

## **Supplement 1**

### **Table of Contents**

1. Original protocol
2. Summary of changes to the protocol
3. Final protocol
4. Original statistical analysis plan
5. Summary of changes to the statistical analysis plan
6. Final statistical analysis plan

**Original Study Protocol**

**The PRICE Trial: A Pragmatic, Randomized Introduction  
of Cost Data through the Electronic Health Record**

January 12, 2015

## **Outline**

1. Abstract
2. Overall objectives
3. Aims
  - 3.1 Primary outcome
  - 3.2 Secondary outcomes
4. Background
5. Study design
  - 5.1 Design
  - 5.2 Study duration
  - 5.3 Target population
  - 5.4 Accrual
  - 5.5 Key inclusion criteria
  - 5.6 Key exclusion criteria
6. Subject recruitment
7. Subject compensation
8. Study procedures
  - 8.1 Consent
  - 8.2 Procedures
9. Analysis plan
10. Investigators
11. Human research protection
  - 11.1 Data confidentiality
  - 11.2 Subject confidentiality
  - 11.3 Subject privacy

11.4 Data disclosure

11.5 Data safety and monitoring

11.6 Risk/benefit

11.6.1 Potential study risks

11.6.2 Potential study benefits

11.6.3 Risk/benefit assessment

## **1. Abstract**

Excessive use of laboratory tests contributes to significant costs in the US healthcare system, and these high costs do not translate to consistent improvement in quality of care and outcomes. One reason for excessive laboratory testing is that most physicians do not know how much tests cost. Inpatient care providers frequently order laboratory tests without any appreciation for the costs of these tests. Computerized order entry systems offer the opportunity to engage providers in cost-control efforts and influence their ordering behavior. This study is a controlled clinical trial to determine whether we could decrease the volume of inpatient laboratory tests ordered by presenting providers with the Medicare allowable fees for lab tests (i.e. the maximum dollar amount that Medicare will reimburse the hospital for a test) at the time of order entry. We will randomly assign about 60 laboratory tests to an active arm (fee displayed) or to a control arm (fee not displayed). The primary outcome will be the change in the number of tests ordered per patient day over time (24 months duration, 12 months pre- and post- intervention) and by study group (active test vs. control). This work will further our understanding of how displaying prices, such as Medicare reimbursement fees, in the electronic health record impacts physician ordering. A reduction in unnecessary tests could result in less blood draws on patients, decreased utilization of resources by phlebotomy and in the laboratory, and cost savings to the health system.

## **2. Overall objectives**

The purpose of this study is to evaluate the impact of presenting Medicare allowable fees for inpatient laboratory tests in the electronic health record on provider ordering behavior.

## **3. Aims**

### *3.1 Primary outcome*

The primary outcome is the number of tests ordered per patient-day.

### *3.2 Secondary outcome*

The secondary outcome is the total associated Medicare allowable fees of tests ordered per patient-day.

## **4. Background**

Healthcare in the United States is increasingly expensive, and these high costs do not translate to consistent improvement in quality of care and outcomes [1,2]. In 2011, over-treatment and excessive use of diagnostic tests contributed upwards of \$226 billion in waste to the US healthcare system [3]. Laboratory testing is widely recognized as a key form of potential waste, with the literature estimating that as much as 25% of diagnostic testing is either redundant or of limited clinical value [4]. One study found that 67.9% (2.01 tests per patient-day) of inpatient

laboratory tests ordered during a 6-month period did not contribute to patient care [5]. Empirical evidence supports the idea that not all tests ordered are needed to provide high quality care and that new payment models are increasingly focused on reducing healthcare utilization and costs as integral to improving health care quality [6,7].

One reason for excessive testing is that most physicians do not know how much tests cost. Studies have demonstrated that physicians have a poor understanding of the costs of care and feel uncomfortable initiating discussions about costs with their patients [8,9]. However, recent data suggests that physicians are willing to participate in efforts to control the rising health care costs [10].

Electronic health records offer the opportunity to engage providers in cost-control efforts and influence their ordering behavior. There has been an array of studies of technology-based interventions to promote cost transparency and improve the use of laboratory testing. In a 1990 study, Tierney et al displayed charges at the time of test ordering in an outpatient academic clinic and found that the number of laboratories and cost decreased but the difference did not persist after the intervention ended [11]. Bates et al in 1997 displayed the hospital charges in an inpatient academic hospital at the time of order entry, using a computer-based system, but found no changes in testing volume [12]. However, a key limitation of this study was contamination between the two randomized groups, which occurred at the patient level. A provider who saw the fee of a complete blood cell count presented for a given patient was likely to remember that information when ordering the same test on a different patient and might have communicated this information to a colleague. Physicians could have learned about charges for tests for patients in the intervention group and applied this information to the control patients. Recently, Feldman et al. demonstrated that providing clinicians with the Medicare allowable price fees of diagnostic laboratory tests at the time of order entry resulted in a modest decrease in test ordering and lower costs [13]. Here the investigators took 61 lab tests, some of which were the most frequently ordered and others were most expensive, and randomized at the test level with 30 tests in an active arm (fee displayed) and 31 tests in a control arm (fee not displayed). They did not, however, assure equal stratification of most ordered and most expensive tests in each arm. Consequently, one key study limitation was asymmetric randomization of tests with more than 3 times more frequently ordered tests in the active arm than in the control arm. This asymmetry may have affected the study's estimate of net changes in charges from baseline to the intervention period.

The purpose of our investigation is to replicate Feldman et al.'s study with an important modification. We will systematically perform symmetric randomization of tests by ensuring equal number of most frequently ordered and most expensive tests are in each arm. We hypothesize that we could influence inpatient providers ordering behavior by displaying prices of laboratory tests in the computerized provider order entry system.

1. Owens DK, Qaseem A, Chou R, Shekelle P. High-value, cost-conscious health care: Concepts for clinicians to evaluate the benefits, harms, and costs of medical interventions. *Ann Intern Med.* 2011;154:174-180. doi:10.1059/0003-4819-154-3-201102010-00007.
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5. Miyakis S, Karamanof G, Lontos M, Mountokalakis TD. Factors contributing to inappropriate ordering of tests in an academic medical department and the effect of an educational feedback strategy. *Postgrad Med J.* 2006;82:823-829. doi:10.1136/pgmj.2006.049551.
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9. Alexander GC, Casalino LP, Tseng CW, McFadden D, Meltzer DO. Barriers to patient-physician communication about out-of-pocket costs. *J Gen Intern Med.* 2004;19:856-860. doi:10.1111/j.1525-1497.2004.30249.x.
10. Tilburt JC, Wynia MK, Sheeler RD, et al. Views of US physicians about controlling health care costs. *JAMA.* 2013;310:380-388. doi:10.1001/jama.2013.8278.
11. Tierney WM, Miller ME, McDonald CJ. The Effect on Test Ordering of Informing Physicians of the Charges for Outpatient Diagnostic Tests.; 1990:1499-1504. doi:10.1056/NEJM199005243222105.
12. Bates DW, Kuperman GJ, Jha A, et al. Does the Computerized Display of Charges Affect Inpatient Ancillary Test Utilization?.; 1997:2501-2508. doi:10.1001/archinte.1997.00440420135015.
13. Feldman LS, Shihab HM, Thiemann D, et al. Impact of providing fee data on laboratory test ordering: a controlled clinical trial. *JAMA Intern Med.* 2013;173:903-908. doi:10.1001/jamainternmed.2013.232.

## **5. Study design**

### *5.1 Design*

This is a controlled clinical trial that will be conducted at the University of Pennsylvania Health System. We have adapted our study design from Feldman et al.'s prior work in the literature in which inpatient providers were presented with the Medicare allowable price fees of diagnostic laboratory tests at the time of order entry and test ordering volume was measured and analyzed. Using data from fiscal year 2014, we will compile a list of about 60 diagnostic laboratory tests, 30 that are the most frequently ordered and 30 that are most expensive. For all selected tests, we will define the display cost as the 2015 Medicare allowable fee, which is the maximum price Medicare will reimburse the hospital for the test. This information will be provided to us from the leadership of the health systems' Division of Laboratory Medicine. Randomization will be performed at the test level. Specifically, the 60-selected diagnostic laboratory tests will randomly be assigned with about 30 to an active arm (fee displayed) and 30 to a control arm (fee not displayed). Our test intervention will be to display Medicare allowable fees for the active tests arm using the computerized order entry system, Sunrise Clinical Manager (Allscript Corp). Our primary outcome is the number of tests ordered per patient-day. Our secondary outcome is the total associated Medicare allowable fees of tests ordered per patient-day. We will analyze change in these outcomes by test arm (active vs. control) and over time (baseline vs. post intervention period).

Of note, the list of 60 diagnostic laboratory tests, 30 that are the most frequently ordered and 30 that are most expensive, include HIV antibody blood test. As a result, we will need to identify the number of tests ordered and performed during the duration of this study. In regards to HIV antibody test information, we would like to clarify that (1) we are not requesting the results of these tests (e.g., positive or negative), but are only interested in the number of tests ordered and performed; (2) this information is necessary to the proposed study objectives. In this study we are testing change in physician ordering (the number of tests per patient-day) before and after the intervention (presenting test Medicare fee data in the electronic health record). The primary outcome is the change in the number of tests ordered per patient-day over time. HIV antibody tests is one of the tests we identified in our intervention arm (fee displayed), and therefore it is necessary to obtain the number of tests ordered and ordered pre- and post- intervention to meet the study objective.

### *5.2 Study duration*

The duration of this study is 6 months. We will define the “baseline period” as the 3 months prior to the intervention. We will define the “intervention period” as the 3 months after. The intervention, itself, will be displaying hospital charges of randomly selected tests in what we will call our “active tests” arm.

### *5.3 Target population*

The target population in the study are all providers, both physician and non-physicians, who order inpatient laboratory tests at our tertiary care academic center.



#### *5.4 Accrual*

Not applicable

#### *5.5 Key inclusion criteria*

Not applicable

#### *5.6 Key exclusion criteria*

None

### **6. Subject recruitment**

No active recruitment

### **7. Subject compensation**

None

### **8. Study procedures**

#### *8.1 Consent*

We are requesting a waiver of consent. This study could not be practicably carried out without the waiver of consent. It is not practical to consent every single ordering provider at UPHS. Nor do we wish to do so, if it was. We believe that a waiver of consent is necessary in order to avoid a confounding factor in ordering behavior by notifying subjects of this research and therefore impacting our study design. We simply wish to assess how seeing charge prices will impact physician behavior.

#### *8.2 Procedures*

Not applicable

### **9. Analysis plan**

We will use t-tests or Wilcoxon rank-sum tests (F-tests or Kruskal-Wallis test) for continuous variables and Pearson chi square tests or Fishers exact tests for categorical variables. In our primary analyses we will use direct comparisons of outcomes by arm and over time. All hypothesis tests will be 2-sided. We will use STATA and/or SAS to analyze the data.

### **10. Investigators**

Mitesh Patel, MD, MBA, MS is the Principal Investigator (PI) and is an Assistant Professor of Medicine and Health Care Management at the Perelman School of Medicine and The Wharton School at the University of Pennsylvania. He has past experience leading six clinical trials and

has conducted several studies using the electronic health record as a tool to change behavior. He currently spends 80% of his effort on research and 20% on clinical and teaching activities. Mina Sedrak, MD, MS is the Co-PI, a fellow in Hematology/Oncology Division. Jennifer Myers, MD is an associate professor of Medicine and associate designated institutional official for quality and safety in Graduate Medical Education. Jessica Dine, MD is an associate program director of the Internal Medicine Residency and an educator of high value care in Graduate Medical Education. Irving Nachamkin, DrPH, MPH is the director of the Division of Laboratory Medicine at HUP and committed to improving resource utilization and reducing cost.

## **11. Human research protection**

### *11.1 Data confidentiality*

Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Wherever feasible, identifiers will be removed from study-related information. Precautions are in place to ensure the data are secure by using passwords and encryption, because the research involves web-based surveys.

### *11.2 Subject confidentiality*

We are requesting to obtain Data that will include MRN and DOB identifiers from PDS. After obtaining the data, each patient will be assigned a unique, numeric identifier that will be used on all collected study information and the MRN information will be deleted. The source document in which the unique identifier is associated with personal information will be stored in a password protected computer file to which only study primary investigators have access. Threats to confidentiality will be minimized by careful data collection and the private and secure web-based platform. At the conclusion of the study, all identifying information will be destroyed and all data will be archived in a password-protected folder. All other study investigators or statistician will be limited to access only de-identified data. All of these personnel will have completed research and confidentiality (CITI) training. All data for this project will be stored on the secure firewalled servers of the University of Pennsylvania, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of communication encryption. Electronic access rights are carefully controlled by UPenn system managers. We will use highly secure methods of data encryption for all transactions using a level of security comparable to what is used in commercial financial transactions. We believe this multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health Systems medical records, greatly minimizes the risk of loss of privacy.

### *11.3 Subject privacy*

Not applicable.

#### *11.4 Data disclosure*

Not applicable.

#### *11.5 Data safety and monitoring*

The principal investigator and co-investigator will work with the patient safety office to monitor any provider or patient safety reports and monitor for any adverse effects. They will also be responsible to ensure that all electronic data will be stored on the University of Pennsylvania approved computers and limited to the members of the research team.

#### *11.6 Risk/benefit*

##### *11.6.1 Potential study risks*

The main risk of this intervention is that displaying Medicare allowable fees directly results in not ordering a test that is needed for a patient resulting in harm. Several prior studies have been conducted at similar institutions, and this has not been associated with patient harm. Bates et al in 1997 displayed the charges in an inpatient academic hospital at the time of order entry, using a computer-based system, and more recently, Feldman et al. in 2013 performed a similar studies using Medicare allowable price fees of diagnostic laboratory tests presented to ordering provider at the time of order entry. Neither of these controlled clinical trials reported any patient harm. We will work with the patient safety office to monitor any provider or patient safety reports and monitor for any adverse effects. We are also deliberately choosing routine lab orders (e.g. complete blood cell count, basic metabolic panel) that are not often associated with adverse effects, and if later they are determined to be needed, they can be ordered STAT, and results may be obtained within one hour. The other risk of this study is loss of data. We have described the measures taken to protect the data including security measures and training of research staff. There are no other direct risks to patients in the sample.

##### *11.6.2 Potential study benefits*

This study could result in improving the understanding of how displaying costs in the electronic health record impacts physician ordering. A reduction in unnecessary tests could result in less blood draws on patients, decreased utilization of resources by phlebotomy and the laboratory, and cost savings to the health system.

##### *11.6.3 Risk/benefit assessment*

The potential for significant direct benefits from reductions in unnecessary lab ordering and insights that can inform other electronic health record interventions outweigh the risks of not ordering a test when needed. Specifically, because these tend to be routine, not emergent tests, and if they are later deemed necessary, they can be ordered and completed within one hour.

## **Summary of Changes to the Protocol**

The original protocol listed the pre-intervention period as 3 months and post-intervention period as 3 months. However, after obtaining approval from the health system to study the longer-term impact, the protocol was modified to compare a 12-month pre-intervention period with a 12-month post-intervention period. No other changes were made to the protocol.

## **Final Study Protocol**

# **The PRICE Trial: A Pragmatic, Randomized Introduction of Cost Data through the Electronic Health Record**

## **Outline**

1. Abstract
2. Overall objectives
3. Aims
  - 3.1 Primary outcome
  - 3.2 Secondary outcomes
4. Background
5. Study design
  - 5.1 Design
  - 5.2 Study duration
  - 5.3 Target population
  - 5.4 Accrual
  - 5.5 Key inclusion criteria
  - 5.6 Key exclusion criteria
6. Subject recruitment
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8. Study procedures
  - 8.1 Consent
  - 8.2 Procedures
9. Analysis plan
10. Investigators
11. Human research protection
  - 11.1 Data confidentiality
  - 11.2 Subject confidentiality
  - 11.3 Subject privacy

11.4 Data disclosure

11.5 Data safety and monitoring

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11.6.3 Risk/benefit assessment

## **1. Abstract**

Excessive use of laboratory tests contributes to significant costs in the US healthcare system, and these high costs do not translate to consistent improvement in quality of care and outcomes. One reason for excessive laboratory testing is that most physicians do not know how much tests cost. Inpatient care providers frequently order laboratory tests without any appreciation for the costs of these tests. Computerized order entry systems offer the opportunity to engage providers in cost-control efforts and influence their ordering behavior. This study is a controlled clinical trial to determine whether we could decrease the volume of inpatient laboratory tests ordered by presenting providers with the Medicare allowable fees for lab tests (i.e. the maximum dollar amount that Medicare will reimburse the hospital for a test) at the time of order entry. We will randomly assign about 60 laboratory tests to an active arm (fee displayed) or to a control arm (fee not displayed). The primary outcome will be the change in the number of tests ordered per patient day over time (24 months duration, 12 months pre- and post- intervention) and by study group (active test vs. control). This work will further our understanding of how displaying prices, such as Medicare reimbursement fees, in the electronic health record impacts physician ordering. A reduction in unnecessary tests could result in less blood draws on patients, decreased utilization of resources by phlebotomy and in the laboratory, and cost savings to the health system.

## **2. Overall objectives**

The purpose of this study is to evaluate the impact of presenting Medicare allowable fees for inpatient laboratory tests in the electronic health record on provider ordering behavior.

## **3. Aims**

### *3.1 Primary outcome*

The primary outcome is the number of tests ordered per patient-day.

### *3.2 Secondary outcome*

The secondary outcome is the total associated Medicare allowable fees of tests ordered per patient-day.

## **4. Background**

Healthcare in the United States is increasingly expensive, and these high costs do not translate to consistent improvement in quality of care and outcomes [1,2]. In 2011, over-treatment and excessive use of diagnostic tests contributed upwards of \$226 billion in waste to the US healthcare system [3]. Laboratory testing is widely recognized as a key form of potential waste, with the literature estimating that as much as 25% of diagnostic testing is either redundant or of limited clinical value [4]. One study found that 67.9% (2.01 tests per patient-day) of inpatient



laboratory tests ordered during a 6-month period did not contribute to patient care [5]. Empirical evidence supports the idea that not all tests ordered are needed to provide high quality care and that new payment models are increasingly focused on reducing healthcare utilization and costs as integral to improving health care quality [6,7].

One reason for excessive testing is that most physicians do not know how much tests cost. Studies have demonstrated that physicians have a poor understanding of the costs of care and feel uncomfortable initiating discussions about costs with their patients [8,9]. However, recent data suggests that physicians are willing to participate in efforts to control the rising health care costs [10].

Electronic health records offer the opportunity to engage providers in cost-control efforts and influence their ordering behavior. There has been an array of studies of technology-based interventions to promote cost transparency and improve the use of laboratory testing. In a 1990 study, Tierney et al displayed charges at the time of test ordering in an outpatient academic clinic and found that the number of laboratories and cost decreased but the difference did not persist after the intervention ended [11]. Bates et al in 1997 displayed the hospital charges in an inpatient academic hospital at the time of order entry, using a computer-based system, but found no changes in testing volume [12]. However, a key limitation of this study was contamination between the two randomized groups, which occurred at the patient level. A provider who saw the fee of a complete blood cell count presented for a given patient was likely to remember that information when ordering the same test on a different patient and might have communicated this information to a colleague. Physicians could have learned about charges for tests for patients in the intervention group and applied this information to the control patients. Recently, Feldman et al. demonstrated that providing clinicians with the Medicare allowable price fees of diagnostic laboratory tests at the time of order entry resulted in a modest decrease in test ordering and lower costs [13]. Here the investigators took 61 lab tests, some of which were the most frequently ordered and others were most expensive, and randomized at the test level with 30 tests in an active arm (fee displayed) and 31 tests in a control arm (fee not displayed). They did not, however, assure equal stratification of most ordered and most expensive tests in each arm. Consequently, one key study limitation was asymmetric randomization of tests with more than 3 times more frequently ordered tests in the active arm than in the control arm. This asymmetry may have affected the study's estimate of net changes in charges from baseline to the intervention period.

The purpose of our investigation is to replicate Feldman et al.'s study with an important modification. We will systematically perform symmetric randomization of tests by ensuring equal number of most frequently ordered and most expensive tests are in each arm. We hypothesize that we could influence inpatient providers ordering behavior by displaying prices of laboratory tests in the computerized provider order entry system.

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## **5. Study design**

### *5.1 Design*

This is a controlled clinical trial that will be conducted at the University of Pennsylvania Health System. We have adapted our study design from Feldman et al.'s prior work in the literature in which inpatient providers were presented with the Medicare allowable price fees of diagnostic laboratory tests at the time of order entry and test ordering volume was measured and analyzed. Using data from fiscal year 2014, we will compile a list of about 60 diagnostic laboratory tests, 30 that are the most frequently ordered and 30 that are most expensive. For all selected tests, we will define the display cost as the 2015 Medicare allowable fee, which is the maximum price Medicare will reimburse the hospital for the test. This information will be provided to us from the leadership of the health systems' Division of Laboratory Medicine. Randomization will be performed at the test level. Specifically, the 60-selected diagnostic laboratory tests will randomly be assigned with about 30 to an active arm (fee displayed) and 30 to a control arm (fee not displayed). Our test intervention will be to display Medicare allowable fees for the active tests arm using the computerized order entry system, Sunrise Clinical Manager (Allscript Corp). Our primary outcome is the number of tests ordered per patient-day. Our secondary outcome is the total associated Medicare allowable fees of tests ordered per patient-day. We will analyze change in these outcomes by test arm (active vs. control) and over time (baseline vs. post intervention period).

Of note, the list of 60 diagnostic laboratory tests, 30 that are the most frequently ordered and 30 that are most expensive, include HIV antibody blood test. As a result, we will need to identify the number of tests ordered and performed during the duration of this study. In regards to HIV antibody test information, we would like to clarify that (1) we are not requesting the results of these tests (e.g., positive or negative), but are only interested in the number of tests ordered and performed; (2) this information is necessary to the proposed study objectives. In this study we are testing change in physician ordering (the number of tests per patient-day) before and after the intervention (presenting test Medicare fee data in the electronic health record). The primary outcome is the change in the number of tests ordered per patient-day over time. HIV antibody tests is one of the tests we identified in our intervention arm (fee displayed), and therefore it is necessary to obtain the number of tests ordered and ordered pre- and post- intervention to meet the study objective.

### *5.2 Study duration*

The duration of this study is 24 months. We will define the "baseline period" as the 12 months prior to the intervention. We will define the "intervention period" as the 12 months after. The intervention, itself, will be displaying Medicare allowable fees of randomly selected tests in what we will call our "active tests" arm.

### *5.3 Target population*

The target population in the study are all providers, both physician and non-physicians, who order inpatient laboratory tests at our tertiary care academic center.

#### *5.4 Accrual*

Not applicable

#### *5.5 Key inclusion criteria*

Not applicable

#### *5.6 Key exclusion criteria*

None

### **6. Subject recruitment**

No active recruitment

### **7. Subject compensation**

None

### **8. Study procedures**

#### *8.1 Consent*

We are requesting a waiver of consent. This study could not be practicably carried out without the waiver of consent. It is not practical to consent every single ordering provider at UPHS. Nor do we wish to do so, if it was. We believe that a waiver of consent is necessary in order to avoid a confounding factor in ordering behavior by notifying subjects of this research and therefore impacting our study design. We simply wish to assess how seeing charge prices will impact physician behavior.

#### *8.2 Procedures*

Not applicable

### **9. Analysis plan**

We will use t-tests or Wilcoxon rank-sum tests (F-tests or Kruskal-Wallis test) for continuous variables and Pearson chi square tests or Fishers exact tests for categorical variables. In our primary analyses we will use direct comparisons of outcomes by arm and over time. All hypothesis tests will be 2-sided. We will use STATA and/or SAS to analyze the data.

### **10. Investigators**

Mitesh Patel, MD, MBA, MS is the Principal Investigator (PI) and is an Assistant Professor of Medicine and Health Care Management at the Perelman School of Medicine and The Wharton School at the University of Pennsylvania. He has past experience leading six clinical trials and

has conducted several studies using the electronic health record as a tool to change behavior. He currently spends 80% of his effort on research and 20% on clinical and teaching activities. Mina Sedrak, MD, MS is the Co-PI, a fellow in Hematology/Oncology Division. Jennifer Myers, MD is an associate professor of Medicine and associate designated institutional official for quality and safety in Graduate Medical Education. Jessica Dine, MD is an associate program director of the Internal Medicine Residency and an educator of high value care in Graduate Medical Education. Irving Nachamkin, DrPH, MPH is the director of the Division of Laboratory Medicine at HUP and committed to improving resource utilization and reducing cost.

## **11. Human research protection**

### *11.1 Data confidentiality*

Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Wherever feasible, identifiers will be removed from study-related information. Precautions are in place to ensure the data are secure by using passwords and encryption, because the research involves web-based surveys.

### *11.2 Subject confidentiality*

We are requesting to obtain Data that will include MRN and DOB identifiers from PDS. After obtaining the data, each patient will be assigned a unique, numeric identifier that will be used on all collected study information and the MRN information will be deleted. The source document in which the unique identifier is associated with personal information will be stored in a password protected computer file to which only study primary investigators have access. Threats to confidentiality will be minimized by careful data collection and the private and secure web-based platform. At the conclusion of the study, all identifying information will be destroyed and all data will be archived in a password-protected folder. All other study investigators or statistician will be limited to access only de-identified data. All of these personnel will have completed research and confidentiality (CITI) training. All data for this project will be stored on the secure firewalled servers of the University of Pennsylvania, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of communication encryption. Electronic access rights are carefully controlled by UPenn system managers. We will use highly secure methods of data encryption for all transactions using a level of security comparable to what is used in commercial financial transactions. We believe this multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health Systems medical records, greatly minimizes the risk of loss of privacy.

### *11.3 Subject privacy*

Not applicable.

#### *11.4 Data disclosure*

Not applicable.

#### *11.5 Data safety and monitoring*

The principal investigator and co-investigator will work with the patient safety office to monitor any provider or patient safety reports and monitor for any adverse effects. They will also be responsible to ensure that all electronic data will be stored on the University of Pennsylvania approved computers and limited to the members of the research team.

#### *11.6 Risk/benefit*

##### *11.6.1 Potential study risks*

The main risk of this intervention is that displaying Medicare allowable fees directly results in not ordering a test that is needed for a patient resulting in harm. Several prior studies have been conducted at similar institutions, and this has not been associated with patient harm. Bates et al in 1997 displayed the charges in an inpatient academic hospital at the time of order entry, using a computer-based system, and more recently, Feldman et al. in 2013 performed a similar studies using Medicare allowable price fees of diagnostic laboratory tests presented to ordering provider at the time of order entry. Neither of these controlled clinical trials reported any patient harm. We will work with the patient safety office to monitor any provider or patient safety reports and monitor for any adverse effects. We are also deliberately choosing routine lab orders (e.g. complete blood cell count, basic metabolic panel) that are not often associated with adverse effects, and if later they are determined to be needed, they can be ordered STAT, and results may be obtained within one hour. The other risk of this study is loss of data. We have described the measures taken to protect the data including security measures and training of research staff. There are no other direct risks to patients in the sample.

##### *11.6.2 Potential study benefits*

This study could result in improving the understanding of how displaying costs in the electronic health record impacts physician ordering. A reduction in unnecessary tests could result in less blood draws on patients, decreased utilization of resources by phlebotomy and the laboratory, and cost savings to the health system.

##### *11.6.3 Risk/benefit assessment*

The potential for significant direct benefits from reductions in unnecessary lab ordering and insights that can inform other electronic health record interventions outweigh the risks of not ordering a test when needed. Specifically, because these tend to be routine, not emergent tests, and if they are later deemed necessary, they can be ordered and completed within one hour.

## **Original Statistical Analysis Plan**

The primary outcome is the number of tests ordered per patient-day. The secondary outcome is the total associated Medicare allowable fees of tests ordered per patient-day.

We will use t-tests or Wilcoxon rank-sum tests (F-tests or Kruskal-Wallis test) for continuous variables and Pearson chi square tests or Fishers exact tests for categorical variables. In our primary analyses we will use direct comparisons of outcomes by arm and over time. All hypothesis tests will be 2-sided. We will use STATA and/or SAS to analyze the data.

## **Changes to Statistical Analysis Plan**

None

## **Final Statistical Analysis Plan**

Same as original statistical analysis plan