

THE PAICAP PROJECT

Conducted by Harvard Medical School and Harvard Pilgrim Health Care Institute

PAICAP Frequently Asked Questions (FAQ)

WHO WE ARE AND HOW TO CONTACT US

Who is conducting this study?

The PAICAP (**P**reventing **A**voidable **I**nfectious **C**omplications by **A**ddjusting **P**ayment) project is funded by the Agency for Healthcare Research and Quality (AHRQ), and is being conducted by researchers at Harvard Pilgrim Health Care Institute, Harvard Medical School and Harvard School of Public Health. Our collaborators include leadership at the National Healthcare Safety Network (NHSN), the Centers for Disease Control and Prevention, the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC), the Institute for Healthcare Improvement, the Society for Healthcare Epidemiology of America (SHEA) and the Centers for Medicare and Medicaid Services.

Why are you conducting this study?

We are conducting this study to help us understand the impact of the Centers for Medicare and Medicaid Services (CMS) policy to adjust payment for healthcare-associated infections (HAIs) in different hospitals. Since October 2008, the following HAIs were affected by the CMS policy:

- Vascular catheter-associated infections
- Catheter-associated urinary tract infections (CAUTIs)
- Ventilator-associated pneumonia (VAP)
- Surgical site infections (SSIs) occurring after certain procedures, such as coronary artery bypass graft (CABG), total knee replacement, total hip replacement and bariatric surgery.

What are the goals of the study?

Our goal is to assess the impact of Medicare's use of nonpayment for preventable complications on health outcomes and costs in hospitals that report data to Medicare and the National Healthcare Safety Network (NHSN).

Who should I contact if I have questions?

The PAICAP staff is available to answer any questions you may have. There are many ways you can reach us:

- Call our project's toll-free telephone line at 1-877-97-PAICAP (1-877-977-2422) to speak with a staff member
- Email us at PAICAP@hphc.org
- Complete and submit a contact form that can be found on our website at www.paicap.org

ENROLLMENT

Who are you recruiting for the PAICAP study?

The PAICAP study is recruiting NHSN participants to join our study. We are very interested in including all NHSN hospitals that are affected by the CMS policy in the U.S. Certain types of facilities that are not affected by the CMS policy will not be included in the study. Facilities that are not eligible include federal hospitals, critical access facilities, long-term care facilities, hospitals that only focus on cancer care, inpatient rehabilitation facilities, and psychiatric hospitals. Please contact us if you are interested and we can provide you with more information and help determine if your hospital is eligible for our study.

What do I need to do?

The only thing you need to do for this study is join the PAICAP NHSN user group. You do not need to do any data collection for this study. We will only use data that your hospital already collects for NHSN. Your time commitment will be 15-20 minutes in total to join our PAICAP user group. We will also provide annual updates of our study findings to PAICAP participants if you are interested in hearing about our findings during this 4½ year study.

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What data will you need for the PAICAP study?

We are asking hospitals to share their **existing NHSN data** on any of the following types of infections: central line associated bloodstream infections, catheter-associated urinary tract infections, surgical site infections after coronary artery bypass graft surgery, and ventilator-associated pneumonia (including post-procedure pneumonia). You do not need to collect any additional data to be a part of the PAICAP study.

We are only interested in aggregate data from hospital units being monitored in NHSN. For example, for device associated infections, we only need to look at the total number of infections, device days and patient days occurring in a particular location in each month that surveillance was performed.

When will my hospital data be accessed?

After you join, we will check your hospital data to make sure that we have the correct information and that patient identifiers have not been included. After we confirm that your hospital has correctly joined our PAICAP user group, we will only need to access the data approximately 1-2 times per year during the 4½ year study period. We will notify you in advance each time we will be accessing your hospital data in the PAICAP user group. We are minimizing the number of times we access hospital data through the PAICAP group in order to minimize any risks to confidentiality.

What are the benefits of participating?

Although there is no direct benefit to your hospital, we hope that the findings from this research will assist policymakers in making informed policy decisions in the future. We will provide annual updates to participating hospitals on the progress of the study and preliminary results.

We haven't joined NHSN yet, but plan to do so – can we still participate?

Hospitals that are in the process of joining NHSN can still participate in the project if they meet the other eligibility criteria. We cannot enroll you until you have joined NHSN, but we can touch base with you around the time you think your enrollment will be completed to finalize participation in the PAICAP project.

I am the NHSN administrator for multiple hospitals – can I just sign up once?

If you report for multiple hospitals using one unique NHSN ID number, then you will only need to confer rights once. However, due to NHSN programming, if each of your hospitals has a unique ID number then you will have to confer rights for each facility separately.

CONFIDENTIALITY

Do I need to share patient identifiers with the PAICAP group?

This study **does not require patient identifiers**. To join our group, you must choose to NOT share patient identifiers with us. Our step-by-step instructions highlight the procedure necessary to exclude all patient identifiers. We will monitor the rights conferred to our PAICAP group and if we find that any patient identifiers are inadvertently included, we will reject your membership and ask you to rejoin our group without patient identifiers to minimize any risks to patient confidentiality.

Who has access to my data?

Hospitals that join our group will NOT be able to see data from other hospitals in the PAICAP group. Your hospital data will only be visible to NHSN PAICAP group administrators, such as Dr. Grace Lee (principal investigator) and Charlene Gay (project manager). Our restrictive policy will ensure that any data provided by hospitals will only be available to IRB-approved study staff and will only be used for the purposes of this study. No collaborators will have access to the NHSN PAICAP group to avoid any unnecessary or unauthorized breach of user privacy.

How will you minimize risks to confidentiality?

We recognize that the information handled by the NHSN system includes sensitive information about member facilities. In addition to the steps described above, we will also do the following to minimize risks to confidentiality of PAICAP NHSN data. First, we will manage and protect all system authentication related controls (passwords, digital certificates, etc.) related to the PAICAP group. Second, PAICAP NHSN group administrators will only access the data in the NHSN group at pre-defined times after alerting PAICAP members. Third, after generating an analytic dataset, all hospital identifiers will be removed and hospitals will be assigned a random, unique study ID. A cross-walk between study IDs and hospital

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identifiers will be stored separately from the analytic dataset in a secure, password protected location and will only be accessible by authorized PAICAP study staff. The record linking the study ID number to your hospital will be destroyed once the study is complete. Risks to confidentiality will be further minimized by the use of password-protected computers and databases secured behind multiple firewalls. Finally, all data will be reported in aggregate, and hospitals will not be identified in any presentations or publications resulting from the study. Information which would permit identification of any hospital will not be disclosed or released to any outside entity without the prior consent of the institution, unless required by law.

MISCELLANEOUS

Do I need IRB approval?

The PAICAP study is IRB approved by the Harvard Pilgrim Health Care IRB. As part of our IRB approval, we have obtained a HIPAA waiver of authorization for the study. Both documents are available upon request. PAICAP staff is available for consultation and assistance with any issues that arise for your hospital, as we want to ensure that we minimize your time burden.

How is financial data being collected?

You do not need to provide any financial data concerning your hospital. Financial data (ie, "billing" data) will be generated from Medicare MedPAR datasets and State Inpatient Datasets. These financial datasets will be analyzed along with NHSN infection data to determine the impact of Medicare's use of nonpayment for preventable complications on health outcomes.