12-Lead ECG Monitoring with the EASITM System in the OR: A Quality Improvement Project

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Keywords: 12-lead ECG, Derived 12-lead ECG, EASITM system, Cardiac monitoring, Operating room.

Impact Statement: A 12-lead ECG is warranted when perioperative ECG changes are seen but is difficult to obtain. A derived 12-lead ECG using the Philips monitor EASITM system can be obtained in the operating room.

Background: A 12-lead ECG is the gold standard for identifying myocardial ischemia and arrhythmias. However, it is often not feasible to place 10 leads during surgery. A derived 12-lead ECG using the EASITM system has been found to produce an accurate 12-lead ECG with any slight waveform differences being clinically irrelevant. When evaluating myocardial ischemia, the EASITM system is equivalent to a conventional 12-lead ECG. The Philips IntelliVue MX 800 monitor has the capability to produce a derived 12-lead ECG at any time if the 5 leads are placed using the EASITM system. This system tolerates up to 5 centemeter deviation in lead placement which is better than a conventional 12-lead ECG. There is also a small but significant increase in P wave detection.

The intent of this project was to assess current use and knowledge of the EASITM system, educate anesthesia providers about the EASITM system, and re-assess knowledge and use of this system in clinical practice. The use of the EASITM system for patients with clinical risk factors⁹ was assessed.

Method: This project was conducted at a mid-sized community hospital which had the Philips monitor with the EASITM system available for current use. The Bryan College of Health Sciences Institutional Review Board reviewed and approved the project (Appendix A). Permission was sought from the department leadership to include all credentialed anesthesia providers (Appendix B) and was obtained (Appendix C). Seventy-four Certified Registered Nurse Anesthetists and Physician Anesthesiologists were invited to participate (Appendix D). A pre-intervention online survey was sent to providers and consisted of 9 closed ended questions to assess the knowledge

and use of the EASITM system in the operating room (Appendix E). Administration of an educational intervention was conducted 2 weeks after the initial survey was sent out. The educational intervention was a 12-minute webinar presentation. The use of the EASITM system, a demonstration of proper chest electrode placement and configuration of monitor settings to capture a derived 12-lead ECG was included(Appendix F). A video of the educational intervention was distributed to all members of the department, regardless of completion of the pre-intervention survey (Appendix G). The post-intervention survey was emailed to providers 2 months later to assess changes in the knowledge and use of the EASITM system in the operating room. Two weeks were allowed for completion. The post-intervention survey consisted of 10 closed ended questions, 9 of which were identical to the pre-intervention survey. Statistical analysis consisted of frequency distributions and Chi-Square tests (Appendix H). **Results:** Of the 74 possible participants, 45 (61%) completed the pre-intervention survey and 28 (38%) completed the post-intervention survey. Awareness of the EASITM system significantly increased from 40% (n=18) in the pre-intervention survey to 93% (n=26) post-intervention (p < 0.00001). Knowledge of the EASITM monitoring system increased from 27% (n=12) in the preintervention survey to 89% (n=24) post-intervention. Knowledge of how to activate the system significantly increased from 9% (n=4) pre-intervention to 89% (n=25) post-intervention (p < 0.00001). Knowledge of the correct chest electrode placement for the EASITM system increased from 11% (n=5) pre-intervention to 86% (n=24) post-intervention.

Clinical use of the EASITM system for patients with selected risk factors was assessed as well. The reported use of the EASITM system increased from 13% (n=6) of participants in the pre-intervention survey to 25% (n=7) post-intervention. This was not a significant change (p=0.205187). In the pre-educational intervention survey, 16% (n=7) selected a patient history of

coronary artery disease as a rational for the monitor compared to 25% (n=7) who selected CAD in the post intervention survey. Nine percent (n=4) of providers chose to use this system for patients with a previous myocardial infarction prior to the educational intervention compared to 11% (n=3) after. Congestive heart failure was chosen by 7% (n=3) of providers prior to education and 11% (n=3) after. Prior to the educational intervention, 5% (n=2) chose to use the EASITM system for patients with valvular defects compared to 7% (n=2) after. Two percent (n=1) of providers chose to use this system for patients with a history of CVA before education and 4% (n=1) after. Two percent (n=1) of providers chose to use this system for patients with elevated serum creatinine before education and 0% (n=0) after.

When identifying which type of surgical procedure this monitoring had been used for, "any type of procedure" was selected by 3 providers (7%) before the educational intervention and 5 providers (18%) after. Vascular surgery was selected by 4 providers (9%) before the educational intervention and by 2 providers (7%) after. Emergent surgery was selected by 3 providers (7%) before education and none (0%) after. "Surgeries where large fluid shifts are anticipated" was selected by 2 providers (4%) before education and 1 provider (4%) after.

In assessing the frequency of use of this capability, "never" was selected by 84% (n=38) of providers before the educational intervention and by 75% (n=21) who completed the second survey. "Rarely (<1 per month)" was selected by 11% (n=5) of providers before education and 14% (n=4) after. The "1-5 cases per month" response was selected by 4% (n=2) of providers before education and 11% (n=3) after. The "1-5 cases per week or more" was not selected by any providers (0%) both prior to and following the educational intervention.

The reason reported for not using the EASITM system was "not necessary" by 5% (n=2) of providers before the educational intervention and 29% (n=8) of providers after. "Too time

consuming" was selected by none before education and 7% of providers (n=2) after. "Did not know it was available" was chosen by 41% (n=18) of providers before education and 39% (n=11) of providers after. "Did not know how to set the monitor to perform EASI" was selected by 55% (n=24) of providers before the educational intervention and 25% (n=7) after.

Lastly, participants were asked in the second survey if they viewed or attended the educational intervention. Sixty-seven percent (n=19) answered "yes" and 32% (n=9) answered "no". Viewing of the education intervention was noted to be completed immediately prior to taking the post-intervention survey by several providers. The lack of time between viewing the education intervention and post-intervention survey could contribute to the lack of increased use.

Discussion: The EASITM monitoring system has been used to continually evaluate ST-segment and J-point changes in coronary care units and this same capability is available in the operating room. Continuous monitoring of ST segments in all 12 leads has been shown to significantly increase detection of ischemic episodes compared to monitoring in 3 leads. Detection can lead to further adaptation of one's anesthetic plan to properly treat the patient and reduce risk of myocardial infarction.

The majority of providers in the department were not aware of, and did not know how to utilize the EASITM monitoring system before the education intervention. The Philips monitors had been in daily use for more than a year prior to the pre-intervention survey. After the education intervention, awareness and knowledge of the EASITM system had significantly increased. Provider use of EASITM monitoring had also increased to 25% (n=7), which although not statistically significant may be clinically significant.

A key limitation of this project was the short time between the educational intervention and post-survey. The educational intervention did increase the knowledge and use of the EASITM

system in the operating room. With more time, the use of the EASITM system may continue to increase and prove to be useful in selected patient populations.

Funding Sources: None

Conflict of Interest: There are no conflicts of interest.

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Notification of Action

Date of Notification: 6/1/21
This letter pertains to IRB actions regarding: Title of Study/Project: 12-LEAD ECG MONITORING WITH THE EASI SYSTEM IN THE OR: A QUALITY IMPROVEMENT PROJECT IRB Number: #2104-002 Submitted by: Marilyn Stephenson
Type of Review Performed: XExempt – Performed by: Michelle Johnson, PhD, RN ExpeditedFull
Date of Review: 6/1/21 Document(s) Reviewed: Revised Request for Review (and supplemental table created by PI).
Decision
The Bryan College of Health Sciences' IRB has made the following decision related to your study:
X_APPROVED: Your study has been found to meet criteria necessary for the protection of human subjects as stated in the Code of Federal Regulations Title 45 Part 46. Data collection may start once all required IRB approvals are obtained.
PENDING APPROVAL CONTINGENT ON MINOR CHANGES: Your study has been found to meet criteria necessary for the protection of human subjects as stated in the Code of Federal Regulations Title 45 Part 46; however minor changes are necessary to strengthen one or more part(s) of the study. Those minor changes are detailed below. Please resubmit the final amended Request for Review, Informed Consent, or any other necessary study documents. After submission of the final documents you will receive an approval letter with the approved, stamped informed consent document if required for the study/project.
MUST BE RESUBMITTED WITH MAJOR CHANGES: Your study HAS NOT been found to meet all criteria necessary for the protection of human subjects as stated in the Code of Federal Regulations Title 45 Part 46. One or more major change(s) must be made as detailed below. DATA COLLECTION MAY NOT BE STARTED until those changes have been made and formal approval has

Obligations to the IRB

The investigators of a study approved by the IRB must fulfill the following obligations in order to retain permission to conduct their study:

CONSENT FORM: If you submitted a consent form for approval, the approved consent will be returned to you marked with a red 'APPROVED.' Colored copies of that approved consent must be made and all participants enrolled in the study must sign one of those colored consent forms. The original, colored consent forms must be saved with the investigator's study documents. Each participant must be given a copy of the informed consent. The participant's copy may be a black and white copy of the original, colored informed consent.

PLANNED CHANGES TO THE STUDY: Any non-editorial change to an approved study/project must be submitted to the IRB for approval before initiation of the change except when necessary to eliminate immediate hazards to the participant(s). These changes include (but are not limited to):

- Names and roles of study/project personnel;
- The number of enrolled participants;
- Change to the methods used in the study/project;
- Change to the study/project's consent form;
- Additional method(s) used to recruit subjects (beyond those approved with the initial review);
- Proposed communication(s) to potential or enrolled subjects.
- Any change initiated prior to IRB approval (undertaken to eliminate immediate hazards to participants) must be reported as soon as possible to the Chair or Secretary of the IRB.

UNANTICIPATED PROBLEM OR ADVERSE EVENTS: The investigators of an approved study/project are required to submit to the IRB a full report of the following within two (2) business days of the occurrence:

- An unanticipated problem or adverse event occurring to one or more enrolled subjects including, but not limited to:
 - o Any breach in confidentiality.
 - o Physical or psychological harm.
 - o Unresolved complaint of a participant, family member, or other individual.
 - o Any other occurrence of an adverse nature related to participation in the study/project.
- Any deviation from the approved study/project protocol with the reason for the deviation and any consequences to the study/project participants or the integrity of the study/project's data.
- The withdrawal of any participant
- If a preliminary review of a study/project's data indicates the probability that continuing with the study/project will result in harm to one or more participants.

ONGOING AND FINAL REPORTS: The investigators of an approved study/project will submit a final report (using the IRB Final Report template) within sixty (60) days of the end of data collection. If an approved study has not completed data collection 12 months after the initial IRB approval date, the investigators must submit an Annual Report (using the IRB *Annual Review* template).

Michelle Johnson, PhD, RN	6/1/21
Secretary, Bryan College of Health Sciences' IRB	Date

Appendix B

Approval Letter to AA-PC:

Dear Associated Anesthesiologists, P.C.,

I am conducting my senior capstone project on the knowledge and use of 12-lead ECG monitoring using the EASITM system in the operating room. The purpose of my quality improvement project is to assess the use of this feature, offer an education intervention about the topic, and determine if this capability is useful.

My project involves sending out a 9-question survey via SurveyMonkey to the anesthesia providers that provide care at Bryan Medical Center. This survey will assess the knowledge and use of 12-lead ECG monitoring using the EASITM system in the operating room. After completion of this survey, administration of an education intervention via zoom will be conducted. This education intervention is a short 10-minute presentation on the topic. The education intervention will also be emailed to all anesthesia providers at Associated Anesthesiologists, P.C. After completing the education intervention, the survey will again be sent out to assess any change in the knowledge and use of this capability. All responses will be confidential and no identifiers will be present, as only the responses to the question will be gathered for data collection. Contract or temporary employees will not be included.

I am writing to seek approval for sending out my survey and conducting an education intervention. If approval is granted, the initial survey will be emailed June 1st, 2021. The education intervention will take place via Zoom on June 16th, 2021. The following survey will be sent out August 16th, 2021.

Thank you, Marilyn Stephenson, SRNA

Appendix C

Approval to email AA-PC providers from Division Chair Dr. Jen Ahlers:

Hi Marilyn,

Thanks for reaching out again. I apologize your emails got buried in my inbox and I hadn't gotten back to them yet.

You have permission to contact AAPC providers for your capstone project. Looking forward to seeing the results!

Dr. Ahlers

Appendix D

Email to Associated Anesthesiologists, PC

To: Anesthesia Providers at AA-PC

From: Marilyn Stephenson, SRNA of Bryan College of Health Sciences

Subject: Capstone project assessing the knowledge and use of 12-lead monitoring using the

EASITM system in the operating room

Hello,

I am Marilyn Stephenson, a Senior SRNA in the Bryan nurse anesthesia program. I am conducting my senior capstone project on the knowledge and use of 12-lead ECG monitoring with the EASITM system in the operating room. I plan to conduct a quality improvement project to assess this topic.

This process will include a pre-test questionnaire to assess current knowledge on the 12-lead ECG in the operating room, an education intervention about this capability, and a post-test questionnaire to compare the knowledge and use of this capability. The education intervention is a short 10-minute Zoom meeting with a PowerPoint presentation on the topic and demonstration of the use of the EASI monitoring system. The presentation will take place on (date) at (time). The Zoom link is (Zoom link) and this link will be emailed to all anesthesia providers at AA-PC again 2 days before the presentation. Participation in the zoom meeting will imply permission by the participant.

Subjects participating in the survey will remain anonymous at all times, as only responses to the closed ended questions will be recorded. Risks to participants include embarrassment about not knowing or using the EASITM system, but the participant will be the only one aware of their knowledge deficits. Therefore, the results of the survey are confidential and no identifying information will be collected.

Participation is voluntary and project participants may withdraw at any time without harming their relationships with the principle investigator, Bryan Medical Center, and the AA-PC organization.

The survey takes less than 5 minutes to complete. Your participation would be greatly appreciated. Consent to participating is implied by accessing the Survey Monkey link.

Thank you! Marilyn Stephenson, SRNA

Appendix E

Pretest

- 1. Are you aware that the monitors in the OR (Philips MX 800) have the capability to produce a derived 12-lead EKG with the EASITM system? Yes or No
- 2. Do you know about the EASITM monitoring system? Yes or No
- 3. Do you know how to activate the EASITM monitoring system? Yes or No
- 4. Do you know the correct lead placement for the EASITM lead monitoring? Yes or No
- 5. Have you ever used EASITM monitoring on your patient in the OR? Yes or No
- 6. Which patient population have you used this monitoring for? (select all that apply)
 - a. Coronary artery disease (CAD)
 - b. Previous myocardial infarction (MI)
 - c. Congestive heart disease (CHF)
 - d. Valvular defects
 - e. History of cerebral vascular accident (CVA)
 - f. Elevated serum creatinine ⁹
 - g. Other (fill in the blank)
 - h. I have not used this monitoring
- 7. Which type of surgical procedures have you used this monitoring for? (select all that apply)
 - a. Any type of procedure
 - b. Vascular surgery
 - c. Emergent surgery
 - d. Surgeries where large fluid shifts are anticipated⁹
 - e. Other (fill in the blank)
 - f. I have not used this monitoring
- 8. How often have you used this capability on your patient?
 - a. Never
 - b. Rarely (<1 per month)
 - c. 1-5 cases a month
 - d. 1-5 cases per week
 - e. 5-10 cases per week
 - f. > 10 cases per week
 - g. Always
- 9. If not using this capability, what is the reason?
 - a. Not necessary
 - b. Too time consuming
 - c. Did not know it was available
 - d. Did not know how to set the monitor to perform EASITM

Appendix F

Education Intervention:

12-Lead ecg monitoring with the EASItm system in the OR

Marilyn Stephenson, BSN, SRNA

Problem

- A 12-lead ECG is the gold standard for identifying myocardial ischemia and arrhythmias.
- However, it is not feasible to have 10 leads on a patient during surgery.
- "Perioperative myocardial infarction is a major cause of morbidity and mortality in patients undergoing noncardiac surgery". 1

Philips Intellivue MX 800

• The Philips IntelliVue MX 800 monitor being used in the operating rooms at Bryan Health Hospital has the capability to produce a derived 12-lead ECG an any time if the 5 leads are placed using the EASITM system.

Clinical Application

- The accuracy of the EASITM monitoring system is acceptable in clinical practice for monitoring of ST segment and J-point parameters.⁷
- There is a high correlation between EASITM leads and conventional leads. ^{2,3}
- The EASITM system identifies the same ischemic changes as a traditional 12-lead ECG when enzyme elevation is used to confirm ischemia.¹²
- The EASITM system is being used in coronary care units to continuously monitor cardiac patients.⁷
- The EASITM derived 12 lead produces the same diagnostic results as a standard 12-lead with any difference not affecting diagnostic criteria.^{7,11}
- The differences between PT, QT, and QRS measurements between the EASITM system and traditional 12-lead monitoring is found to be clinically nonsignificant.⁸
- The EASITM system shows a small but significant improvement in P wave amplitude and identification.⁶

Activating the EASITM system

- Once in the operating room, turn on the monitor and touch the screen where the heart rate is usually displayed.
- This menu will appear. (see picture)
- Beside "Lead Placement", usually "STANDARD" is displayed.
- Touch the word STANDARD and an option to select EASI will appear.

- This option will automatically reset to standard at the end of each case.
- Once the patient is on the OR table, leads will need to be placed in the EASITM configuration.
- "The electrodes are placed on the upper sternum, the lower sternum at the level of the 5th intercostal space, on the right and left midaxillary lines at the same level as the lower sternum. The ground electrode can be placed anywhere." ¹⁰

Capturing a Derived 12-Lead ECG

- After the patient has been hooked up to ECG monitoring, one can touch the monitor where the heart rate is displayed and this menu will appear.
- Simply hit "Capture 12 Lead" and the next picture will appear.
- Once the first 12-lead appears, hit "Capture Waves" and the next image will appear.
- This image can be used for comparison to previous ECGs and analysis of current ST segment and J-point analysis.
- Options for "Print Report" and "Store and Send" are displayed under the 12-lead. Further information is being gathered to be able to utilize these features.
- PACU monitor capabilities are also being investigated.

Monitoring while using the EASITM system

- While monitoring in the OR using the EASITM system, 2 ECG lines will be displayed.
- By the second line, one will see "EASI V1" displayed.
- "V1" can be selected and changed to any desired V lead at any time.

Target Population

- Surgical Procedures (see reference pictures)
- The following list from Nagelhout also addresses cases where cardiac risk is elevated.
- I believe patients with intermediate or high risk would also benefit from continuous 12-lead ECG monitoring using the EASITM system.

Variation in lead placement

- One study has been done to investigate the effect of misplacement of leads with the EASITM system as compared to a standard 12-lead ECG.
- The EASITM system is easier to place leads correctly due to clearly defined landmarks and availability with most surgeries.
- "From these experiments, it would appear that the increase in error associated with
 moving the standard precordial leads away from their correct locations is greater than the
 increase associated with moving EASI leads away from their correct locations. It would

appear that the EASI leads are more tolerant to electrode misplacement, within the ranges of misplacement error considered within this study,+/- 5cm." ³

Appendix G

Reminder email to Associated Anesthesiologists, PC

To: Anesthesia Providers at AA-PC

From: Marilyn Stephenson, SRNA of Bryan College of Health Sciences Subject: Reminder email regarding Capstone project assessing the knowledge and use of 12-lead monitoring using the EASITM system in the operating room

Hello again,

I am Marilyn Stephenson, a Senior SRNA in the Bryan nurse anesthesia program. I am conducting my senior capstone project on the knowledge and use of 12-lead ECG monitoring with the EASITM system in the operating room. I recently sent out a survey regarding this capability.

There is now one week left to complete the survey and help me assess the knowledge and use of this capability. The survey takes less than 5 minutes to complete. Your participation would be greatly appreciated.

The full process includes a pre-test questionnaire to assess current knowledge on the 12-lead ECG in the operating room, an education intervention about this capability, and a post-test questionnaire to determine further knowledge and use of this capability. The education intervention is a short 10-minute zoom meeting with a PowerPoint presentation on the topic and a demonstration of the use of this feature. The presentation will take place on (date) at (time). The Zoom link is (Zoom link) and this link will be emailed to all anesthesia providers at AA-PC again 2 days before the presentation.

Subjects participating in the survey will remain anonymous at all times, as only responses to the closed ended questions will be recorded. Therefore, no email addresses or dates/times will be collected.

Thank you again for your participation! Marilyn Stephenson, SRNA

Appendix H

Post-test:

The capstone process includes a pre-test questionnaire to assess current knowledge on the 12-lead ECG in the operating room, an education intervention about this capability, and a post-test questionnaire to compare the knowledge and use of this capability. This is the post-test, and therefore should be answered after the educational intervention has been viewed.

- 1. Are you aware that the monitors in the OR (Philips MX 800) have the capability to produce a derived 12-lead EKG with the EASITM system? Yes or No
- 2. Do you know about the EASITM monitoring system? Yes or No
- 3. Do you know how to activate the EASITM monitoring system? Yes or No
- 4. Do you know the correct lead placement for the EASITM lead monitoring? Yes or No
- 5. Have you ever used EASITM monitoring on your patient in the OR? Yes or No
- 6. Which patient population have you used this monitoring for? (select all that apply)
 - a. Coronary artery disease (CAD)
 - b. Previous myocardial infarction (MI)
 - c. Congestive heart disease (CHF)
 - d. Valvular defects
 - e. History of cerebral vascular accident (CVA)
 - f. Elevated serum creatinine 9
 - g. Other (fill in the blank)
 - h. I have not used this monitoring
- 7. Which type of surgical procedures have you used this monitoring for? (select all that apply)
 - a. Any type of procedure
 - b. Vascular surgery
 - c. Emergent surgery
 - d. Surgeries where large fluid shifts are anticipated9
 - e. Other (fill in the blank)
 - f. I have not used this monitoring
- 8. How often have you used this capability on your patient?
 - a. Never
 - b. Rarely (<1 per month)
 - c. 1-5 cases a month
 - d. 1-5 cases per week
 - e. 5-10 cases per week
 - f. > 10 cases per week
 - g. Always
- 9. If not using this capability, what is the reason?
 - a. Not necessary
 - b. Too time consuming
 - c. Did not know it was available
 - d. Did not know how to set the monitor to perform EASITM
- 10. Did you view or attend the June 16th educational intervention?
 - a. Yes
 - b. No