EPA 2: Enroll and Treat Patients on Clinical Research Trials

Supervision Scale for This EPA

1. Trusted to observe only
2. Trusted to execute with direct supervision and coaching
3. Trusted to execute with indirect supervision and discussion of information conveyed for most simple and some complex cases
4. Trusted to execute with indirect supervision but may require discussion of information conveyed for a few complex cases
5. Trusted to execute without supervision

Description of the Activity

Clinical research trials have played a key role in improving outcomes for children with hematologic and oncologic disorders.

Participation is in many ways considered standard of care for these patients. Thus, it is essential for pediatric hematology/oncology subspecialists to learn the skills necessary to properly enroll and treat patients on clinical research trials.

The specific functions which define this EPA include:

1. Reviewing and selecting the appropriate clinical research trial to offer a given patient
2. Explaining details of a clinical research trial to patients and families of varying educational backgrounds
3. Obtaining informed consent for participation on a clinical research trial
4. Fulfilling all requirements necessary to enter a patient on a clinical research trial
5. Properly adhering to study requirements and reporting adverse events as indicated
6. Ensuring patient safety and recognizing when the best interest of the patient necessitates deviation from the study protocol

Judicious Mapping to Domains of Competence

- Patient Care
- Medical Knowledge
- Practice-Based Learning and Improvement
- Interpersonal and Communication Skills
- Professionalism
- Systems-Based Practice
- Personal and Professional Development
Entrustable Professional Activities
EPA 2 for Pediatric Hematology-Oncology

Competencies Within Each Domain Critical to Entrustment Decisions*

| PC 1: | Gathering information |
| PC 7: | Developing management plans |
| PC 11: | Using information technology |
| MK 2: | Practicing EBM |
| PB LI 10: | Engaging in lifelong learning |
| ICS 1: | Communicating with patients/families |
| P 2: | Demonstrating professional conduct |
| SBP 2: | Coordinating care |
| SBP 5: | Working in interprofessional teams |
| PPD 8: | Dealing with uncertainty |

*Based on original Pediatrics Subspecialty Milestones ©2015 ACGME/ABP. All rights reserved.

Context for the EPA

Rationale: Great strides have been made in the treatment of children with cancer and blood disorders over the past several decades, leading to significant improvements in cure rates for many diagnoses. These improvements have in large part been due to participation of a high percentage of these patients on clinical trials designed to assess and directly compare the current standard treatment with an experimental treatment. To continue to make these advancements, it is critical that trainees in pediatric hematology/oncology understand the importance of properly conducted clinical research to our field, acquire the necessary knowledge and skills to enroll and treat a patient on a clinical trial, and, to the extent possible, have their patients actively participate on clinical research trials.

Scope of Practice: Scope of practice involves any child from birth to young adulthood who has been diagnosed with a cancer or blood disorder and who may be eligible for participation on a treatment study. It will require that the pediatric hematologist/oncologist practice at an institution that is able to provide the support needed, such as a functioning institutional review board and adequate research assistant support, to meet the requirements and regulations necessary to open and successfully run treatment studies. Since pediatric cancer is a rare disease and it is difficult to successfully carry out single-institutional research studies, it is important that the institution is able to collaborate with other institutions and participate on multi-institutional studies, through such organizations as the Children’s Oncology Group.