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Photo by Terry Dagradi

Director's Corner

This issue of our newsletter focuses on Yale's IT initiatives and how Epic, the electronic medical record, and OnCore, the clinical research management system, are increasing the efficiency and quality of both clinical care and research.

When we were awarded the Clinical and Translational Science Award (CTSA) in 2006, one of our first priorities was to implement an IT platform that would support clinicians and investigators in delivering and developing innovative medical care. At that time, medical records and clinical research used a patchwork of databases, spreadsheets and paper forms that impeded access to data and the management of clinical research. We've come such a long way in just a few years.

For the first time ever, Yale has a single IT system for clinical care, scheduling, and billing utilized across the health system. We also have a clinical research management system that has streamlined the initiation and management of clinical trials, easing the administrative burden for investigators while improving reporting and compliance. Best of all, we have broken new ground in integrating the two systems. Yale was the first institution to integrate Epic and OnCore, and is paving the way for other academic medical centers eager to reap the rewards of this approach. This initiative enhances the ability of investigators to plan and conduct clinical research while improving the experience of those who participate in clinical studies.

As the Epic and OnCore teams continue to work fast and furiously to refine the systems and bring new tools online, we should all be proud of the great strides we've taken to make Yale's IT vision a reality.

Robert Sherwin, M.D.
YCCI Director

Epic: Changing the Way Medicine is Practiced

Now that Epic, Yale's electronic medical record (EMR) system, is in place across the entire Yale New Haven Health System, clinicians and patients are reaping the benefits of a single database poised to transform both clinical care and research.

On the clinical side, Epic's seamless flow of data enables collaboration among physicians; facilitates communication between providers and patients; improves access to health information; and helps to standardize care. From the research standpoint, having a wealth of data in one place represents a potential that investigators are just beginning to explore. While the system is refined and updated continuously, clinicians are becoming increasingly comfortable using it. "There was a steep learning curve, but we wouldn't want to go back to the way things were," said **Allen Hsiao, M.D.**, associate chief medical information officer for Yale New Haven Health System (YNHHS), and associate professor of pediatrics (emergency medicine) and of emergency medicine. "We've all gotten used to having a better understanding of our patients and their illnesses as a whole because of all the information we have available to us now. Having ambulatory, inpatient, emergency department, and operating room information all in one place has dramatically changed the way we practice medicine for the better."

The Big Bang

Yale's implementation of Epic – completed under budget and on time – is nationally recognized for its efficiency and is serving as a model for other institutions. Over the span of three years, Epic has been implemented at Yale-New Haven Hospital; Greenwich Hospital; Bridgeport Hospital; the Yale Medical Group (YMG); Northeast Medical Group; and Yale Health, the health plan for Yale employees and students. There are currently over 1,200 physicians using Epic in their offices and more than three

million patients enrolled in the system. "We moved quickly, but always with an eye toward patient safety and the care we provide," said **Lisa Stump, VP**, associate chief information officer for YNHHS, who served as project director for the Epic implementation.

Yale chose a "big bang" approach to implementing Epic, bringing the entire system – comprising clinical care, scheduling, and billing – live simultaneously at each site. "That makes it a much more robust experience for the end user, and the users get the benefit of seeing an integrated record," said **Lisa Edwards**, director of clinical applications for YNHHS. Rather than getting bogged down in perfecting each element, Yale took a broad approach in soliciting input from all stakeholders and user groups, following a clear plan that included standards for building and testing as well as adhering to a strict timeframe. Physicians from across

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Photo Nicholas Licht

Allen Hsiao, M.D. and Daniel Barchi

Don't miss the Third Annual All-Scholar Retreat on April 1. See page 6 for details.

the health system collaborated to create standardized protocols, using their collective experience to create a single source of content. As a result of careful planning, the collaborative build phase, in which decisions were made on ways to customize Epic for Yale's needs, was completed in just six weeks for the ambulatory application and 12 weeks for the inpatient and revenue cycle applications. Every time a site went live, the Epic team immediately addressed problems, allowing the team members to devise solutions and improve each successive go-live. For example, when the first YMG practice went live in October 2011, there were more than 250 trouble tickets for issues that needed fixing; when the last YMG practice went live in November 2013, there were only three.

Using BPAs to Improve Care

Yale is in the process of activating some of the clinical Best Practice Alerts (BPAs), Epic's version of medical logic modules, which were not turned on during the go-live. "As we get feedback and experts determine whether an alert is useful or clinically relevant, we are fine-tuning them," said Hsiao. The Epic team is conscious of alert fatigue and has turned off or dialed down alerts that fire too often. At the same time, team members are eager to provide clinicians with this quality improvement tool.

One example of how BPAs might be used to improve care is a pilot BPA related to smoking cessation. **Steven Bernstein, M.D.**, professor of emergency medicine and a leading expert on tobacco cessation, wanted to determine whether computerized decision support would help patients quit smoking. He obtained a grant for a

research study in which physicians are randomized to receive computerized decision support when caring for patients who smoke.

When a patient is identified as a smoker in Epic and admitted to internal medicine at YNHH, physicians in the intervention arm receive an alert in the patient's EMR prompting them to consider ordering a smoking cessation medication. The alert contains a link to the suggested order set for dosages in order to make it as easy as possible to order the intervention. The alert also goes one step further by automatically sending a note to the primary care physician on record in the Yale system; sending an alert to Connecticut's Tobacco Quitline, which provides resources and encouragement to stop smoking; and adding tobacco use to the patient's list of problems.

"To our knowledge, no one on Epic has done something like this before, because it actually does things proactively," said Hsiao. "Our hope is that all of these things combined will help physicians help patients quit smoking."

Hsiao and his colleagues are interested in using BPAs to assist investigators conducting research in recruiting patients. The ultimate goal is to feed information from Helix (see "Epic & Clinical Research," page 3) and OnCore into a BPA that can help investigators hone in on eligible subjects for research studies. Investigators who would like to propose a research-related BPA pilot may contact Allen Hsiao at allen.hsiao@yale.edu.

Improved Communication, Information, and Efficiency

Comprised of 19 modules that have been fully integrated and customized for Yale, Epic is seamless from the user's perspective. It provides a wealth of information that was previously either inaccessible or cumbersome to access. "Before, whatever the patient didn't know firsthand was a black box to us, which is magnified if the patient is unconscious or has altered mental status," said Hsiao. "Now we can draw on the expertise of all of our colleagues in Epic—their notes, conclusions, diagnoses—as well as the information in the patient's record." This integration helps

physicians keep better track of patients from visit to visit. "You can open the chart in multiple locations and see what all the providers have contributed, so it's really become the patient's chart," said **Ada Fenick, M.D.**, assistant professor of pediatrics (general pediatrics). "You see a more holistic view of the patient."

For **Christian Pettker, M.D.**, associate professor of obstetrics, gynecology, and reproductive sciences, having access to information from different sites has been useful. He and his colleagues can now access electronic fetal heart rate monitoring from any location through a link in Epic. "It's very helpful for us to get advice from each other or to review charts for quality assurance. That's been very powerful for us," he said.



Christian Pettker, M.D.

Epic promotes collaboration among physicians by allowing them to connect easily with one another—an advantage in caring for patients and managing work flow. Its robust messaging system allows asynchronous communication and immediate access to information that avoids the hassles and delays of the past. Epic also allows providers to identify specialists quickly, even down to expertise in a particular area.

Epic was touted as a way to improve efficiency and it delivers on this promise, once the data have been entered and providers have learned how to use the system. **Jonathan Grauer, M.D.**, associate professor of orthopaedics and rehabilitation and of pediatrics, is impressed by the time Epic saves in patient reporting and communication. “Yesterday, by the end of the day I had read the radiologist’s report for almost every one of the X-rays I had taken; I had dictated all my notes, signed off on them, and probably three-quarters of them were finalized and sent to everybody. That used to take weeks and now it’s hours.”

Ongoing Improvements

The Epic implementation at the end of January at Yale Health marks the completion of the installation; however, the project is ongoing.

“We need to continue to invest time and energy making it work better and even more efficiently,” said **Daniel Barchi**, chief information officer of YNHHS. “The work will go on for years because this is a tool we would like to use for the next 15 or 20 years based on our investment.”

Optimization is being handled through a multi-pronged approach. Enhancement requests can be submitted through the Epic portal for review by experienced clinical support staff members, who are available to help providers when problems arise. Advanced-level training is also available both in the classroom and in the clinic. Epic training experts and analysts are scheduling site visits to each of more than 100 YMG practices to observe the physicians’ work flows to determine whether there are efficiencies to be gained. Although this process will take time, providers won’t have to wait long to benefit from lessons learned along the way; this information will be integrated into the system and disseminated to providers so that everyone benefits.

“Epic can be improved and we will improve it, for instance to decrease the number of clicks for physicians, but it’s going to take some time,” said Hsiao. In the meantime, Yale is installing a new version of Epic—an onerous process due to the content and

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“Epic is not just a fantastic tool that is helping to improve the delivery and quality of care, it is also on the brink of becoming an important component of our research enterprise.”

Paul Taheri, M.D., M.B.A.,
CEO of Yale Medical Group and
Deputy Dean for Clinical Affairs

Epic & Clinical Research

From a research perspective, having information in disparate silos, whether paper files or separate EMRs, made it difficult to pull together data to look at patients globally across large numbers and long periods of time. Complex queries to identify patients who meet specific criteria were all but impossible. With Epic, all of Yale’s clinical data is in one place—in addition to scheduling and financial data—but there are also such other types of information as genomics data that are useful for research. “We need a common place to put that information so we can extract it, analyze it, and use it,” said Hsiao.

Enter Helix, Yale’s version of Epic’s Cogito data warehouse, which will allow Yale to combine the data from its dozen or so data repositories. “We don’t believe all of these separate data warehouses will position us long-term for what we need to do,” said Hsiao. “Helix is our first step to a warehouse that has all the clinical data but also allows us the ability to add outside data.”

Yale has already successfully tested a trial version of Helix, and is in the process of installing the database and populating it with clinical data from Epic. The next step will be to add outside data. One of the areas at the top of the list is the healthy volunteer database maintained by YCCI via www.yalestudies.org. This database contains demographic data but lacks health information; linking it to Epic will make it much more powerful. “Instead of sending out surveys to thousands of people to find out if they’re eligible for a study, with the right analytics, we’ll be able to query the database and immediately find a subset of eligible subjects,” said Hsiao. “I think our investigators are thirsting for a tool like this.”

In the meantime, the data contained in Epic has already proven useful to researchers. Last November, YCCI published a diabetes newsletter in concert with American Diabetes Month highlighting the diabetes and obesity studies conducted by **Kevan Herold, M.D.**, professor of immunobiology and of medicine (endocrinology); and **Silvio Inzucchi, M.D.**, professor of medicine (endocrinology) and director of the Yale Diabetes Center. The newsletter was sent to 22,000 patients whose data were pulled from Epic. “I was impressed at how quickly we were able to put this together and get the word out about our research,” said Inzucchi. “This capability will be tremendously helpful to clinical investigators who need to recruit patients rapidly for their trials.”

Diabetes newsletter



Photo Robert A. Lisak

MyChart: Supporting Patient Care & Research

Events Calendar

Third Annual Scholar Day Retreat

April 1

Noon, TAC Auditorium

Half-day event for students, trainees, Scholars and faculty members who are participating or interested in clinical or translational research. Speakers include **Christopher P. Austin, M.D.**, director of the National Center for Advancing Translational Sciences (NCATS) and **Richard Flavell, Ph.D., FRS**, founding chair of the Department of Immunobiology.

Research-in-Progress Meetings

These meetings feature presentations from YCCI Scholars and Investigative Medicine Program students, as well as trainees from the Medical Research Scholars Program (MRSP). We encourage all faculty and staff to attend.

All meetings listed below will take place at noon in TACN203. (Lunch is provided)

March 10, 24

April 14, 28

May 12

June 9, 23

Please visit our website at <http://ycci.yale.edu/education/lectures/schedule/index.aspx> to find the list of presenters and projects.

Coffee and Conversation

Third Wednesday of each month

8:00 a.m., Cohen Auditorium

(Coffee at 7:30 a.m.)

Lunch and Learn

Second Thursday of each month

Noon, Cohen Auditorium

(Lunch is provided).

For the schedules for Coffee and Conversation and the Lunch and Learn series, please visit: <http://ycci.yale.edu/education/stafftrain/index.aspx>

To register, visit: www.yale.edu/training; browse courses by course owner; then select CTSA/YCCI; select Clinical Trials.

For more information: email **LaToya Howard** at: latoya.howard@yale.edu or call, 203.737.3661

MyChart, the Epic portal that allows patients to access portions of their medical record and communicate with providers, continues to gain momentum, with several hundred active providers and over 40,000 users as of March 3. Besides increasing patient satisfaction and fulfilling meaningful use requirements under the Health Information Technology for Economic and Clinical Health (HITECH) Act, MyChart has the potential to become a key support for health initiatives that will benefit patients.

The Department of Orthopaedics and Rehabilitation has embraced the adoption of MyChart and is aggressively recruiting patients to sign up. In most cases, patients are given an activation code after a clinic visit that enables them to enroll in MyChart, but there is no guarantee they will follow through. Orthopaedics takes a more proactive approach by enrolling patients during their office visits. “That made a huge difference,” said **Jonathan Grauer, M.D.**, “Many providers worry that MyChart’s ability to allow patients to communicate with providers electronically will translate into an avalanche of e-mails from patients; but according to Grauer, that hasn’t been the case. “We’re not seeing a huge change in the need for electronic correspondence, but there’s a lot of comfort in knowing you could contact us,” he said. The benefit of communicating via MyChart is that there is a record of the correspondence in the medical record which providers can easily reference if needed.

The idea behind the department’s push to enroll patients is to be able to perform outcome measures as more features come online. Orthopaedics has developed questionnaires that patients will complete regarding their health – both general and disease-specific – and that will be used as benchmarks to track their progress over time. “We would like every patient, for all of our interactions, to do this,” said Grauer. “It’s where medicine is going: patient-centric, responding to how patients rate themselves.” Instead of evaluating a patient on how an X-ray looks, for example, the concept is to evaluate patients on how they’re actually doing.

Having a large percentage of its patients enrolled in MyChart will allow the department to send the questionnaires to patients through the portal several days before their visit. There are also plans to have a kiosk in the clinic where staff members can assist those who haven’t completed the questionnaires beforehand. Grauer hopes this approach will become standardized across the health system. “In an ideal world, the health system would have the same overall health measure and then each department would administer its own disease-specific measure,” he said. This process will be feasible, however, only if patients actively use MyChart. Grauer is aggressive about enrolling patients because he didn’t want to tackle both initiatives at the same time.

Enrolling as many patients as possible in MyChart can also benefit research efforts. Future plans may include linking OnCore, Yale’s clinical research management system, to MyChart to facilitate recruitment for clinical trials, and utilizing MyChart for electronic data capture for patient-reported outcomes for quality-of-life studies and other research. 🌐



Jonathan Grauer, M.D.

Photo Robert A. Lisak

“It’s where medicine is going:
patient-centric, responding to how
patients rate themselves.”

Connecting OnCore with Epic to Support Research

The completed rollout of Epic's Enterprise electronic medical record (EMR) this past November and the continued implementation of OnCore, Yale's clinical research management system (CRMS), are paving the way to an integrated information technology environment that fully supports research. Each system on its own plays a critical role in Yale's success as a leading clinical research organization. Integrating the two platforms holds even more promise; and Yale stands on the leading edge of adopting new industry standards that enable increased integration between a CRMS and an EMR.

"Yale should be very proud of its leadership in this area. The commitment to adopting new industry standards and the willingness to share lessons learned in the process will help shape the future of what such integration can look like," said **Nancy Smider, PH.D.**, Research Informatics Implementation Lead for Epic Systems Corporation in Verona, Wisconsin.

The implementation of OnCore by itself has been essential to Yale's infrastructure. Investigators have been forced in recent years to spend increasing amounts of time administering and reporting on clinical trials, which detracts from their ability to conduct actual research. "During our search for a clinical research management system, I was very mindful of selecting a system that would meet the needs of our entire research enterprise," said **Thomas Lynch, Jr., M.D.**, director of Yale Cancer Center. "I couldn't be more pleased at how OnCore is helping to support researchers at the Cancer Center and across the medical campus." OnCore now supports 90 multicenter clinical trials and almost 1,500 protocols – of which almost five hundred are investigator-initiated studies – and has generated over 17,000 case report forms.

Epic, a strong proponent of the standards defined by the nonprofit Integrating the Healthcare Enterprise (IHE) organization; and Forte Research Systems (the manufacturer of OnCore, which also supports a standards-based approach) agreed to work with Yale to help realize our vision of supporting and expanding clinical and translational research more effectively. The early phases of this integration have resulted in more efficient and effective planning for clinical studies; faster initiation of studies resulting from easier access to potential patient populations and registries; and general improvements to the research experience for study participants. To the best of our knowledge, Yale is the first institution to adopt the Clinical Research Process Content (CRPC) component, which uses IHE standards for interoperability between EMRS and specialized research systems, in an actual live environment. This adoption enables the sharing of more complex study billing definitions between OnCore and Epic.



Photo Robert A. Lisak

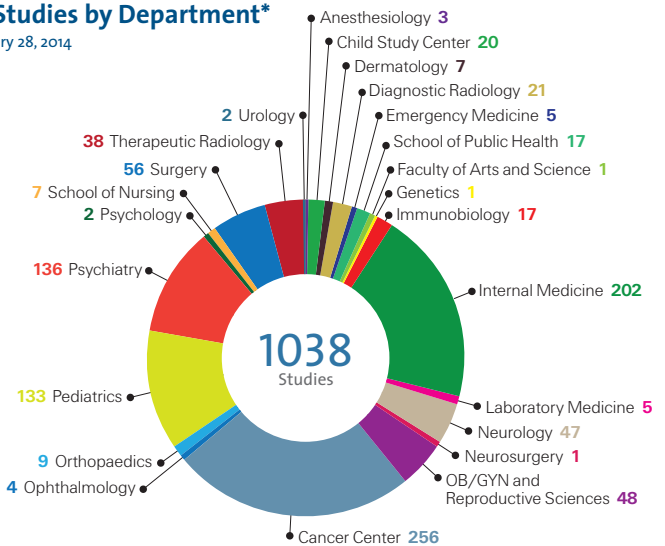
Liat Modiano, Business Systems Analyst, vcci; Kelly M. Anastasio, Associate Director, Clinical Trial Resources, vcci; Sharlene Seidman, M.B.A., Director, Financial and Revenue Applications, vnhhs and vmcg

Future opportunities being explored by vcci include the ability to use Epic's MyChart patient portal as part of direct-to-patient recruitment efforts; interfaces to improve the regulatory landscape by pushing adverse events information from Epic into OnCore; the ability to complete OnCore case report forms without leaving Epic; and patients' ability to complete periodic assessments through MyChart for quality-of-life and other research.

Yale is breaking new ground in its initiative to connect OnCore with Epic using industry standards, and is serving as a model for other academic institutions. Although there is still work to be done, there are also many new opportunities to explore. Today, Yale is well on its way to reaching its goal of integrating health care delivery and research functions to improve the understanding of disease; improve the quality of health care; and ultimately move toward personalized medicine. 🌐

Active Studies by Department*

As of February 28, 2014



* These are studies that are currently active in OnCore and are not representative of all clinical research projects at Yale.

Today, Epic populates subject demographic information in OnCore with the touch of a button, effectively eliminating duplicate data entries and the associated risk of data entry errors. Almost 6,000 subjects have been enrolled so far without the need to rekey demographic data. Information on all active studies and individual participant enrollment status is communicated from OnCore to Epic automatically and in real time, keeping this information in sync between the two systems. In addition, study billing definitions are created in OnCore and transmitted to Epic, which then uses this information to provide enhanced research billing compliance functions. vcci has also worked with Epic and Forte to create an interface for laboratory data that eliminates the need to record lab values manually in OnCore.

vcci's ongoing focus includes developing opportunities for investigators to access clinical data in new ways to support their research efforts, including enabling researchers to assess more accurately whether they will be able to meet accrual requirements, or with appropriate permissions, to tap into the clinical data of over 150,000 patients currently entered in Yale's Epic disease registries. All these changes pave the way for better outcomes-based research – an area that is expected to grow over the next few years.

YCCI Hosts Third Annual All-Scholar Day Retreat

YCCI's third annual All-Scholar Day Retreat is slated for Tuesday, April 1, at the Anlyan Center. This half-day event is open to all students, trainees, Scholars and faculty at Yale who are participating or interested in clinical or translational research.

Scholar Day Registration

You can register online until March 24.

Visit:
<http://ycci.yale.edu/news/3rdscholardayretreat/registration.aspx>.

Registration will be accepted at the event after that date.

The event begins at noon with a poster session and lunch in the foyer of TAC. This year, YCCI welcomes speaker **Christopher P. Austin, M.D.**, director of the National Center for Advancing Translational Sciences (NCATS). He will be joined by **Richard Flavell, Ph.D., FRS**, founding chair of the Department of Immunobiology. There will be an oral presentation of two abstracts in addition to our speakers.

Prior to his present appointment in 2012, Austin served as director of the NCATS Division of Pre-Clinical Innovation (DPI). He is leading NCATS in its mission to generate innovative methods and technologies to enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of diseases and conditions. Austin came to NIH in 2002 from Merck, where his work focused on genome-based discovery of novel targets and drugs. He began his NIH career as the senior advisor to the director for translational research at the National Human Genome Research Institute (NHGRI). He has also served as director of the Therapeutics for Rare and Neglected Disease program and the NIH Chemical Genomics Center, and as scientific director of the NIH Center for Translational Therapeutics.



Christopher P. Austin, M.D.



Richard Flavell, Ph.D., FRS

Richard Flavell is Sterling Professor of Immunobiology and an Investigator of the Howard Hughes Medical Institute. His research uses mouse genetics to study innate and adaptive immunity, T cell tolerance, apoptosis and autoimmunity, and the regulation of T cell differentiation. Among his recent discoveries is the finding that genes interact across chromosomes in T cells, where a master control gene on mouse chromosome 11 may physically touch a gene on chromosome 10, inducing it to produce a protein that primes the cell to fight infection in a specific way. This finding has wide-ranging implications for human diseases that include autoimmune disorders and cancer. Most recently, Flavell has established the connection between inflammasomes, microbial homeostasis, and chronic diseases. 🌐

Using OnCore for Biospecimen Management and Patient Registries by Helen Seow, Ph.D.

OnCore is helping investigators manage biospecimens through its Biospecimen Management (BSM) module, which supports all aspects of sample inventory management. From scheduling, collection, and annotation, through specimen processing, storage, and distribution, BSM can provide easy-to-use solutions with improved safety and security for your valuable samples while eliminating the risk of losing institutional knowledge through staff turnover. Paired with OnCore's Unified Registries Management (URM), which uses electronic case report forms for research subject registries and has the capacity to track clinical outcomes, BSM and URM represent an unprecedented opportunity to move laboratory-based research forward.

Launched less than a year ago, BSM already actively manages records of more than 30,000 biospecimens for over 125 protocols in the School of Medicine. YSM investigators are already capturing research subject data in more than 90 URM custom electronic case report forms. As a Web-based management system, BSM provides easy access to your data while storing them in a HIPAA-secure environment. Additional security features encourage Yale investigators to manage multicenter trials with specimens in BSM by allowing collaborating institutions to enter data into a single system through restricted-access portals. Research subject registration is

supported by an interface with Epic that enters demographic information directly into BSM. Your research operation is further supported by BSM's ability to record detailed tracking of barcoded samples through specimen requests; working lists for reserving and restocking samples; and bills of lading generated for shipping. Like every module in OnCore, standard reports provide investigators with a bird's-eye view of inventory and performance, while BSM's ad hoc reporting capabilities allow detailed views of sample inventory.

YCCI is actively supporting OnCore biorepository projects, including the Yale Healthy Volunteer Biorepository, which includes a list of over 2,500 volunteers available to provide samples for your study. Furthermore, a recent collaboration with Yale's Program on Aging has the potential to expand this list to over 7,500 volunteers.

If you have an HIC-approved protocol for biobanking, clinical research involving specimen collection, or a patient registry and data manager who can collaborate with our data analysts to customize your databases, you are ready to get started with the URM and/or BSM systems. Contact **Helen Seow, Ph.D.**, YCCI's associate director of research administration, at helen.seow@yale.edu. 🌐

How To Avoid Rejection of Your Manuscript

1. Are you an investigator conducting **research involving human subjects**?
2. Have you enrolled your **first subject**?
3. Do you intend to **publish the results of your study**?
4. Did you **register your study on clinicaltrials.gov**?

If you answered **yes** to the first three questions and **no** to the last one, **your manuscript will be rejected by many publications.**

Many journals, including such top-tier publications as the *New England Journal of Medicine* (NEJM) and the *Journal of the American Medical Association* (JAMA), adhere strictly to the policy of the International Committee of Medical Journal Editors (ICMJE) requiring registration of clinical research in a public database in order to be considered for publication. That means that if your study isn't registered before the first subject is enrolled, some journals may not even consider publishing it. Manuscripts from Yale and other institutions have been rejected by NEJM and other journals for failing to adhere to this policy.

If you think your study isn't considered a clinical trial and therefore doesn't need to be registered, you're probably wrong. The ICMJE definition of a clinical trial is: "Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome." Drugs, surgical procedures, devices, behavioral treatments, process-of-care changes and dietary interventions fall under the definition of medical intervention. In fact, the only studies which are exempt are studies that are purely observational.

Other compelling reasons to register your study:

- You want to bill research-related costs to Medicare. Studies that involve Medicare-billable services must be registered on clinicaltrials.gov in order to be reimbursed.
- It's required by law. The Food and Drug Administration Amendments Act of 2007 (FDAAA) requires the registration of clinical trials on clinicaltrials.gov. Failure to comply could result in fines of \$10,000 per violation and the withholding or recovery of grant funds for federally funded trials.

Many investigators have ignored the registration requirement because they think it doesn't apply to them. Don't make this mistake. YCCI provides resources and support to help investigators register their studies. For information on how to register a trial on clinicaltrials.gov, visit <http://ycci.yale.edu/researchers/ors/registerstudy.aspx>. If you need help registering your study or have questions, please contact **Meghan McCarthy** at meghan.mccarthy@yale.edu, or **Jesse Reynolds** at jesse.reynolds@yale.edu. If you have already enrolled subjects but have not yet registered your study, these staff members can provide guidance on how to proceed. ☺

“... if your study isn't registered before the first subject is enrolled, some journals may not even consider publishing it.”



“If you think your study wouldn't be considered a clinical trial and therefore doesn't need to be registered, you're probably wrong.”

“We now have the ability to leverage all the tools we have in place to help drive and support these programs.”

customized information contained in the system. Many improvements requested by Yale will be addressed. For example, since Epic wasn't designed to document academic workflow, the last person who signed the note was identified as the author. In the new version, both the trainee's and attending's names will appear and it will be clear who is the authority. Other academic medical centers will benefit from these changes, and as more of them come online with the system, they will join Yale in guiding Epic on needed functionality.

“The EMR and its tools are dynamic,” said Stump. “What often sounds like a negative – you mean I have to keep working on this forever? – is really the positive of having a flexible set of tools that allows us to adapt to changing needs of patients and the way we deliver care.”

As Yale continues to improve Epic, it will be able to broaden its capabilities across the entire continuum of care. For example, Yale is a beta site for Retrieve Form for Data Capture (RFDC) and is working with Epic and Forte, the company responsible for Yale's clinical research management system, to support data transfer directly into case report forms. Yale will also implement Epic's electronic ICU tool which allows intensivists to monitor ICU patients 24/7. A central location with information displays of clinical parameters will allow physicians to assess the patient's condition and communicate with nurses more efficiently.

Now that the system has been deployed throughout the Yale New Haven Health System, the focus can shift to quality improvement. “We now have the ability to leverage all the tools we have in place to help drive and support these programs,” said Edwards. “This is a really exciting time.”

New Administrator to Support All Areas of Clinical Research

In order to expand support for clinical research across the enterprise, **Rhoda Arzoomanian, RN, MSM**, will join Yale on April 1 as associate director of YCCI and Yale Cancer Center.

A nationally recognized expert in cancer clinical research, clinical trials databases, and the management of an NCI-designated cancer center, Arzoomanian has over 25 years of clinical research experience. She has held the position of associate director of administration at the University of Wisconsin Carbone Comprehensive Cancer Center (UWCCC) since 2010. She began her career at the UWCCC as a research nurse in the Phase I Clinical Research Program and rose to Phase I program manager and assistant director for clinical research before assuming her most recent position. She was responsible for overseeing the UWCCC's operational activities, including administrative, finance, research administration, clinical research, clinical informatics and strategic development.



Photo Michelle Allen

Rhoda Arzoomanian, RN, MSM

At Yale, her role will encompass clinical research across the medical campus, including Yale Cancer Center. She will oversee clinical research regulatory units, developing results-oriented strategies for these areas, as well as testing and verifying compliance and good clinical practices. Her experience over the past 15 years working on three NIH Cancer Center Support Grants at the UWCCC, most recently overseeing the entire renewal and site visit in 2012, will be invaluable in her role at Yale, as will her ability to bring people from diverse backgrounds together.

“We are thrilled to have Rhoda join our team and help us expand Yale's clinical research program,” said **Robert Sherwin, M.D.**, director of YCCI.

“Her experience in cancer clinical research will translate across our entire research enterprise as we seek to fortify and grow clinical trials at Yale.”

YCCI has a history of collaboration with Yale Cancer Center, as evidenced by their identification of shared goals and resources to solidify a mutually beneficial partnership. The two centers jointly support the Yale Center for Analytical Sciences and several research cores; have worked together to implement OnCore; and merged components of the infrastructure to support clinical and translational research, including financial administration, billing, IND support and development, quality assurance, and training. Arzoomanian's familiarity with cancer clinical research and her role in overseeing clinical trials across the entire institution help cement the relationship between YCCI and Yale Cancer Center, which has benefitted clinical research as a whole at Yale.

“We are delighted to welcome Rhoda to Yale Cancer Center. She will bring a bolt of energy to our efforts to build a rigorous infrastructure to support our expanding portfolio of clinical research,” said **Thomas Lynch, Jr., M.D.**, director of Yale Cancer Center.

At the UWCCC, Arzoomanian worked with both Epic and OnCore, an approach similar to Yale's enterprise-wide adoption of these systems as the foundation of its IT platform. She was a subject matter expert and worked on the design of the financial billing module prior to and during the OnCore implementation at the UWCCC, which was the first site to implement this system. The UWCCC is also a Clinical and Translational Science Award (CTSA) site, and she has worked with Yale colleagues as the two institutions have collaborated and shared lessons learned over the past several years.

“I am absolutely thrilled to be joining Yale,” said Arzoomanian. “I'm excited to be part of this amazing team and I hope my past experience can bring a fresh new perspective.”