December 6, 2019

Regarding: Oncology Care First Model: Informal Request for Information

To Whom it May Concern:

I am writing in response to the Oncology Care First (OCF) Model informal request for information. I would like to specifically address the care transformation model, which will include a new initiative to “gradually implement electronic patient-reported outcomes (ePROs).” (pg 5).

I am a cancer survivor and research patient advocate who has become educated and has volunteered on many projects in the area of patient reported outcomes (PRO). I have also participated in clinical trials as a cancer patient that have required PROs as part of the study. After advocating for PROs for many years in clinical trials and clinical care, I do believe thoughtful PRO development and clinical evidence have progressed and PROs are now being more broadly incorporated in clinical trials and implemented in clinical care.

I applaud CMS for their forethought to add the implementation of ePROs into clinical care and most importantly have it in the OCF Model for appropriate reimbursement and support. I know there have been some challenges raised (listening session on November 4, 2019), from providers and others. Therefore, I think it is important to hear from patients about the importance of the implementation of ePROs as part of the OCF Model.

**PROs in clinical care is important to patients**

There have been substantial advances in the use of PROs beyond clinical research. There is growing support that PROs may be beneficial to patients and their doctors, including symptom monitoring by using patient questionnaires. Hearing directly from patients about symptoms they are experiencing will add value to the care of patients. There are many ways I think PROs in clinical care can benefit me, as a patient.

1. **Symptom control.** One of the most bothersome and sometimes serious consequences patients experience during cancer treatment are harmful side effects. These are usually events that patients have never experienced in their life before this time. They are unusual
and many times patients do not know whether or not to call the doctor. If patients could report on all symptoms in a timely manner from their homes, then the doctors and medical staff can let the patient know if what they report is something that needs to be addressed immediately or if it can wait until their next appointment. This enables symptoms that can possibly lead to hospital stays or emergency room visits to be taken care of before they need such drastic interventions. Allowing patients to report symptoms in real time can ease their mind and gives a positive message to patients that they can use their voice during their cancer treatment.

2. **Adherence to oral anti-cancer medication.** The increased development and use of oral cancer drugs have been a great advantage in treating cancer patients; Allowing for fewer office visits and easier administration. However, it has also revealed a new challenge - patients discontinuing their medication on their own. Often but not always, this can be due to uncontrolled and/or intolerable side effects. Identifying patients who are having side effects that are bothersome, may initiate a conversation between the doctor and patient. This may lead to modifications (lower dose, other meds to counter side effect, etc....) that allow the patient to stay on their treatment. Identifying patients at risk of discontinuation will help them directly. Patients cannot benefit from therapies they do not take.

3. **Decision-making and discussions between the patient and doctor.** If patients are asked to fill out an ePRO questionnaire prior to their doctor visit, there is a very good chance this will enhance doctor/patient communication by concentrating the discussion on appropriate symptoms that the patient reported and those that matter to the patient. Sometimes patients are more anxious and feel rushed once they enter an oncology clinic, which means they forget to mention everything that they wanted to talk about. Also, doctors do not have time to ask about every possible symptom, the PRO can do that. Many patients feel that if the doctor does not mention it, it must not be important.

4. **Improve survival.** There have been several publications recently on the impact of patients reporting symptoms during clinical care, including how incorporation of PROs increases survival. This includes a pivotal presentation at the 2017 ASCO Annual meeting and publication in JAMA (Basch et. al., JAMA 2017; PMID: 28586821). The survival advantage compared similarly to that seen in some new drugs that were touted for their great advantage. There are current studies underway looking at PROs in multiple institutions, academic and rural, across the US to see if this is true in a diverse patient population. This makes sense from my perspective (as a patient), that if symptoms can be controlled, adherence to medication can be maintained and patient/doctor communication can be improved, then survival can improve.

**Implementation of PROs into clinical care**

There are currently hospitals considering including PRO measures in clinical care. How PROs are implemented is really important. As discussed during the listening session, patient burden (number of questions), ease of answering questions (simple vs complex), timing of completion
(home vs clinic) and real-time assessment, are all items that need to be considered. Therefore, flexibility in implementation will need to be allowed, to best fit the clinic and their patient population. *Patients are more than willing to fill out PRO assessments if they are relevant, easy to answer and will make a difference in their care.*

1. **Relevant PRO questions.** It is not appropriate to cast such a wide net with 86 questions that may not improve patient care. We do know that symptom monitoring is important. There has been a publicly available symptom monitoring questionnaire developed by the National Cancer Institute (NCI) called PRO-CTCAE. This was developed with many stakeholders (including patients) and since it was developed by the NCI it is freely available to everyone. There are many other advantages to the use of PRO-CTCAE as part of standard of care in the OCF Model.

2. **PRO-CTCAE is modular.** PRO-CTCAE is a set of 124 items representing 78 symptomatic toxicities drawn from the CTCAE (NCI). The 124 items are validated and tested individually. This means you can pick which items best fit the patient population depending on their diagnosis and treatment plan and purpose of the questionnaire. This means patients only answer questions that are relevant and important to them. The questions were developed in a collaborative manner and are easy to interpret and understand.

3. **ePRO as mode of administration.** Advances in ePRO administration and acceptance by patients has increased. The use of e-PROs using computers, tablets and smartphones is constantly changing in the real world and widely accepted by many. Although there are pockets of access limitation to cell towers, internet and devices in some areas, this too is likely to change in the future. Meanwhile, the opportunity to complete e-PROs in clinics is an advantage over paper administration. The use of e-PROs eliminates errors in transcription and time/resources needed to enter PROs into charts. With all patients having eHRs, this is the time to include ePRO symptom management into clinical care.

4. **Importance of getting information directly from patients.** Using PRO-CTCAE as an example, PRO-CTCAE collects more than just if a symptom is being experienced, it also asks frequency, severity and interference of normal activities. This is such important information for patients to communicate to their doctor and can only be accurate if reported directly from patients themselves. For example, although peripheral neuropathy is a common symptom that can be severe, the way the pain interferes with daily living is also really important to capture. Additionally, the perceived severity of the symptom may differ between patient reported or clinician reported measurements (Nyrop et. al., Cancer 2019, PMID:31090930). Another advancement is allowing for free text symptom reporting during cancer treatment, which has been deemed feasible and informative (Chung, et. al., JIMIA 2019, PMID: 30840079).

5. **Assessing geriatric patients through PROs.** The use of geriatric assessments (GAs) to evaluate older cancer patients is becoming more common in oncology practices. This assessment evaluates many items that will give the oncology team a better assessment
about the fitness of the patient to undergo treatment. Recent studies have suggested that implementing the GA can change treatment decisions in up to a quarter of older patients (Festen et. al. JGO 2019, PMID: 31031193). Implementation of a GA or just questionnaire GA could lead to more appropriate management of cancer in older patients. Age is not the most reliable determination of fitness to undergo cancer treatments.

In summary, I support and encourage the continued inclusion of “gradually implement electronic patient-reported outcomes (ePROs)” in the new OCF Model. I realize change is difficult and there will be challenges. However, the patient should come first and implementation of ePROs in cancer clinical care would be a way to value and engage patients in their own care. Patients feel like they have lost so much of their ability to control their lives when they are diagnosed with cancer and undergo cancer treatment. Giving patients a voice during their treatment is a step in the right direction to engage patients in a positive way throughout their care. As mentioned previously, controlling symptoms, staying out of the hospital, relieving anxiety, enhancing patient/doctor communication, and improving survival are just a few of the potential positive outcomes from implementing ePROs in cancer clinical care.

Sincerely,

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