IRB Protocol
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CRC Rotation
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A. Study Purpose and Rationale

In many intensive care units (ICUs), including those at NewYork-Presbyterian/Columbia University Medical Center (NYP/CUMC), most patients undergo daily chest x-ray (CXR). These studies are ordered to monitor the positioning of certain devices, such central venous catheters and endotracheal tubes, and to track the progression of acute cardiopulmonary disease. Their potential benefits, however, must be weighed against their cost and associated radiation exposure. Although the radiation associated with a single chest film is minimal, the cumulative exposure to the population is significant.

Studies from the 1980s suggested that routine radiographic assessment of critically-ill patients was justified because of the frequent detection of novel findings. One prospective study[1] examined 140 patients admitted to the ICU of a major academic medical center. The primary reason for admission was postsurgical care, and 0.7 portable CXRs were performed per patient per day. The authors found that 44% of the post-admission radiographs contained a cardiopulmonary finding (e.g. "pneumothorax, collapse, diffuse or focal infiltrate, effusion, and congestive heart failure"); however, it is unclear how many of these findings were new since the admission film, and the abstract and main text were inconsistent on this point. The authors also claimed that 65% of the radiographs led to changes in management; however, it is unclear whether such changes yielded any clinical benefit. Several similar studies[2,3] from this period reached similar conclusions despite comparable limitations.

Nonetheless, many centers adopted a policy of obtaining routine daily CXRs in critically-ill patients. In fact, until recently even the American College of Radiology appropriateness criteria stated that "routine daily portable radiographs are indicated for patients with acute cardiopulmonary problems." More recent work, however, suggests there may be no basis for this practice. For example, a recent meta-analysis[4] found that both routine and "on-demand" CXRs (i.e. based on a change in clinical status) were associated with similar lengths of stay and mortality rates. Only two of the nine studies in this meta-analysis, however, were randomized-controlled trials (RCT). One RCT[5] included 94 intubated patients in the medical ICU, who were randomized based on their record number to one of these two imaging strategies; the authors found no difference in length of mechanical ventilation, length of ICU stay, or mortality, but it is unlikely the data were powered to detect such differences. The other RCT[6] also examined mechanically ventilated patients and reached similar conclusions, but despite having about twice the sample size, it too was likely underpowered.

Although these RCTs may provide some evidence that mechanically ventilated patients do not need routine CXRs, they do not include other sub-populations for whom such surveillance is still considered valuable. Such sub-populations include, for example, patients with pulmonary edema or multifocal pneumonia. In the NYP/CUMC cardiac care unit (CCU), most patients with acute pulmonary edema undergo routine CXR to monitor the effect of diuresis, even though the advantages over physical examination alone remain unproven.

B. Study Design and Statistical Analysis
This study is a randomized-controlled trial comparing the clinical outcomes associated with daily routine CXR or "on-demand" CXR in the CCU.

It will include consecutive patients admitted to the CCU with the primary diagnosis of acute volume overload secondary to heart failure. These patients will be evenly randomized either to daily or on-demand CXR, with a list of suggested indications provided for the latter. The randomization will depend on the month of the admission date; those admitted in even-numbered months will receive daily CXRs (in addition to any other imaging studies that are clinically indicated), while those in odd-numbered months will receive on-demand CXRs. This strategy obviates the need for individualized consent and, in addition, will help the on-service physicians become more reliant on clinical findings other than imaging. Once a patient is randomized to a group, no crossover will be permitted.

In the "on-demand" group, appropriate indications for CXR will include:
- Insertion or adjustment of an endotracheal tube
- Insertion of adjustment of an endovascular catheter
- Suspicion of a misplaced endotracheal tube or endovascular catheter
- Suspicion for a new cardiac or pulmonary process

    - Fever
    - Increased cough or increasingly purulent secretions
    - Absence of breath sounds
- Any other change in clinical status for which the on-service physician feels a CXR is indicated

In the “on-demand” group, inappropriate indications for CXR will include:
- Routine monitoring of the position of an endotracheal tube or endovascular catheter
- Routine assessment of the degree of pulmonary edema
- Evaluation of an interval change in a pneumonia (unless more than two weeks have passed since the last imaging assessment, or a new pneumonia is suspected)

Physicians are already required to indicate a reason for a CXR when placing the order. The CCU physicians will be asked to complete this information as accurately as possible so that it is available for analysis.

In this pilot study, the primary outcomes will be mean length of stay in the CCU. Assuming that this variable is normally-distributed with a standard deviation of 2 days, 257 patients will be required in each group in order to have a power of 0.8 to detect a half-day difference, if such a difference actually exists, using an unpaired t-test with an alpha less than 0.05. An additional endpoint will be a composite of intubation, readmission to the CCU within thirty days, cardiac arrest, and death; however, this initial study will not be powered to detect differences in these variables. We will also record the number of CXRs performed per group and their indications.

C. Study Procedure.
The study will not require any additional drugs or procedures beyond what is typically provided in the CCU. CXRs can be conducted either in a radiology suite or at the bedside. In the latter case, they are known as “portable” studies. Essentially all of the x-rays performed on CCU patients are portable studies, since patients typically cannot stand upright for a regular film and, moreover, are unable to leave the CCU without physician supervision. A technician can obtain a portable film in about five minutes.

Because the CCU has 36 beds, and each admission lasts an average of about five days, we estimate it will take three months to enroll an adequate number of patients.

D. Study Drugs: N/A

E. Medical Device: N/A

F. Study Questionnaires: N/A

G. Study Subjects
The inclusion criteria will include:
- Acute heart failure, either systolic or diastolic, with or without a chronic component
- A primary diagnosis of volume overload — as determined based on physical examination (jugular venous distension, adventitial breath sounds, peripheral edema, etc.) laboratory data (azotemia, elevated BNP, etc.), and baseline radiograph (pulmonary vascular congestion, pleural effusions, etc.) — irrespective of concomitant diagnoses

The exclusion criteria will include:
- Age less than 50 years (because of radiation exposure)
- Pregnancy (because of radiation exposure)
- Presence of a Swan-Ganz catheter (because of concern for pulmonary infarction)

Factors such as the use of inotropes or mechanical ventilation will not affect the decision to enroll. All patients will exit the study either when the composite adverse events outcome is reached or at the time of CCU discharge.

H. Recruitment of Subjects
Subjects will be automatically enrolled at the time of admission. Because all admissions in a given month will be assigned to a particular x-ray ordering strategy, individual consent will not be required.

I. Confidentiality of Study Data
Each patient will have a unique study identifier linked to his or her medical record number, and this information will be stored in a secure location accessible only to the investigators. All other information –

including number of x-rays, length of stay in the CCU, intubation, cardiac arrest, death, and so on – will remain in the secure electronic medical record.

J. Potential Conflict of Interest
There is no possible conflict of interest relevant to this study.

K. Location of the Study
The study will be conducted entirely in the CCU, located on the fifth floor of Milstein Hospital Building and the Heart Center of NewYork-Presbyterian Hospital / Columbia University Medical Center.

L. Potential Risks
The risk to those in the on-demand x-ray group is that the diagnoses that would have been made with routine imaging will instead be missed. The existing literature, however, suggests this risk is minimal and that even if such diagnoses are missed, the clinical course is unlikely to be affected.

The risk to those in the daily x-ray group is of increased radiation; however, such exposure is clearly considered acceptable to most physicians, since daily x-ray is often considered the standard of care. Also see (P) below.

M. Potential Benefits
The major benefit to those in the "on-demand" group will be avoidance of the radiation and inconvenience associated with daily chest x-rays.

N. Alternative Therapies N/A

O. Compensation to Subjects
Subjects will not be compensated.

P. Costs to Subjects
Subjects will not incur additional costs beyond that typically associated with a CCU admission, which in nearly all instances is covered by insurance. In those who do not have preexisting insurance, emergency Medicaid is typically instated to cover the costs of the admission.

Q. Minors as Research Subjects N/A

R. Radiation or Radioactive Substances
Although this study involves radiation, it does not expose the subjects to any more radiation that would be incurred during a typical CCU admission.

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2. Janower ML, Jennas-Nocera Z, Mukai J. Utility and efficacy of portable chest radiographs. AJR Am J Roentgenol 1984;142:265-7.
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