DOMINICAN HOSPITAL
Quality Improvement Study

Study coordinator: Kathy Finnigan, RN, MSN CNS, OCN

Study population: Dominican Hospital Infusion Center Outpatients

Total number: 43

PROBLEM IDENTIFIED/SUMMARY:

Comprehensive Accreditation Manual for Hospitals – The Joint Commission RI.01.03.01
"Obtaining informed consent presents an opportunity to establish a mutual understanding between the patient and the licensed independent practitioner or other licensed practitioners with privileges about the care, treatment, and services that the patient will receive. Informed consent is not merely a signed document. It is a process that considers patient needs and preferences, compliance with law and regulation, and patient education. Utilizing the informed consent process helps the patient to participate fully in decisions about his or her care, treatment, and services."

Dignity Health Dominican Hospital has established policies regarding consent / informed consent. The Dominican Hospital Infusion Center operates under the Dignity Health Dominican license and practices under the hospital's policies. A process exists in which the steps, as defined in the prior paragraph, to informed consent are well practiced for patients being treated in the Infusion Center. This process includes the physician's offices, members of the Katz Cancer Resource Center, and the Infusion Center staff.
During regular chart review, it was noted by the Infusion Center Manager, that signed, informed consent is not consistently found in the patient chart for those treatments determined to require informed consent. This study was conducted to determine compliance with the presence of witnessed informed consent forms in the patient record in the Dominican Hospital Infusion Center.

CRITERIA USED TO STUDY PROBLEM:

California Hospital Association Consent Manual - 2016

F. Duration of Informed Consent

A consent remains effective until the patient revokes it or until circumstances change so as to materially affect the nature of, or the risks of, the procedure and/or the alternatives to the procedure to which the patient consented. For example, if a patient has been admitted for a specific course of treatment, including a specific operation, but in the course of studying the patient several days elapse and the anticipated operation changes considerably, the physician should obtain a new informed consent. Similarly, if the patient's condition changes or new information is learned about the patient's condition, resulting in increased or different risks to the patient from the contemplated procedure or treatment, a new consent should be obtained.

B. IDENTIFYING PROCEDURES THAT REQUIRE INFORMED CONSENT

"Informed" consent, as distinguished from "simple" consent, is not required for all medical treatments. The *Cobbs* court held that treatments or procedures that are "complicated" require that informed consent (as described above) be obtained. Procedures that are "simple and common" do not require informed consent (although they still require consent, usually obtained in the "Conditions of Admission" form (CHA Form 8-1) *(see chapter 8)*). The court stated that a physician is not expected to explain risks that are commonly understood to be remote. The performance of a blood count was cited as an example of a "simple and common" procedure.

2016 Updated ASCO/ONS Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology

Domain 2: Treatment Planning, Patient Consent, and Education

2.1	The health care setting has policy that documents a standardized process for obtaining and documenting chemotherapy **consent or assent.** [27]
2.2	Informed consent and assent (optional) for chemotherapy treatment, as appropriate to the treatment population, is documented before initiation of a chemotherapy regimen.

Dignity Health Dominican Hospital policy 8610pc-185 Consent/Informed Consent – pertinent excerpts listed

4.0 PROCEDURES THAT REQUIRE INFORMED CONSENT

4.1 Complex Procedures. Informed consent must be obtained for procedures that are "complex" in that they involve material risks that are not commonly understood. Specifically informed consent must be obtained for:

4.1.3 Chemotherapy

4.2 Special Requirements. In addition, "informed consent" will be obtained as required by law, and consistent with the special requirements set forth in the CHA Consent Manual for the following procedures:

4.2.3 Investigational drugs or devices
4.2.8 Blood transfusion

7.0 INFORMED CONSENT

7.3 Documenting Informed Consent

7.3.7 If the form is completed in the hospital, a hospital staff member shall serve as the witness.

FINDINGS:

Most nursing care delivered at the Infusion Center is covered by the Dominican Hospital Conditions of Admission. Senior Director of Quality, Risk Management & Medical Staff Services, the Dominican Hospital Director of Quality and Risk Management, and the Dominican Hospital Infusion Center Manager (the study coordinator) met to determine what treatments require written informed consent and secondly, how often consent should be obtained.

Based on the references cited above, the determination was made that the following treatments, provided at the Infusion Center, require informed consent:

- Chemotherapy / Biotherapy – medications charged as chemotherapy
  - New consent is required with each new regimen or change in ordering physician
- Blood product transfusion
  - Consent is valid for one calendar year when outpatients require ongoing transfusion therapy
- Invasive Procedures performed on-site by physician, with each occurrence
  - Lumbar Puncture
  - Paracentesis
  - Bone marrow aspiration
- Therapeutic Phlebotomy performed by RN, with each occurrence
- Investigational Drugs
  - Informed Consent obtained by Investigator

100% of chart audits were performed in August and September of 2017. The following results represent totals in which new orders / regimens were initiated for patient treatment:

Month	Chemo / Biotherapy		Blood Transfusion		Thera Phlebotomy		Total	
	Number	Percent	Number	Percent	Number	Percent		
August	13	61.5%	18	94.4%	16	87.5%	47	83%
September	19	73.7%	10	100%	8	87.5%	37	86.1%

There was no incidence of Investigational Drugs nor Invasive Procedures performed by physicians initiated in the 2 months studied.

Charts discovered having missing / incomplete informed consent forms were flagged for follow-up, including those with orders / regimens initiated in prior months.

NATIONAL BENCHMARKS USED:

Centers for Medicare & Medicaid Services

Center for Clinical Standards and Quality / Survey & Certification Group

§482.24(c)(4) All records must document the following, as appropriate

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written consent.

In order to participate in the Medicare and Medicaid programs, hospitals must meet the Conditions of Participation. Auditing of patient records by the California Department of Health Services could put hospital participation in jeopardy if inconsistent compliance with CMS standards is discovered.

The Joint Commission Elements of Performance for RI.01.03.01 (quoted in opening paragraph)

Dignity Health Dominican Hospital is accredited by The Joint Commission. The ability to operate as a hospital in providing and billing for services is dependent upon meeting regulatory standards published in TJCs Comprehensive Accreditation Manual for Hospitals.

OUTCOME/DISCUSSION:

The study results disclosed particular vulnerability with documenting informed consent with chemotherapy / biotherapy. A drill down into the data of the 14 total occurrences of missing consent form revealed the following patterns:

- RN failure to complete the witness portion of the form
- RN failure to recognize complex biotherapy (remicade,ocrevus, rituximab for autoimmune) as a requirement for informed consent
- Established patient with new regimen or new prescribing physician

The Dominican Hospital Infusion Center RNs held varying opinions regarding what treatments required informed consent and how often such consent should be documented in the patient record. This resulted in varying practices, including documentation of informed consent for all nursing services provided in the Infusion Services.

ACTION TAKEN:

An Infusion Center staff meeting was held during which the guidelines for obtaining informed consent were discussed utilizing the California Hospital Consent Manual and Dominican Hospital Consent / Informed Consent Policy.

PLAN TO MONITOR FOLLOW UP:

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Daily chart review will be performed to monitor compliance with documentation of informed consent. Regulatory compliance by CMS and TJC standards compels a goal of 95% compliance moving forward. This data will be reported as a quality initiative to the Dominican Hospital Quality Committee. Results will be reported to the Cancer Committee during 2018.