Research Updates

The next presentation is scheduled for September 8, from 11:30 – 1:00 in WHM 3034.

New Announcements:

- **Laboratory Charges.** Recently, there have been a few questions related to the drawing of research labs. For example, if a treatment center nurse draws research labs without any other standard of care (SOC) labs being drawn, assumptions have been made that if the port was already being accessed for chemotherapy as a part of SOC there would be no additional charges. However, when this gets charted a biller/coder reviews the activities of the day and assigns appropriate charges. So if the RN charted “research labs drawn”, the coder would then put in a charge for the blood draw via port access. If the consent form says that they will not be charged for the blood draw, it is important that the charge route to the grant.

- **Price Changes for FY2015.** A summary of price changes effective 7/1/14.
  - Most Hospital Technical Fee Codes were increased by approximately 5.0%
  - Professional Fee Codes (TNMC Pro Fee Codes were increased by 5%) UNMC-P Pro Fee Codes were not increased, with some exceptions; most UNMC-P fees will increase effective Jan 1, 2015.
  - Room rates and observation were increased in aggregate by approximately 15% (varies by accommodation code)
  - Visit codes were increased by 5%
  - Supply & Drug prices were based on the financial plan inflation assumptions for FY15 of 1.17% for supplies and 5% for drugs.
  - Areas with special adjustments:
    - Endoscopy and PACU charges have been reduced
    - Perioperative services base rates and minutes have been synced between TNMC & BMC for consistent pricing throughout the Clinical Enterprise.
Codes listed with a zero price do not have prices “hard-coded” on the Charge Master but come from another system (ie. Pharmacy Willow or Mediclick) or may require manual entry.

Pricing information can be found on the NHS/Chargemaster drive: 
R:\NHS\Chargemaster\EPIC - Chargemaster\FY15 Clinical Enterprise Price Increase.xlsx

In addition this file is updated twice per month to show any new codes or changes.

R:\NHS\Chargemaster\EPIC - Chargemaster\_EPIC Chargemaster History in Excel.xlsx

The remainder of this newsletter contains a brief summary of the topics that were discussed during the June 12 meeting.

In the Know: Clinical Enterprise Research Updates

*Presented By Chris Kratochvil, MD*

There is no doubt that change is inevitable and our Clinical Enterprise is transforming how research is done at UNMC as well. Through the Enterprise Research Performance Improvement Project clinical research initiatives are advanced. If you have questions or ideas for process improvement contact the Clinical Enterprise Research Transformation Team through Dr. Chris Kratochvil.

**Enterprise Research Performance Improvement Project:**
- The workstream team reports to the clinical leadership weekly. The team is led by UNMC Associate Vice Chancellor for Clinical Research Chris Kratochvil.
- The Research Pharmacy has added additional space in the Lied Transplant Center and has added an additional pharmacist and pharmacy technician.

The **Conditions of Treatment** form will be undergoing some changes in the near future. Soon COT forms will contain a “contact me for research” statement and an “opt out” checkbox. This will provide an additional mechanism for ethical access to patient populations for clinical trial recruitment.
Research Billing

Presented by LuAnn Larson, RN, BSN, CCRP

A research billing plan has been formulated in response to deficiencies which were revealed during a recent DeLoitte audit. Issues that were cited were:

- Dates of Service (DOS) related to research studies were not identified as research-related in Epic.
- Subject lists were incomplete or had incorrect DOS
- V70.7 was not being added
- Clinical Trials NCT# was not on required bills
- Q1 modifiers were not being added to Standard of Care bills when patients were enrolled in studies.

Measures that are being implemented to address these deficiencies include:

- Developing educational tools for coordinators and billers.
- Assessing research related billing policies
- A new research billing position will be created that will be responsible for revising and monitoring the research billing process.

You can contact:

- ITS Help Desk for answers to research questions (9-7700 - option #2; ask to be transferred to the “How To” desk)
- Amy Swenson to move hospital or profee charges 2-3491; aswenson@nebraskamed.com

Pro Fees

Presented by Chris Kratochvil, MD

Budget preparers are encouraged to negotiate budgets as close to full cost recovery as possible with their sponsors. Effective June 28, 2014 professional fees in clinical research will be automated in Epic for research billing. The Clinical Enterprise currently subsidizes professional fees such that your research account will be automatically billed at 25% of the rates posted on the Chargemaster. If 100% write-off is needed, the protocol will need to be submitted to the Clinical Translational Research Review Committee for additional subsidization. Contact LuAnn Larson for details.
MI29 Investigational Devices
*Presented by Grace Videtich, BS, Sponsored Programs Administration*

A new policy, MI29, detailing the use of investigational devices went into effect on June 11, 2014. This policy is the first to bridge use across both the Clinical Enterprise and UNMC. A review, similar to that of the SRC, by the Investigational Device Review Committee (IDRC) must now take place prior to IRB review. The committee will review details such as device acquisition, storage and labeling. The policy can be accessed through the TNMC Employee Resources Policy and Procedures Manual, reference MI29.

Measuring Performance in a New Way
*Presented by Deb Vetter, M S, Director, Sponsored Programs*

Recognizing that days to contract are an important industry consideration when selecting a study site and critical to an efficient academic health center, UNMC Sponsored Programs (SPA) has set a new performance measure for FY15: To finalize 70% of clinical research negotiations within 75 days.

Partnering with you and other stakeholders, such as the Sponsor, the IRB, Legal Counsel, the Compliance Office, and the PI, is key to achieving this goal. SPA will be implementing several approaches to reduce time to contract. As a first step, our focus is on communication.

We plan to tell you the status of our contract negotiations. We are interested in knowing the status of your IRB, how to prioritize your pending agreements and if your unit is no longer interested in continuing with an identified study. We share your goal of being an efficient study site.

SPA will continue to provide updates on our efforts to reducing time to contract.
CITI and Good Clinical Practice (GCP)

*Presented by Jenny Kucera, MS, CIP*

In an effort to provide clinical investigators and research personnel with high quality training the GCP modules have been incorporated into the CITI Group 1 biomedical course. This course meets the GCP training requirements of many sponsors and will now be required for all personnel listed on an IRB application for a clinical trial. To see a list of sponsors for which this training meets minimum GCP training requirements, click [HERE](#).

Completion of the Group 1 biomedical and GCP course will be required at the time of initial CITI training and at re-certification. When you log into CITI you will be required to answer questions that will enroll the learner into the appropriate course. Those involved in the conduct of clinical trials will be required to select the “Human Subjects Research” option, “Group 1” course. Additional information and instructions can be found on the [UNMC IRB website](#).

Contact Jenny Kucera in the IRB for questions (9-6119 or jikucera@unmc.edu).

Certification & Credentialing

*Presented by LuAnn Larson, RN, BSN, CCRP*

A **certification** plan is being explored that will require all research coordinators whether Clinical Enterprise or UNMC employed to be certified by the organization. Suggestions are being solicited; contact LuAnn Larson with your ideas (9-8555 or llarson@unmc.edu)

TNMC’s **credentialing** policy (HR44) ensures that the hospital assesses the ongoing qualifications of allied health professionals not under their employment. UNMC employees who interact with patients within the Enterprise are required to be credentialed. Efforts are being made to reduce the redundancy between the two systems and to streamline the credentialing and annual review process.
Pharmacy Reminders

Presented by Chris Kratochvil, MD

Outpatient Pharmacy Orders If a patient requires investigational medication for home use or use in a clinic (other than Lied, Village Point, or Bellevue Infusion Clinics) then you will need to provide a prescription to the outpatient pharmacy.

Handwritten Prescriptions Green, carbon copy investigational prescriptions are available for handwritten prescriptions. Contact Jon Beck for blank prescriptions.

OneChart Printed Prescriptions All investigational medications should be listed in the patient’s electronic medical record. A printed prescription can be generated during this process and presented to the outpatient pharmacy. For this reason, patient information including medical record number needs to be accurate in OneChart.

Hard Copies Required OneChart investigational orders are never sent electronically to the outpatient pharmacy; a hardcopy must be provided. Please follow verbal orders and email orders with a hardcopy for the record. Be advised that outpatient pharmacy staff need a valid prescription to fill orders.

Valid Prescriptions contain patient name, date, study medication, form, quantity, route, directions for use, and signature of authorized study member. Please also include IRB and medical record numbers.

For help with the OneChart process please see Courtney Kennedy’s Tip Sheet on investigational medications “documenting patient’s medications in the chart.”