Short Report

Oncology Nurse Coordinators in Clinical Trials – Shaking up the Melanoma Team

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ABSTRACT

In recent years, melanoma research has undergone a renaissance. The disease that was once viewed, at least in a metastatic setting, as intractable and untreatable is now revealing its molecular "weaknesses." The year 2011 was a landmark year for melanoma therapy, with the introduction of two new agents – the anti-cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) antibody ipilimumab and the BRAF (V-raf murine sarcoma viral oncogene homolog B1) inhibitor vemurafenib. These two agents were shown to confer a survival benefit, which was followed by the approval by the Food and Drug Administration (FDA). In 2014, other immune checkpoint inhibitors, such as pembrolizumab and nivolumab, were approved for the treatment of metastatic melanoma. By 2019, the FDA had also approved pembrolizumab as adjuvant therapy. Target therapy and immunotherapy are now the standard of care for melanoma patients. Clinical trials are currently ongoing for new neoadjuvant therapies. Rapidly evolving knowledge will perhaps downgrade melanoma to the level of a chronic, manageable disease from the intractable "black cancer," it was in the past and a disease that struck fear into the hearts of those who were diagnosed. Changes in immunotherapy treatments were followed by a large volume of clinical trials. This situation has resulted in the need for changes in the roles of existing melanoma multidisciplinary team members, including the clinical trials nurse (CTN). The role of the CTN is not suitable for these new conditions. A new role and tasks need to be established, evolving the CTN into an oncology nurse coordinator (ONC). In this article, we have described the role and responsibilities of an ONC and the changes that have taken place within the multidisciplinary melanoma team.

Key words: Clinical trials, Hadassah Medical Center, Israeli nursing, Jerusalem, Melanoma nurse coordinator

Introduction

The Hadassah Medical Center in Jerusalem

This center, established in 1960, is one of the leading Israeli medical organizations that operate within two university hospitals at Ein Kerem and Mount Scopus in Jerusalem. The hospitals are affiliated with the Schools of Medicine, Dentistry, Nursing, Pharmacology, and Occupational Therapy at the Hebrew University of

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Jerusalem. Hadassah employs 850 physicians, 1,940 nurses, and 1,020 paramedical support staff. The two hospitals include around 1,000 beds, 31 operating rooms, and 9 specialized intensive care units. Every year, Hadassah provides hospital services to nearly one million people. Most of the oncology facilities are provided by the Sharett Institute of Oncology at Ein Kerem hospital, so most cancer patients are treated in that hospital.

The Sharett Institute of Oncology at Ein Kerem Hospital

This institute was established in 1977 as a national institute for the cancer prevention, treatment, and research in Israel. The Sharett Institute of Oncology, which serves the population of Jerusalem and the surrounding area, is a referral center for cancer patients from worldwide. More than 3,500 new patients are referred to the Sharett Institute each year. The institute has five units, namely the Ambulatory Treatment Unit (outpatient), Inpatient Care Department, Radiotherapy, and Research.

Clinical Trials

Today's standard of care is yesterday's clinical trial.[1,2] Oncology clinical trials have been and will continue to be the cornerstone for improving outcomes for individuals at risk and those living with cancer.[3-5]

Government sponsors, pharmaceutical companies, and private entities embark on the hundreds of clinical trials each year.[6] Thousands of patients volunteer to participate in clinical trials, which study new treatments, interventions, or products. These studies occur in the inpatient and outpatient settings and in community settings. Many groups and individuals are involved in clinical trials, from external agencies such as pharmaceutical companies, to the Food and Drug Administration (FDA) and the inhouse team.

Nursing experience at Hadassah

Methodical conduct is essential for the many groups and individuals that are involved in a clinical trial. Effective coordination between the different groups that are taking part in the process can make the difference between success and failure. To meet these demands, a person with the appropriate skills and capability to coordinate the task is critical. In our new melanoma team structure, this is the oncology nurse coordinator (ONC), whose aim is to bring all the groups together. Members of the melanoma team interact with the members of their research team throughout the process of the clinical study.[6,7]

The clinical trial oncology nurse coordinator-the core person in the process

The precedent and character of nursing involvement in patient care are maintained throughout the study. The clinical trial ONC is the person central to the patient and family, the investigator, and the hospital facilities. The proper conduct of the clinical study is dependent on the nurse who is responsible for relating medical information to the patient/family. The nurse's responsibilities are also to facilitate patient, family, and physician discussion of priority issues, and promote communication regarding perceptual incongruences among and between patients, their family members, and the physician.[8,9]

Oncology nurses have the unique opportunity to lead the way by developing and embracing creative and innovative strategies to untangle clinical trial complexities. By merging the roles of nursing team members into one central position of nurse coordinator, we aimed to achieve this goal. This novel and central position in our opinion may minimize future conflicts arising from differing perceptions and may ultimately preserve the rapport between the patient and the health team. Participating in all these roles promotes patient autonomy and independence and may encourage active participation in the management of their care and participation in clinical trials.[9] In our opinion, oncology nurses are well suited to this role as they serve in a specific way to fulfill those expectations that permit the resolution of disparities before the initiation of therapy, ensuring a clear understanding of what is proposed.

The experienced oncology nurse in the role of an ONC has the disease-specific knowledge necessary to provide patient-centered care throughout the cancer continuum and promote positive patient outcomes. The role of the ONC has a positive impact on both the patient and the cancer team, by providing continuity of care and improved communication.[1,7]

The melanoma team

The melanoma team at the Sharett Institute of Oncology at Ein Kerem hospital was established together with other unit teams just after the establishment of the institute in 1977. The team members were:

- Head of melanoma team – physician responsible for patients during clinic visits, treatments, and team meetings, new protocols panning, and establishing in-house trials
- Dermatologist – physician responsible for patients in clinic, treatments, and consultations. Took part in team meetings
- Laboratory team – responsible for new programs and analyzing patients' laboratory test results (not routine blood tests)
- Hospital facilities – radiology, laboratory, phytology, etc.
- Clinical trials nurse (CTN) – roles and tasks as described below.

Clinical trials nurse – roles and tasks

Clinical practice

Provision of nursing care to participants in clinical studies. Care requirements are determined by study protocol, the clinical condition of the patient, and the requirements and clinical effects of study procedures. This activity includes:

1. Administration of study therapy and compounds
2. Facilitating processing and handling of study specimens
3. Recording study data on approved study documents as case report forms and study database
4. Recording information in patient files, as per the hospital regulations
5. Monitoring the patient during and at the end of treatment and reporting any adverse events
6. Facility scheduling of study visits and procedures.

Study management

Management of support activities to ensure patient safety, study needs, study protocol integrity, and accurate data collection.

1. Recruitment of participants
2. Evaluating potential participants' eligibility
3. Study-specific materials to patients
4. Preparation of the appropriate reports for regulatory and monitoring bodies
5. Protect patient data in accordance with regulatory requirements
6. Support study budget.

Care coordination and continuity

Coordination of study and clinical activities to meet clinical needs, completed study requirements, and manage linkage with other providers.[10]

1. Giving written information on study treatment to other providers (as infusion center or community team)
2. Collaborating with other providers to create a plan that allows for a safe and effective patient treatment
3. Addressing study patients' inquiries and concerns
4. Ensuring initial and ongoing informed consent is obtained, as per the protocol requirements
5. Supporting patients in the informed consent process
6. Coordinating with the team members (PI, SPI) in an ongoing plan.

As the number of clinical studies was relatively small, the present melanoma team was sufficient, and the roles and tasks of the nurses were achievable. The combination was within a reasonable framework and capacity.

The Need for Change

2011 was a landmark year for melanoma therapy,[6] with two new agents, the anti-cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) antibody ipilimumab and the BRAF (V-raf murine sarcoma viral oncogene homolog B1) inhibitor vemurafenib, being shown to confer a survival benefit.[6,11] In 2014, other immune checkpoint inhibitors such as pembrolizumab and nivolumab were approved for the use in metastatic melanoma settings.[12] By 2019, the FDA had approved pembrolizumab for the use in the adjuvant setting.[11] Target therapy and immunotherapy are now the standard care for metastatic and adjuvant melanoma.

These new treatments were followed by a large volume of clinical trials and the number of patients grew significantly. The workload of the melanoma team, especially of the CTN, increased and the need for new physicians grew. The need for enlarged facilities to deliver the new clinical trials programs also expanded. This change required a new melanoma team structure, with new role descriptions and changes in areas of responsibility.[13]

The New Melanoma Team

- Head of melanoma team – physician responsible for patients in clinic, including some clinical trials as the PI. Representing the melanoma team in various meetings concerning future clinical trials. Planning and establishing in-house trials. Participating in weekly scheduled melanoma team meetings
- Dermatologist – physician responsible for patients in clinic, during treatments, and consultations. Part of weekly team meetings. Part of the clinical trial team, and PI in adjuvant and neo-adjuvant studies. Extra workload as some of the new immunotherapy treatments have adverse dermatologic events. The need for an extra dermatologist has been evaluated
- New team – physicians-three new physicians to join the melanoma team, participating as PI or SPI in the study protocol, also responsible for patients in clinic during clinic visits
- Laboratory team – responsible for new programs and analyzing patients' test results (not routine blood tests)
- Hospital facilities – radiology, laboratory, phytology, etc., Weekly meetings with designated radiology personnel, now part of the melanoma team, and monthly meetings with designated pathology personnel to evaluate the pathology reports
- Four new melanoma study coordinators (not nurses) were hired to facilitate in the ongoing new melanoma studies. The new members are qualified study coordinators
- Permanent consultants – ophthalmology (as there are uveal melanoma patients), general surgery plastic surgery, radiology, endocrinology, pulmonology, ENT surgery, and radiotherapy

- External advisors – social workers dedicated to melanoma and dietitians
- ONC – the previous CTN changed to ONC including changes in tasks and roles. A new work description and working plan were established.

Oncology Nurse Coordinator Tasks and Roles[14]

Clinical practice – patient tools

1. Chart reviews – designed templates were established (Excel Spread Sheets were used). The detailed study participants list, including their place in the study, is delivered by the study coordinator to the ONC weekly. The hospital files are reviewed to examine the accuracy between the study data and the data in the hospital patient files[13,15]
2. Study coordinator meetings – weekly meeting (every Sunday 08–15) with the study coordinators. (1) Article review (prepared by a different study coordinator each time). (2) Individual meeting with each study coordinator to evaluate the study patients and solve problems
3. Evaluation of potential adverse events – self-literature review regarding reports on the early phase in the ongoing studies to evaluate and foresee potential adverse events
4. Infusion center meeting – weekly meeting with representative nurse from the infusion center, as most patients are treated in that facility. Evaluation of ongoing treatments and problem-solving. A written report will be delivered to study coordinators and melanoma team members

Study management-process tools[16]

1. Evaluation of potential study patient – the weekly preclinic visit patient list will be delivered by the team secretary to the ONC. Hospital files will be reviewed. If the information indicates that the patient may be suitable for a study, this information will be delivered to the assigned study coordinator and the assigned PI or SPI at the preclinic visit. All the study coordinator will prepare required study materials
2. Patient recruitment – the ONC, with the study coordinator and the assigned PI or SPI, will take part in the consent process. The patient and family members will be informed about study participation, the study protocol, and clinic and treatment visits. Communication information will be given to the patient and also reported in the visit summary in the patient files
3. Study coordinator report – the assigned study coordinator will prepare a time schedule for the new patient. Information regarding a new patient and upcoming visits will be delivered to the infusion center
4. Facilitates the education of the interdisciplinary team on the study requirements. For each patient under study, a short summary of the study protocol is prepared. This information will accompany the patient to all necessary activities (infusion center, or clinic visits at other facilities)
5. Weekly meeting with the melanoma team – the meeting includes all the melanoma team, with invited external specialist for individual cases. A list of patients that are going to be presented will be delivered. A summary of ongoing studies will be presented, there will problem-solving if needed, and recruitment barriers will be discussed. A detailed summary of this meeting will be recorded at the hospital
6. Education – monthly literature review will be presented by one of the melanoma team. The subject and the representing personnel will be assigned by the head of the melanoma team
7. Hospitalized patients – daily visit with the study coordinator. Evaluating patients' condition with the PI or SPI. Meeting with patients' family to answer questions. If needed, a clinic visit will be scheduled by the study coordinator with the PI or SPI and family members
8. Study representative – monthly meeting with representatives from Pharmaceutical companies to evaluate ongoing studies and proposed future studies, including the head of the melanoma team.

Conclusion

The role integrates patient necessities with coordinating a large multidisciplinary team that is still adjusting and developing new members. The various steps form basic landmarks that are part of an ongoing process.

The ONC plays a noteworthy role in the health-care system. In view of the variety of roles that the nurse coordinator assumes in different units, performance standards must be adapted to the performance areas for each unit, as well as the nurses' professional development requirements. Changes in a service organization due to outside forces or relevant research, as in the case of the melanoma team, highlight the need to develop and strengthen the role of a nurse who coordinates treatment over the entire continuum of care.

Clinical trials are changing rapidly, penetrating all practice settings and extending into a global industry. Nurses can demonstrate and articulate the evolution of clinical trials.

From our perspective, there is no doubt that the growing number of clinical trials has made a big impact on the

melanoma team, and adjustments may still be needed as the number grows. Further research is needed, which validates the use of these tools in future studies. Suggestions for further research could include the formation of a questionnaire, rating the usefulness of these types of tools by navigators. Once their usefulness is validated, these tools can be further refined.

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Conflicts of interest

There are no conflicts of interest.

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