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Utilizing Schedule Overview Tools to Orchestrate Long Study Visits

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Description of the Problem

Early phase oncologic clinical trials often require patients to endure long days in the infusion suite of the Seattle Cancer Care Alliance (SCCA). This is especially true during the first few cycles of an investigational treatment when the greatest quantity of safety and pharmacokinetic assessments are being conducted. Over the course of a full day, numerous overlapping and invasive study procedures must be timed in perfect synchrony. These types of study visits are prone to protocol deviations by clinic staff error and may cause undue patient anxiety. Furthermore, patient anxiety at such a foundational stage in their clinical trial participation can be deleterious to their future relationship with research staff and may precipitate other unforeseen compliance issues.

Challenges for Coordinators

Translating Protocol Logistics
Study protocols typically list the procedures that are required for each study visit. However, protocols lack practical information about the logistical relationships of these procedures. Instead, it is up to the research coordinator (RC) to translate a protocol's outline of the study visits and transcribe them into "itineraries" with concrete deliverables (e.g., clinical orders for site staff).

Navigating Study Communications
The communication plan for patients and staff is also left to a RC's discretion. Consent forms provide enough information to help patients formulate a basic understanding of their study participation. However, neither the protocol nor consent forms address brass tacks at the core of a patients' study experience (e.g., when to expect their next bathroom break or meal; whether or not to keep their implanted port accessed).

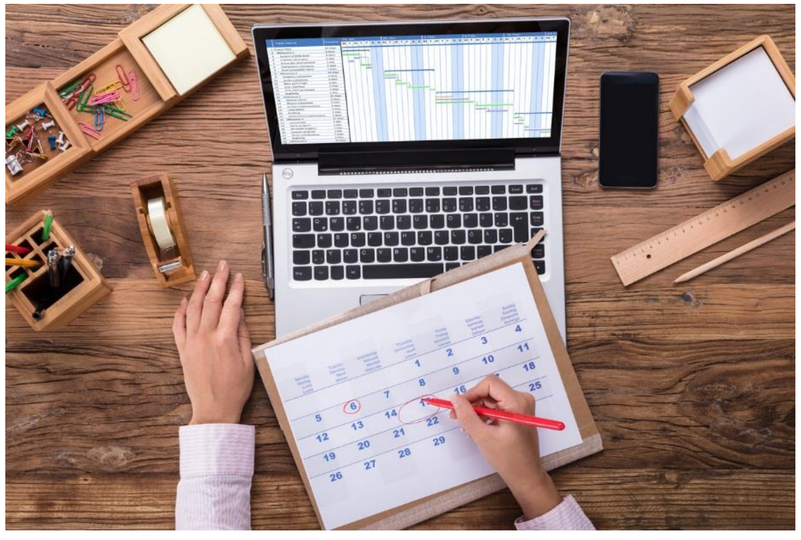
Best Practice

To develop a simple, yet versatile schedule overview tool that provides a clear and immediate picture of a study visit's itinerary to minimize confusion among patients and clinic staff.

- ►Increase patient's understanding of what they will experience in a study
- ►Improve participant management by site staff
- ►Improve overall communications

At a Glance: Schedule Overview Tools

Schedule overview tools are referable documents that guide clinical trial stakeholders (patients and clinic staff) through the labyrinth of precise and timed procedures required for a study visit. The tool typically consists of a single-page document for clinic staff or descriptive email to patients.



Methods

1. Create a customized schedule overview tool for patients and clinic staff that includes the following elements:
   - **Name of each procedure**
   - **Timing of each procedure (including windows, for nursing staff)**
   - **Relevant footnotes (e.g., fasting requirements)**
   - **Contact information of research staff**
2. Ensure each patient and clinic staff member has time to review the tool in advance of the visit (1-2 days for patients and up to several hours for clinic staff).
3. Follow up with one-on-one discussions prior to the visit to answer questions and provide clarifications.

Outcomes

- Patients are more actively engaged in the informed consent process throughout the study
- With the one-on-one discussions, patients and staff have a forum to address concerns to RCs
- Standardized communication enables consistency across all patient visits, promoting high-quality research data
- RCs have greater control over the management of protocol deviations
- Should deviations occur, the RC can use details from the tool to identify and correct the problem
- Schedule transparency supports a positive and productive clinic experience for long study visits
- Relationships between patients, clinic staff, and research staff are improved

Suggestions

- Information in the tool may already be included in clinical orders, so it is helpful to clinic staff to provide detailed examples of patient schedules
- Collaborate with regulatory coordinators to ensure that the most appropriate information is presented to patients following institutional requirements