Implementation of a Chemotherapy Specific Consent Form: An Evidence-Based Process Improvement Project

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Introduction/Background

- The Oncology Nursing Society (ONS) and the American Society of Clinical Oncology (ASCO) are the prevailing professional organizations for oncology practice, for nursing and medicine, which publish the standards of care in the field.
- Since 2009, ONS and ASCO have published Chemotherapy Administration Safety Standards which represent the best evidence-based practice in this field.
- In early 2016, the Acute Care Service line (ACS) of Valley Presbyterian Hospital (VPH) introduced the Clinical Nurse Specialist (CNS) role. The CNS is an advanced practice nurse uniquely trained to drive evidence-based practice changes throughout an organization. The CNS is a chemotherapy/biotherapy certified oncology RN with oversight over the oncology practice at VPH.
- Also in 2016, ONS and ASCO published an update to their Chemotherapy Administration Safety Standards, which included best practice on chemotherapy administration consent.
- Although it was assumed that any patient admitted for chemotherapy treatment was consented by their oncologist, and the same patients signed the general admission agreement, there was no record of specific consent for the chemotherapy treatment in the hospital records. Therefore, the CNS could not ensure that any patient undergoing chemotherapy treatment had an understanding of their treatment risks and benefits that met evidence-based standards.

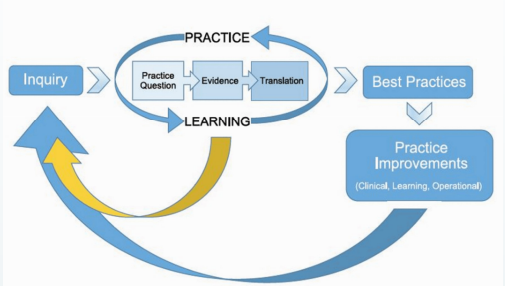
Aims

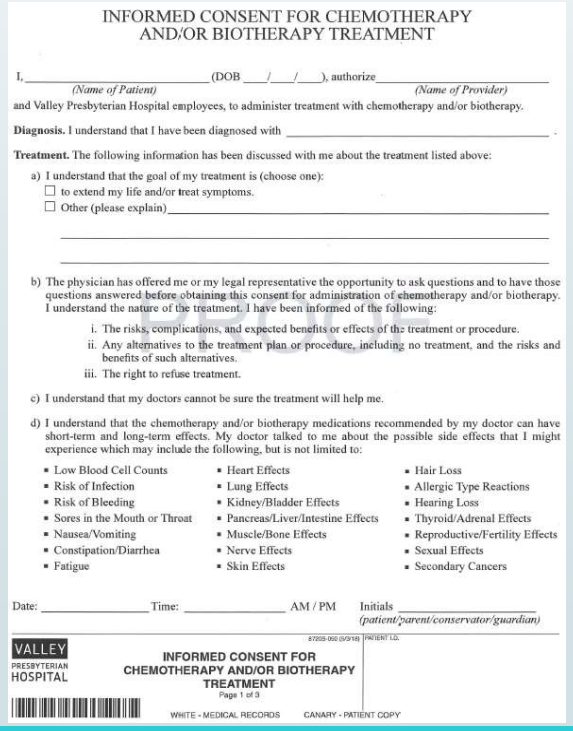
- To implement the use of a specific chemotherapy/biotherapy treatment consent form as recommended by the ONS and ASCO to meet the highest level of evidence-based practice for the safety of oncology patients at VPH.

Methods

- The CNS utilized the Johns Hopkins Evidence-Based Practice Model (JHNEBP) which is composed of the three interrelated components of inquiry, practice, and learning.
  - **Inquiry:** A focused effort to question, examine, and collect information about a problem, an issue, or a concern.
  - Samples of consent forms currently in use from around the country were obtained through ONS membership outreach.
  - Samples of consent forms currently in use from local private oncology practices were obtained.
  - A community standards survey was conducted with both hospitals and private oncology practices to ascertain current practice in these institutions.
  - Copies of both the 2016 ASCO/ONS Chemotherapy Administration Safety Standards and the 2008 ASCO Member Resource on Informed Consent for Chemotherapy were reviewed.
  - **Practice:** The translation of what nurses know into what they do.
  - Traditionally nurses base their practice on policies, protocols and procedures. Evidence-based practice is a prominent aspect of the *New Knowledge, Innovations, and Improvement* component of the Magnet Model, and therefore the foundation for this practice change as VPH pursues their Magnet recognition.
  - All evidence obtained throughout inquiry was presented to VPH medical professionals and other senior leadership in order to come to a consensus on the language for the consent form and the policy changes required for its use.
  - The Chemotherapy administration policy was updated to reflect the use of this consent and vetted through all system-wide committees for approval.

The Johns Hopkins Nursing Evidence-based Practice Model





INFORMED CONSENT FOR CHEMOTHERAPY AND/OR BIOTHERAPY TREATMENT

I, _____ (DOB ___/___/___), authorize _____
(Name of Patient) *(Name of Provider)*
and Valley Presbyterian Hospital employees, to administer treatment with chemotherapy and/or biotherapy.

Diagnosis. I understand that I have been diagnosed with _____.

Treatment. The following information has been discussed with me about the treatment listed above:

a) I understand that the goal of my treatment is (choose one):
☐ to extend my life and/or treat symptoms.
☐ Other (please explain) _____

b) The physician has offered me or my legal representative the opportunity to ask questions and to have those questions answered before obtaining this consent for administration of chemotherapy and/or biotherapy. I understand the nature of the treatment. I have been informed of the following:
i. The risks, complications, and expected benefits or effects of the treatment or procedure.
ii. Any alternatives to the treatment plan or procedure, including no treatment, and the risks and benefits of such alternatives.
iii. The right to refuse treatment.

c) I understand that my doctors cannot be sure the treatment will help me.

d) I understand that the chemotherapy and/or biotherapy medications recommended by my doctor can have short-term and long-term effects. My doctor talked to me about the possible side effects that I might experience which may include the following, but is not limited to:

- Low Blood Cell Counts
- Risk of Infection
- Risk of Bleeding
- Sores in the Mouth or Throat
- Nausea/Vomiting
- Constipation/Diarrhea
- Fatigue
- Heart Effects
- Lung Effects
- Kidney/Bladder Effects
- Pancreas/Liver/Intestine Effects
- Muscle/Bone Effects
- Nerve Effects
- Skin Effects
- Hair Loss
- Allergic Type Reactions
- Hearing Loss
- Thyroid/Adrenal Effects
- Reproductive/Fertility Effects
- Sexual Effects
- Secondary Cancers

Date: _____ Time: _____ AM / PM Initials _____
(patient/parent/conservator/guardian)

87255-000 (9/3/18) PATIENT I.D.

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INFORMED CONSENT FOR CHEMOTHERAPY AND/OR BIOTHERAPY TREATMENT
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WHITE - MEDICAL RECORDS CANARY - PATIENT COPY

Methods (continued)

- **Learning:** Braungart, Braungart, and Gramet tell us that "learning is a relatively permanent change in mental processes, emotional functioning, skill, and/or behavior as a result of experience" (as cited in Dang & Dearholt, 2018, p. 42).
- Utilizing the established learning management system Healthstream, the CNS included education on the use of the new consent form and the evidence as to its importance along with the annual education on chemotherapy administration precautions for all registered nurses (RNs).
- Within the education, a clear go live date coordinated with the passing of the supporting policy was communicated.
- Once printed, the CNS delivered the new forms to each appropriate unit to ensure that leadership was aware of its presence and required use.

Conclusions

- The official commencement of the use of the chemotherapy specific consent form was Monday, April 1, 2019.
- The CNS will continue to monitor the use of this consent form to ascertain compliance as it is too soon to determine the efficacy of this process at this time.

Implications & Recommendations

- The use of this consent form can serve as a guide for physicians to conduct their conversations with oncology patients to help ensure that all required elements are covered.
- As the consent form is used, leadership will be able to ascertain if patient's knowledge of treatment and side effects of treatment are clearly communicated through the U.S. Department of Health survey results (Hospital Consumer Assessment of Healthcare Providers and Systems Survey [HCAHPS]).
  - Before giving you any new medicine, how often did hospital staff tell you what the medicine was for?
  - Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?

References

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