Creating a Reliable Method for Reviewing Emergency Uses of Investigational Drugs, Biologics and Devices

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Background

FDA regulations require physicians and IRBs to follow certain procedures when using investigational drugs, biologics and devices for clinical care in emergency situations when there is no time to obtain prior IRB review and approval. [See 21 CFR 56.104(c) and 21 CFR 56.102(d)]

Problem

Seattle Children’s Human Subjects Protection Program (HSPP) lacked a standard process for handling emergency uses (EU) of investigational drugs, biologics and devices. The combination of infrequent incidence, complex regulatory criteria and no standard report form led to confusion on behalf of physicians and unnecessary HSPP staff time spent ensuring regulatory requirements were met. In 2011, using Continuous Performance Improvement (CPI) methodologies (a.k.a. “lean” methodologies), HSPP staff refined the processes for receiving and reviewing an EU. As part of this CPI overhaul, a reliable method was created to handle EUs.

An Introduction to CPI

At Seattle Children’s, we call “lean” CPI, which stands for Continuous Performance Improvement. The methodology of CPI focuses on taking a balanced approach to improvement through the continuous elimination of waste.

Our Philosophy & Strategy

• Ask why five times to get to the root cause of the problem (we call this the “5 Why’s”)
• Focus must be on the patients and families
• Front-line staff and physicians are the foundation of our change strategy
• Facts and data drive decisions
• Perfection is the enemy of the good
• Technology is an enabler, not the answer
• Promote continuous learning using the Plan-Do-Check-Act (P-D-C-A) cycle
• CPI is a long-term, generational effort

Applying CPI to the Emergency Use Process

HSPP staff identified the root causes of the unclear EU process and determined they mainly stemmed from a lack of policies, forms and templates to guide physicians and HSPP staff, as well as a lack of education/outreach by HSPP staff and clinics/departments regarding EU requirements. As a result, the following actions were taken by HSPP staff to create an accessible and well documented process:

Action 1: Update IRB Policy
HSPP staff refined IRB policy to help physicians and HSPP staff understand the different regulatory criteria for drugs/biologics and devices and the physician's and IRB’s responsibilities before and after initiating an EU.

Action 2: Create a Standard EU Report Form
HSPP staff created an EU report form to guide physicians step-by-step through the reporting process. This form serves several different functions. It provides information on the timing of the necessary players in the process (independent physician, manufacturer, sponsor and/or FDA), approvals and reports, and it also acts as an IRB follow-up report form.

Action 3: Create an EU Consent Form Template
Although IRB approval of an EU consent form is not required, past experience indicated that many physicians looked to the HSPP for guidance. In response, HSPP staff generated an institutionally approved emergency use consent form template to assist physicians in providing as many patient protection measures as possible to recipients of the drug or device.

Action 4: Update IRB Webpage
HSPP staff created a simple webpage outlining the emergency use process. This page is easily found from the IRB homepage and includes links to the IRB policy, emergency use report form and emergency use consent form.

Results

Since implementing this reliable method, both HSPP staff and physicians have seen an increase in consistency, transparency and efficiency. Primarily:

• A decrease in search time for all involved
• A decrease in re-work for physicians
• A decrease in research time for HSPP staff
• A decrease in communications/questions about the EU process

It is important to note that this process is always subject to the PDCA cycle. If additional problems are identified over time, the process is revisited and actions are taken when necessary.

Contact Information
For copies of this presentation or to obtain additional information: kelly.hebner@seattlechildrens.org
For information on Seattle Children’s emergency use process and associated documents: http://www.seattlechildrens.org/research/support-services/institutional-review-board/emergency-use-process/