay will also be recorded. The participant's medical chart will be accessed to obtain the data points and times mentioned in the data sheet.

At the 30th day, each participant will be contacted by a blinded member of the study team by telephone to be asked questions regarding readmissions to the hospital, the reason for the admission and duration of this hospitalization will be asked. The phone call will take approximately 2-4 minutes to complete.

10.0 Data and Specimen Banking: N/A

11.0 Data Analysis and Management

The primary outcome measure will be *the percentage of intraoperative time above a* body temperature of 36^{o} C. Melton GB at el. reported the absolute percentage of time above

the threshold of 36 °C was 57% in patients receiving standard forced air warming intraoperatively. (10)

The number of subjects (N=146) was determined for two groups of 73 in each group to achieve 83% power to detect a difference of 10% between the active warming underbody mattress and forced air warming device, assuming that the standard forced air warming method would achieve a value of 57% and that non-inferiority would be set as a marginal difference of -10%. This sample would provide a significance level of 0.042 using a onesided Z test. Seven patients will be added to each group for protocol violations and data lost in follow up making 160 the total number of subjects that will be recruited.

Interim analysis is preplanned with two looks at n=74 and n=146. Significance and futility boundaries for look 1 and 2 are set at:

Boundaries for Scenario 1

	-- Significance Boundary --		----- Futility Boundary -----	
	Z-Value	P-Value	Z-Value	P-Value
Look	Scale	Scale	Scale	Scale
1	2.72119	0.00325	0.16869	0.43381
2	1.54065	0.06170	1.54065	0.06170

The data will be stored in a departmental password-protected computer with a 5-minute logout. This computer is accessed behind locked departmental doors. Participants will each be assigned an ID number, which will be used as the sole identifier on any documents. Subject data will be compiled onto a single password protected file, where they will only be identified by their ID number. An enrollment log will be the only file where subject names are correlated with ID numbers. This will be kept in a separate, secure, password-protected file in the Department of Anesthesiology. Confidentiality is secured after transferring the data from paper questionnaires to a password protected departmental computer which is uploaded to the departmental server, which is also password protected with limited access to study team only. Data (both electronic and paper) will be destroyed 3 years after data analysis using current departmental standards and vendors. The completed data set is controlled by the PI and only select study team members will have access to the data set. The data set will not be transported. The departmental computer is located at the Department of Anesthesiology, 676 North St Clair Street, Ste 10-501, Chicago, IL 60605.

11.1 Describe how data will be handled study-wide:

- *What information will be included in that data?*
  The information on the data sheet, patient code identifier list and a copy of the consent.
- *Where and how data will be stored?*
  Department of Anesthesiology, Arkes Pavilion 10th Floor.
- *How long the data will be stored?*

The data both electronic and paper will be destroyed 3 years after manuscript completion using departmental approved methods of destruction.

- *Who (role on the study) will have access to the data?* Authorized study personnel will have access to the data.
- *Who (role on the study) is responsible for receipt or transmission of the data?* Principal Investigator
- *How data will be transported?* All paper data sheets will be kept in binders and stored in a locked cabinet in the department of Anesthesiology. Paper data will then be logged into in a single computer in the department of Anesthesiology by authorized research personnel.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects N/A

13.0 Withdrawal of Subjects*

Participation is voluntary. Participants can withdraw at any time. The data collected up to the withdrawal period will be kept for data analysis.

13.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent, including stopping participation for safety reasons.
Although we have not experienced any issues with the VitaHeat underbody mattress, participants may be withdrawn/excluded if the device does not work properly. The participants will then receive the standard forced air warmer.

13.2 *Describe any procedures for orderly termination.* N/A

13.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

The data collected up to the time of withdrawal or exclusion will be kept for data analysis.

14.0 Risks to Subjects*

One possible risk is burn injury or skin irritation from the heating mattress but multiple sensors that are placed within the blanket prevent the device from overheating above 41 degrees C. The risk for loss of confidentiality is another risk but strict measures are in place to prevent this from happening. Participants will be identified as a participant number an all data will be de-identified. Consents will be kept separately from the data collection.

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15.0 Potential Benefits to Subjects

There is no direct benefit to the participants. However, the information may help investigators learn more about maintaining core body temperature which may lead to less surgical site infections.

16.0 Vulnerable Populations N/A 17.0 Community-Based Participatory Research N/A 18.0 Sharing of Results with Subjects

The results of the study will not be shared with the participants. The data will be shared with VitaHeat. Inc.

19.0 Setting

Authorized research personnel will approach potential participants who are scheduled to undergo abdominal surgery, specifically colon surgeries such as open or laparoscopic, total or partial colectomies, abdominoperineal resections, low anterior resections, and proctocolectomies.

Research recruitment will be performed at the following locations:

Northwestern Memorial Hospital
Feinberg Pavilion, Floor 5
Olson Pavilion, Floor 6
Prentice Pavilion, Floor 6
Lavin Pavillion, Floor 11 and 12
A community advisory board will not be created for this study.

20.0 Resources Available

Principal Investigator
Dr. Meltem Yilmaz is an Associate Professor in the Department of Anesthesiology at the Northwestern University Feinberg School of Medicine in Chicago, Illinois. Dr. Yilmaz has been a faculty member for over 10 years and has contributed chapters for a number of textbooks and is published in peer reviewed journals. Dr. Yilmaz has over 8 years of research experience in study conduct and design.

The study co-investigators are qualified for the proposed research project and have current Citi-training certificates. All investigators are adequately informed about the protocol and their responsible duties.

20.1 Describe other resources available to conduct the research: For example, as appropriate:

Approximately 2-4 abdominal surgeries are performed per week at NMH. If we are able to recruit 8-10 patients per

month, the study will take approximately 9 months to first look and 18 months to complete.

All authorized research personnel will meet prior to the conduction of the study to review the documents and procedures associated with the study.

21.0 Prior Approvals

Department of Anesthesiology Research Committee

22.0 Recruitment Methods

22.1 Describe when, where, and how potential subjects will be recruited.

Potential participants who are scheduled for abdominal surgeries will be identified and approached by research personnel. Research personnel will approach the patient on the day of the procedure in the preoperative holding suite approximately 45 to 90 minutes before surgery. They will explain the study and answer all questions that the participants may have. Patients will be recruited at Feinberg pavilion 5th Floor, Olson Pavilion, Floor 6, Lavin Pavilion Floor 11 & 12, and Prentice Pavilion floor 6.

Participants will not be paid to participate.

23.0 Local Number of Subjects

The number of subjects to be accrued is 160. There are two groups of 80 subjects.

24.0 Confidentiality

Data both electronic and paper stored in departmental server and departmental password protected computers will be destroyed using current departmental standards and vendor 3 years after manuscript preparation.

25.0 Provisions to Protect the Privacy Interests of Subjects

25.1 The PI/CO-PI will assure participants that their responses will be held anonymous and that the data collected will be used for research purposes.

25.2 The participants will be allowed to place limits on with whom they interact. They will be assured that participation is voluntary. The research team will make effort not to make participants feel uncomfortable by pressing for information. There are no correct or incorrect answers to the questions.

25.3 Authorized research personnel may access the participant's medical record (Powerchart) to obtain surgical and anesthesia time periods as specified in the data sheet.

26.0 Compensation for Research-Related Injury

This study is not classified as more than minimal risk

27.0 Economic Burden to Subjects

There are no costs to the participants for volunteering to participate in this study.

28.0 Consent Process

We will be obtaining informed consent from the participants. The consenting process will take place at Northwestern Memorial Hospital, Feinberg Pavilion, Floor 5, Olson Pavilion, Floor 6, Prentice Pavilion Floor 6, and Lavin Pavilion Floors 11 & 12.

- *Any waiting period available between informing the prospective subject and obtaining the consent.*

  Yes, research personnel will approach the patient on the day of the procedure in the preoperative holding suite approximately 45-90 minutes before surgery.

- *Any process to ensure ongoing consent.*

  Participation is only 30 days and there will be no further contact with the participants.

- *Whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, describe:*
  - *The role of the individuals listed in the application as being involved in the consent process.*

    Meltem Yilmaz, M.D.: Involved/consent process
    Ljuba Stojiljkovic, M.D, Ph.D.: Involved/consent process
    Kelsey Oldaker: Involved/consent process
    Natalie Rodriguez: Involved/consent process
  - *The time that will be devoted to the consent discussion.*

    The consent will be reviewed with the participant. The participant may ask any questions or concerns they may have at this time. There will be ample amount of time to read the consent prior to the procedure.

  - *Steps that will be taken to minimize the possibility of coercion or undue influence.*

Participation is voluntary and an alternative is not to participate. The participant may withdraw from the trial at any time.

- *Steps that will be taken to ensure the subjects' understanding.*

The consent will be reviewed with the participant. The participant may ask any questions or concerns they may have at this time. There will be ample amount of time to read the consent prior to the procedure.

29.0 Process to Document Consent in Writing

29.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be documented in writing.

A documentation of consent checklist will be used.

29.2 If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. Consent Attached

30.0 Budget

This is a VitaHeat Medical Inc. sponsored study.

31.0 Drugs or Devices

31.1 If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

The heating mattress (VitaHEAT) will be stored in the Feinberg pavilion 5th floor ready room. This is a secured area that requires badge-card entry. The prentice 6th floor, Olson 6th floor, and Lavin Pavilion Floor 11 &12 workrooms are secured by combination lock entry or badge-card entry. Research personnel will be responsible to ensuring placement in the proper OR room and retrieving the mattress after the procedure. Each mattress has an RFI sticker in order to be tracked if necessary. The mattress has been approved and is currently used in some cases at Northwestern Memorial Hospital.

32.0

32.0 Financial Disclosure: Dr. Yilmaz, the person responsible for the conduct of this research study is a paid member of the Scientific Advisory Board of the company that is sponsoring this research.

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33.0__COI Management Plan: The principal investigator will disclose her conflict of interest on the protocol, consent, and all presentations, manuscripts, and publications that arise from this study. The documentation of the operating room temperature will be recorded either by authorized research personnel or by the PI. If the PI records the operating room temperature, then she will initial the data form signifying that it was she who recorded the room temperature. The department statistician will perform the data analysis. If there are changes to the financial relationship, the FSM and NUCOI will be notified immediately.

Abdominal Surgery Normothermia Data Collection Form

PATIENT INFORMATION

Subject #: _____ Date: _____

Surgeon: _____ OR Room Number: _____

Surgical Procedure: _____

TEMPERATURE MEASUREMENT

Pre-Op Temp (Oral)

Temp upon arrival to ASU: _____ Time: _____

Temp at transfer from ASU: _____Time:_____

Epidural:

Yes / No (Circle Answer)

Surgery Type (Circle):

Open

Laparoscopic

Heparin Pre-Op:

Yes / No (Circle Answer)

ANESTHESIA PROVIDER: PLEASE COMPLETE BELOW

PATIENT Intra-Op Temp (Core and Skin)

Ensure that EMR is recording patient temperatures at intervals of 1 minute

Patient Position (Circle):

Supine

Lithotomy

Operating Room Temp

OR Room temp (upon patient arrival): _____

OR Room temp (at time of incision): _____

OR Room temp (at time of extubation): _____

Arm position (Circle):

On arm boards

Tucked

Warming Device Used (Circle):

Bair Hugger

VitaHEAT

Fluid warmer

Presence of posterior skin surface injury: (for burn injury)

Yes _____ No _____

If Yes describe: _____

Anesthesiologist (Print Name): _____

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PACU DATA SHEET

Post-Op Temp (Oral) **Warming Device Used (Circle):**

Temp at admission: _____ Time: _____ Bair Hugger

Temp at discharge: _____ Time: _____ Fluid warmer

Abdominal Surgery Normothermia Patient De-identifier Code List

Case	Name	Date of Surgery	Medical Record Number	Telephone #
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APPENDIX B: DATA COLLECTION FORM

Abdominal Surgery Normothermia

Investigator: Meltem Yilmaz, M.D.

Subject: ____ ▪ Diagnosis:_____ Date of procedure:___/___/___ Time:_____

▪Sex: □M □F ▪ Weight: ___lbs/kg ▪ Height: ___in Age: ____

▪ Subject Demographics: Caucasian: ___ African American: __ Asian:___

Hispanic: __Middle Eastern: __Other: _____

Amount of blood loss_____

Blood product transfusion given: ___yes ____no, If yes_____

Postoperative opioid consumption:_____

_____

Epidural catheter use for pain control? ___Yes ___No

Time to return of bowel function (time to first flatus):_____

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Infections:

___urinary tract infections

___pneumonias

___cardiac events:

__cardiac arrest myocardial,

__infarction thromboembolic complications (DVT/PE)

___Length of stay; Discharge time: _____

Follow up (phone call)

Where you readmitted to the hospital for any reason? ___No ____Yes

1. What was the reason:_____
2. How long was the length of stay for the readmission? _____

Where you prescribed any antibiotics in the past 30 days? _____No _____Yes

1. What is the reason for the antibiotics?
   a) ___Urinary tract infection
   b) ___Pneumonia
   c) ___Cardiac (heart) issues
   d) ___surgical wound infection