Utilization of Shared Medical Appointment for First Day Observation for Fingolimod

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Rationale

The concept of Shared Medical Appointments (SMA) is a recent innovation in health care allowing groups of patients with a common diagnosis to be seen simultaneously. SMA can also be used for follow-up care and treatment plan implementation. A shared medical appointment provides a secure but interactive setting in which patients have improved access to their health care providers with the benefit of sharing experiences and advice with one another. Shared medical appointments can provide added value to the current management of neuro-inflammatory diseases. SMA are an appropriate forum for advanced practice nurses/clinicians to meet individually with a patient and monitor patients as a group who are receiving a new medication therapy.

Patient education has long been a domain of nursing practice and has been instrumental in patients obtaining a better understanding of their disease processes, medications and symptoms that reflect disease status. Review of the literature supports that nursing education has been crucial in chronic disease management. Specifically for MS, nursing interventions have been helpful in improving DMAT drug adherence in patients. (Caom et al. 2010). Frondman et al. (2009) reported that one of the most common reasons patients were nonadherent to DMAT regimens was that they "forgot" to take the medication. Additionally, medication adherence may be related to the patient's perceived benefit of therapy (Tuncer et al., 2007), another area for nursing intervention.

The Cleveland Clinic piloted utilizing SMA approximately 10 years ago to improve patient access and quality of care. SMA have been utilized in chronic disease management, women's health, diabetes, cardiac and breast departments. (Bronson 2004). SMA offer the opportunity to manage patients with similar health issues and have been shown to help patients form support networks as they openly discuss their symptoms and disease management with each other and a common health care provider. This forum offers the opportunity to identify trends among patient groups and universal management techniques as well as develop individual plans of care. Furthermore, these care trends often lead to avenues for research to establish evidence-based practice.

Fingolimod

Fingolimod (Gilenya®) was approved by the FDA for use in the United States on 9/22/10. The Food and Drug Administration in conjunction with Novartis, developed a risk evaluation and mitigation strategy (REMS) to ensure the benefits of Gilenya outweigh the potential risks. In addition to the recommended screening tests prior to start of medication, this REMS strategy also recommended monitoring of the patients pulse rate and blood pressure intermittently for a six hour time period after the first dose of Gilenya.

A plan was developed at the Mellen Center to start patients on fingolimod and complete the first day observation (FDO) in the same visit. This plan was implemented for one month. The testing that was recommended as part of the REMS prior to FDO includes recent (i.e. within six months) CBC:
- Transferrin and bilirubin levels
- Baseline electrocardiogram (EKG) is important for patients using antiarrhythmics (including beta-blockers and calcium channel blockers, Class Ia and Class II antiarrhythmics), or with a history of 2nd degree or higher AV block, sick sinus syndrome, prolonged QT interval, ischemic cardiac disease, congestive heart failure, hypothyroidism (less than 5.0 ng/dl) or aortic aneurysm.

Baseline ophthalmologic examination to rule out macular edema.
- Pregnancy testing: Counseling women of childbearing age on potential for adverse fetal outcomes and need for contraception.
- Variola zoster virus (VZV) serology for patients with a history of chicken pox or prior vaccination. If patient is negative for antibodies, VZV vaccine should be considered. Patients who receive VZV vaccination should not begin Gilenya treatment for one month.
- Other appropriate exams or testing:
  - Pulmonary function tests (for patients with history of pulmonary disease, abnormality or other conditions affecting pulmonary function).
  - Skin Exam by dermatologist (recommended for those patients with history of melanoma).
  - Consultation with a cardiologist for an abnormal ECG.

Starting Fingolimod

The process begins with completing a service request form (SRF) which is both consent for Novartis to begin the insurance verification process and the initial prescription of Gilenya. Our office is notified by Novartis when insurance approval has been obtained. Then all recommended screening tests are completed. Additionally, MC clinicians determined that ECG would be completed for all patients prior to FDO. Results of all screening tests, pregnancy status (if applicable) are documented in patient's notes (abstract format in electronic medical record) and once the clinical team OK's the approval, medication is ordered. Clinicians at the Mellen Center wait for insurance approval (or patient availability) and medical clearance prior to ordering the first dose starter pack. Currently the Mellen Center requires all patients for the first dose starter pack to be shipped to our center, with the exception of governmental insurance.

Once the starter pack has arrived a FDO, the patient is notified by the appointment office to schedule the first dose observation (FDO). The FDO takes place in a shared medical appointment (SMA) with other patients starting Gilenya that day.

Overview of Shared Medical Appointment

Resources needed:
- Staffing: Billing Provider (MD, APC)
- Other Clinical (Medical Assistant)
- Clinical Support
  - Operational Requirements
    - Scheduling
    - Conference Exam room
    - Comfortable chairs
    - Computer
    - Educational Information
    - Bathroom Facilities
    - Pulse and Blood Pressure Monitoring Equipment

Schedule for FDO

Prior to the FDO the advanced practice clinician (APC) who is managing the session confirms all requirements to participate in the FDO have been met and that the medication has arrived. This process has been established to ensure patients are medically cleared and that the medication is on hand to be administered during the observation. During the SMA the APC facilitates the group process, flags interaction between patients and manages time.

Quality Improvement

A questionnaire to collect data about this type of visit was collected as part of a quality improvement project. The 10 questions focused on patients ratings of the shared medical appointment and the components of the visit.

Conclusions

SMA for FDO for Fingolimod constituted a practical system to meet the demand for accessibility of the new treatment option for MS. Most patients had a favorable response/experience at the SMA and strongly agreed (89%) that the type of appointment met their needs for first dose observation. When asked if they would be interested in future use of Shared Medical Appointments for Gilenya first dose follow up appointment or Multiple Sclerosis education session, the response rate fell to 39% who strongly agreed. (This type of response has been previously reported about SMA)

At the time of this paper, however, the conclusion of SMA for FDO remains uncertain with the new monitoring criteria.

References

Bronson, D.L., Maxwell, R., Shared Medical Appointments: increasing patient access without increasing physician hours. Cleveland Clinic Journal of Medicine 2004; 71: 369-377