Goal of Treatment as Part of the Chemotherapy Consent Process

by

Christina E. Boord

Under Supervision of

Mary Ellen Connolly

Second Reader

Nancy Bolan

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School of Nursing, University of Maryland at Baltimore
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Abstract

Problem: Patients consenting for chemotherapy require a clear understanding of the goal of treatment to make an informed treatment decision reflective of their own goals and values. Identified barriers to patient understanding include lack of information on the consent form and the use of ambiguous language by providers. Both the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) recommend goal of treatment as part of the consent process.

Purpose: The purpose of this quality improvement project was to develop and implement a new chemotherapy consent form that includes goal of treatment; to improve documentation compliance and to evaluate patients' understanding of their treatment goal.

Methods: A multidisciplinary committee at the project site decided to include three goals of treatment: curative, palliative, and palliative/life-extending as part of the consent form. Goal definitions using plain language were included to ensure consistency across providers in how these terms were defined during consent conversations. Patient surveys were developed to evaluate perceived satisfaction with the information provided during the consent conversation as well as the patient's own perceived goal of treatment.

Results: Between August 31, 2020 and December 11, 2020, 155 patients were consented for chemotherapy with 54% of patients completing the patient survey. Goal of treatment documentation compliance increased from 8% to 99% with adoption of the new consent form. Goal concordance, defined as a patient's ability to correctly identify their goal of treatment compared to the physician's documented goal of treatment, increased from 42% to 61%; an increase of 43%. However, a chi-square test of independence revealed no significant association between the rate of agreement and consent form used (X^2 (1, N = 84) = 2.72, p = .10).

Conclusions: Goals of treatment are a vital part of consent conversations. Including goal of treatment as part of the consent form creates opportunity for meaningful, in-depth goals of care conversations which can help patients make treatment decisions reflective of their own goals and values. Although improvement in goal concordance did not reach statistical significance, a 43% improvement in concordance with the new consent form cannot be overlooked.

Goal of Treatment as Part of the Consent Process

Introduction

Each year, more than 650,000 individuals receive chemotherapy as part of their cancer treatment (Centers for Disease Control and Prevention, 2019). Prior to the initiation of treatment, patients are required to provide informed consent. Studies have demonstrated up to two thirds of individuals receiving palliative chemotherapy believe it is for curative purposes (Lennes et al., 2013; Weeks et al., 2012). Furthermore, patients who believed they were going to live for at least six months were 2.6 times more likely to accept intense chemotherapy compared with patients who believed there was at least a 10% chance they would not live six months (Ghandourh, 2016). More importantly, patients who chose to receive intense chemotherapy did not have longer survival times and yet were more likely to be admitted to the hospital, undergo resuscitation, or die while on the ventilator (Ghandourh, 2016).

It has been recommended that consent conversations include the goal of treatment. Consent forms are commonly used to capture the elements of the consent conversation. However, the chemotherapy consent form currently used at a comprehensive cancer center associated with a large tertiary academic center does not contain information regarding the goal of treatment. As a result, there is no clear mechanism to verify the patient has been provided information regarding the goal of treatment. Baseline data at the project site revealed clinical notes included the documentation of goal of treatment less than 15% of the time. The purpose of this quality improvement project was to develop and implement a new chemotherapy consent form that includes goal of treatment with plain language definitions; to improve documentation compliance and to evaluate patients' understanding of their goal of treatment. It was anticipated this practice change would increase documentation compliance of the goal of treatment. A

second aim of this implementation was to increase concordance between the documented goal of treatment and the patient's perceived goal of treatment.

Literature Review

This review is a synthesis of the evidence in support of incorporating goal of treatment as part of the chemotherapy consent form with a focus on providing written information regarding the goal of treatment and establishing explicit goals of care. The quality of evidence was determined using Melnyk and Fineout-Overholt's (2015) level of evidence and the Newhouse's (2006) quality rating scheme (Tables 1 & 2). Although the evidence supporting this practice change is based on descriptive studies and expert opinions, the potential impact on a patient's decision to undergo treatment is significant. Patients must be able to appreciate both the risks and benefits of treatment while considering the goal of treatment and then weigh this information in light of one's own goal and values to be able to decide whether or not to undergo chemotherapy.

At the request of membership, the American Society of Clinical Oncology (ASCO) created a chemotherapy consent template in 2008. The template included the goal of treatment as a fill in the blank item providing flexibility in how this information would be disclosed. Since the template included all the required elements of the consent conversation, it was suggested the form could serve both as a guide for providers during consent conversations and as a take home reference to patients (Storm et al., 2008). The inclusion of the goal of treatment as part of patient education prior to chemotherapy has now been established as a standard of care (Neuss et al., 2017). In addition, oncology practices applying to the Quality Oncology Practice Initiative (QOPI) certification program must demonstrate discussion of the goal of treatment through documentation using either a consent form or within a provider's note (American Society of Clinical Oncology, 2018). Despite these recommendations, a recent study by Monga and

colleagues (2019) demonstrated the goal of treatment was only documented 45.4% of the time when using a physician note thus lending support to the use of a consent form as a means of documenting the goal of treatment. To ensure providers adhere to best practice guidance, the United Kingdom has moved towards national standardized regimen-specific chemotherapy consent forms which include goal of treatment (National Chemotherapy Board, 2018). In addition to a standardized consent form, the National Chemotherapy Board (2018) recommends a duplicate copy of the completed consent form be given to patients upon completion of the consent process.

Evidence suggests discussion regarding the goal of treatment is not enough to ensure patient understanding (Lennes et al.,2013; Monga et al., 2018; Weeks et al., 2012). Hall and colleagues (2012) state a patient's comprehension is influenced by patient specific factors such as age, education, intelligence, cognitive function, locus of control, and anxiety. On the other hand, Gumusay and colleagues (2016) found a patient's education level to be the only factor to have a direct impact on the patient's understanding of the goal of treatment. For this reason, defining goals of care using plain language can help ensure patients are not unintentionally mislead regarding the goal of treatment by the use of ambiguous language (Hall et al., 2012; Monga et al., 2018).

Theoretical Framework

Lewin's Change Theory was chosen to guide and support this quality improvement project. Lewin's Change Theory describes the process of change in three distinct phases. The first phase, unfreezing, is characterized by increasing the driving forces and/or decreasing the restraining forces towards a change (White, 2016). Change is the second phase and is identified

as movement towards a new process (White, 2016). Refreezing is the final phase and is described as sustained change (White, 2016).

A significant restraining force for change was due to the lack of a regularly scheduled review process for the consent form. As a result, the consent form had not been updated in several years. However, providers at the project site were increasingly reporting the consent form was not meeting their needs. This project capitalized on the perceived shortcomings to incorporate changes supported by ASCO and the Oncology Nurses Society (ONS). Initially, providers were surveyed to gather information regarding desired changes and how goals of treatment were described to patients. This information was then utilized by a multidisciplinary committee at the project site which determined how best to incorporate the recommendations outlined by ASCO and ONS for education during the new process. Once the new consent form was outlined, a draft was sent to the oncology attending physician team at the project site for feedback. Following minor revisions, the form was barcoded and then uploaded as an electronic file available for download within the organization's electronic database for forms and thus created a natural refreezing phase.

Methods

This quality improvement project was implemented in an outpatient National Cancer Institute (NCI) Comprehensive Cancer Center. Project participants were comprised of adult patients receiving treatment at the project site and undergoing the consent process for chemotherapy. A variety of cancer diagnoses and treatment options are seen in the population at this clinic. Patients enrolled in research trials or those receiving only oral chemotherapy treatment were excluded.

A multidisciplinary team consisting of attending physicians, nurses, and a pharmacist met to discuss updating the consent form and adding goal of treatment to align with ASCO/ONS recommendations for patient education as part of the consent process. The committee decided to include three goals of treatment: curative, palliative, and palliative/life-extending (Appendix A). Additionally, definitions of these three goals using plain language were included to provide practitioners with a consistent definition of the terms to share with patients during treatment discussions. Attending physicians, fellows, and nurse practitioners were made aware of the consent changes during faculty meetings prior to go-live (Appendix E). The updated consent form was made available on the institution's form database as well as the cancer center's intranet page.

Structure, process, and outcome measures were identified to not only track implementation progress but also to assess any changes in patient understanding of the goal of treatment secondary to the new consent process. Data collection consisted of weekly chart audits (Appendix C) and information gathered from patient surveys (Appendix B). The survey was modified from a patient survey developed by Lennes and colleagues (2013) and included three questions asking patients to rate the quality of information they were given regarding their cancer diagnosis, their cancer treatment options, and their goal of treatment. In addition, patients were asked if they had received a copy of their completed consent form, if someone was with them during the consent conversation, and to identify their current understanding of the goals of treatment.

The structure measure tracked during implementation was the percentage of patients with a documented goal of treatment. Baseline data was obtained by reviewing provider notes to determine if the goal of treatment was documented. After implementation of the new consent

form, data was only obtained by reviewing the completed consent form. It should be noted that prior to a patient's first treatment, a thorough review process takes place which includes not only reviewing the chemotherapy orders but also the consent form. If a consent form was found to be incomplete during this process, the provider was notified the consent was incomplete and needed to be corrected. However, if the consent was not completed prior to the review process and found to be incomplete during chart review by the DNP student, an email was sent to the provider making them aware of the issue.

The process measure tracked during implementation was the percentage of patients who had received a copy of their consent form. This data was collected based on the 'yes/no' response to this question on the survey. If a patient wrote 'unsure', it was documented as a no response. Prior to the go-live for the new consent form, 23 nurse coordinators were educated that patients should receive a copy of their completed consent form. However, this process varies depending on the involvement of the nurse at the time of consent. During staff huddles the week of go-live, coordinators were reminded to ensure patients receive a copy of the completed consent form. When chart audits revealed this measure was not being met, emails were sent to coordinators as a reminder of this expectation.

The outcome measure tracked during implementation was the percentage of patients with concordance between the goals of treatment. Concordance was defined as a patient's ability to correctly identify their goal of treatment compared to the physician's documented goal of treatment. At baseline, the DNP student compared the patient's survey response to the physician documented goal of treatment within their clinical note. If the note did not state the goal, the goal documented within the electronic chemotherapy ordering system was used. However, the goal options found within the ordering system do not exactly match the goals outlined on the consent

form. Therefore, all goals documented as ‘Control’ or ‘Other’ were defined as ‘Palliative/Life-extending’. After implementation, the DNP student compared the patient’s survey response to the physician documented goal of treatment on the consent form.

Data analysis examined potential relationships between concordance and the consent form used. The influence of the type of cancer, presence of a significant other person during the consent process and whether a patient received a copy of the consent form was also examined. All information collected for data analysis was de-identified and entered into a spreadsheet which was stored on a password-protected computer only accessible by the DNP student at the clinical site (Appendix D).

Results

Data collection took place over a 15-week time period from August 31, 2020 to December 11, 2020. During that time, a total of 155 patients were consented for chemotherapy and 84 patients completed the survey. Documentation of the goal of treatment significantly improved from 8% to 99% (Appendix F). More importantly, during the last six weeks of data collection compliance was 100%. Although a process change was put in place to ensure patients received a copy of their completed consent form, data revealed those patients who received a copy of their consent decreased from 75% to 67% during the data collection period (Appendix G). However, whether or not a copy was received was determined based on patient survey responses and therefore may not accurately reflect actual practice due to limited patient response. By including goal of treatment on the consent form, goal of treatment concordance increased from 42% to 61%, an increase of 43% (Appendix H).

Statistical analysis was performed using Chi-square and Fisher’s exact test to look for potential associations between variables. No significant relationship was found between the

patient's ability to correctly identify their goal of treatment and the consent form used during the consent conversation (X^2 (1, N = 84) = 2.72, p = 0.10), whether someone was present during the consent conversation (X^2 (1, N = 84) = 6.01 x 10^{-4}, p = 0.98), or whether the patient received a completed copy of their consent form (X^2 (1, N = 84) = 0.27 p = 0.56). Furthermore, the difference between the satisfaction scores with the new consent form (M = 4.61, SD = 0.78, n = 51) and the satisfaction scores with the old consent form (M = 4.48, SD = 0.80, n= 33) were not statistically significant t(82) = -0.70, p = 0.24 (one tail).

Discussion

Overall, the development of a chemotherapy consent form with clearly identified goals of treatment is an effective intervention. As a result of the project, goal documentation compliance, a QOPI certification quality measure, reached 100%. Furthermore, goal concordance increased by 43%. Although this was not statistically significant its clinical relevance cannot be overlooked. The creation of a consistent place to document goal of treatment also proved extremely helpful for social work. Social workers meeting with patients to discuss goals of care have stated they are referencing the goal of treatment outlined on the chemotherapy consent form during their discussions with patients.

There are several notable limitations of the QI project. The relatively small sample size provides insufficient power to be able to detect whether the findings were significant. Patient surveys were completed at the first chemotherapy infusion appointment creating a variable timeframe between when a patient was consented and when the survey was completed. Therefore, patient responses may have been impacted if there were several weeks between the time of consent and the time treatment was started. Although it is recommended that patient education be provided using plain language, consent conversations were not observed as part of

this project. As a result, the variability in how goals of treatment are presented to patients between not only providers but also for the same provider between patients is unknown.

During chart audits, several issues were identified related to the selection of the goal of treatment on the consent form. On several occasions, it was noted that a provider had chosen both ‘Palliative/Life-extending’ and ‘Palliative’ as the goal of treatment. Additionally, the choice of ‘Other’ had been selected for a patient with a cancer diagnosis. Moving forward, it is recommended two changes be made to the consent form to provide additional clarity when providers are completing the goal of treatment section (Appendix I). First, the addition of the statement “Select One” before the listed goals of treatment would help to remind providers to select the goal that best describes the goal of treatment at the time of consent. Second, since the option ‘Other’ matches the goal option available within the electronic ordering system, this choice may be confusing if the provider does not review the definition when completing the form. Therefore, it is recommended to remove the ‘Other’ portion of the goal and simply have the choice state ‘Non-cancer Diagnosis’. The complete removal of this option is not possible because the consent form is utilized by providers recommending chemotherapy/biotherapy for non-oncological diseases.

Conclusion

In conclusion, goals of treatment are a vital part of consent conversations. Patients require an accurate understanding of their goal of treatment in order to make a treatment decision which reflects their own goals and values. As such, the inclusion of the goal of treatment on the consent form creates an opportunity for meaningful treatment discussions. Furthermore, updating the consent form ensures sustainability of this project initiative for years to come. The successful implementation of this project has led the institution to spear-heading a project to adopt the

consent form across the hospital system. The system is also looking to move towards an electronic consent. This change will be a significant step towards ensuring patients have access to a copy of their consent form. Availability of the form within the patient portal of the electronic health record will also alleviate the need to print and then make copies of the consent.

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Table 1

Evidence Review

Citation: https://practice.asco.org/sites/default/files/drupalfiles/2018-08/QOPI%20Certification%20Standards%20Manual%206.1.18.pdf American Society of Clinical Oncology. (2018). Domain 2: Treatment planning, patient consent, and education . In *QOPI Certification Program: Standards Manual* (Version 6.1.18). Retrieved from https://practice.asco.org/sites/default/files/drupalfiles/2018-08/QOPI%20Certification%20Standards%20Manual%206.1.18.pdf					Level: VII
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"Defines requirements for consent and education processes prior to treatment."	Nonexperimental – Guideline: ASCO's QOPI certification standards	N/A	N/A	Quality Practice Oncology Initiative (QOPI) certification program standards provide commentary related to the chemotherapy administration standards. Elements specific to consent and education cover allowing practices to document informed consent either using a standardized form or within a clinical note and providing the patient with a documented goal of treatment using either a specific education document, consent form, or treatment plan.	• QOPI certified practices are recognized as champions of quality oncology care • Over 300 outpatient oncology practices have earned QOPI certification.
Citation: https://link-springer-com.proxy-hs.researchport.umd.edu/article/10.1007/s13187-015-0827-y Gumusay, O., Cetin, B., Benekli, M., Gurcan, G., Ilhan, M.N., Bostankolu, B., Ozet, A., Uner, A., Coskun, U., & Buyukberber, S. (2016). Factors influencing chemotherapy goal perception in newly diagnosed cancer patients. *Journal of Cancer Education*, 31(2), 308-313. doi:10.1007/s13187-015-0827-y					Level: VI
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"evaluate the extent of perception of chemotherapy goal among cancer patients scheduled to	Nonexperimental – Descriptive Observational	Sampling Technique: Convenience sampling at one Turkish institution.	Intervention fidelity: Patients informed by doctor their diagnosis and treatment goal.	DV: Consistency between patient perception and physician perception of chemotherapy goal. Procedure: 12 item questionnaire assessed for status of social support,	Statistical procedures and Results: Associations evaluated using the

receive chemotherapy for the first time as well as the factors involved in patients' perception of treatment goals."		Inclusion criteria: ≥ 18 years of age, cancer diagnosis, scheduled for first chemotherapy treatment and able to read and understand Turkish # Eligible: 216 # Accepted: 216 Power analysis: none Group Homogeneity: Median age 58 54.6% male 89.4% diagnosed with solid tumor 37.5% graduated high school or university 85.2% married 46.8% receiving palliative treatment 43.6% reported anxiety	Written material describing goal provided to patient.	quality of information provided by physician, treatment goal, whether written material was provided, language spoken, level of education, marital status, and whether patient was hopeful. Depression measured using the "Distress Thermometer" and anxiety measured using "Hospital Anxiety and Depression Scale". The question designed to measure understanding treatment purpose had four choices: 1 – aimed at preventing disease recurrence, 2 – aimed at maintaining a prolonged disease-free period, 3 – aimed at prolonging survival by slowing down the cancer growth, and 4 – aimed at reducing cancer-associated symptoms and increasing the quality of life. Options 1 & 2 were considered curative and options 3 & 4 were considered non-curative. Patients who chose a "curative" and "palliative" option were considered "confused". Physician goals were considered curative if the patient was receiving adjuvant or neo-adjuvant protocols and a non-curative purpose for metastatic patients.	chi-square test and Fischer's exact test for categorical variables and independent-samples T test for continuous variables. Multivariable logistic regression test was used to determine factors associated with patient's understanding of the chemotherapy goal. 32.2% of patients perceived the goal of treatment incorrectly and 18.9% were confused. Age, gender, depression, and anxiety did not impact accurate perception of treatment purpose. Multivariable analysis found level of education impacted accurate perception of treatment purpose ($p = 0.025$).

Citation: https://www.cmaj.ca/content/184/5/533 Hall, D. E., Prochazka, A. V., & Fink, A. S. (2012). Informed consent for clinical treatment. *Canadian Medical Association Journal*, 184(5), 533-540. doi:10.1503/cmaj.112120					Level: VII
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"make several practical suggestions as to how clinicians might optimally approach the informed consent process"	Nonexperimental – Review: Synthesis of knowledge regarding ethics and policy of informed consent	N/A	N/A	Several categorical limitations of informed consent were identified including patient comprehension, patient's use of information, patient autonomy, demands on providers, and physicians meeting minimal standards. Suggestions made for improving consent process including establishing explicit goals of care and taking into account patient preferences for information and decision-making styles. Proposes more than one approach may be necessary to document consent process including consent forms and notes within the electronic medical record.	N/A
Citation: https://www.cancerresearchuk.org/sites/default/files/consent_guidance_doc_v2018-06.pdf National Chemotherapy Board. (2018). Consent for systemic anti-cancer therapy. Retrieved from https://www.cancerresearchuk.org/sites/default/files/consent_guidance_doc_v2018-06.pdf					Level: VII
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results

"Outline guidance relating to the process of providing information and obtaining consent from adults for treatment with SACT."	Nonexperimental – Guideline: UK National Chemotherapy Board	N/A	N/A	Provides guidance regarding consent for systemic anti-cancer therapy in the United Kingdom (UK). Proposed recommendations include national standardized consent forms, providing the patient with a copy of the consent form, and providing written information to include likely side effects and who to contact should problems arise. Key aspects of form include aims and intent of treatment, regimen and constituent medications, route of administration, what treatment is likely to involve, toxicities and how these may be managed, common side-effects and life-threatening complications, effects on fertility and if relevant, ability to confirm avoidance of pregnancy and contact information should a patient experience issues or have questions regarding their treatment.	• Guidance document reviewed and ratified by The Association of Cancer Physicians, The Royal College of Radiologists, The Royal College of Physicians, The Royal College of Pathologists, The UK Oncology Nursing Society, and the British Oncology Pharmacy Association
Citation: https://ascopubs.org/doi/10.1200/JOP.2016.017905 Neuss, M. N., Gilmore, T. R., Belderson, K. M., Billett, A. L., Conti-Kalchik, T., Harvey, B. E., ... Polovich, M. (2017). 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards, including standards for pediatric oncology. *Oncology Nursing Forum*, 44(1), 1-13. doi:10.1200/JOP.2016.017905					Level: VII
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"update the ASCO/Oncology Nursing Society (ONS) Chemotherapy Administration Safety Standards and to highlight standards for pediatric oncology"	Nonexperimental – ASCO/ONS Safety Standards	N/A	N/A	Outlines standards related to chemotherapy with the intention to allow oncology providers to conduct self-assessments and inform quality improvement projects. Standards address four domains: creating safe environment, treatment/patient consent/education, ordering/preparing/dispensing/ administering chemotherapy, and	• Standards approved by ASCO and ONS board of directors

				monitoring after chemotherapy is administered including adherence/toxicity/complications. Important aspects of consent include having a standardized process for obtaining and documenting consent and consent is documented prior to initiation of chemotherapy. Minimum education requirements include: diagnosis, goal of treatment (cure, prolong life, reduce symptoms), duration/schedule of treatment, drug names, potential drug interactions, adverse effects including infertility risks, when to seek medical attention, procedures for handling medications in the home, procedures for handling body secretions in the home, and follow-up plans.	
Citation: https://onlinelibrary-wiley-com.proxy-hs.researchport.umd.edu/doi/pdfdirect/10.1111/ecc.12973 Monga, V., Maliske, S.M., Kaleem, H., Mott, S.L., Zamba, G.K., & Milhem, M. (2019). Discrepancy between treatment goals documentation by oncologists and their understanding among cancer patients under active treatment with chemotherapy. *European Journal of Cancer Care*, 28(2), e12973. doi:10.1111/ecc.12973					Level: VI
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"investigate the use of the "treatment goal" field in BEACON software, the documentation of the same in the oncologist's clinic note, and the discrepancies among	Nonexperimental – Descriptive Observational	Sampling Technique: Convenience sample from one institution. Inclusion criteria: English-speaking, ≥ 18 years of age, cancer diagnosis, receiving cycle 1 of	Intervention fidelity: Compare physician documented treatment goal to patient perception of treatment goal	DV: Concordance of physician-patient treatment goal Procedure: Patients were interviewed within 21 days of initiation of treatment to determine perceived treatment goal. Patient responses were compared to physician documented treatment goals within BEACON and the consent	Statistical Procedures(s) and Results: Adjusted McNemar's test utilized to assess disagreement in physician/patient perception of

adult cancer patients and their respective oncologists regarding communication and understanding of the treatment goals"		chemotherapy and able to give informed consent # Eligible: 207 # Accepted: 133 Power analysis: none Group Homogeneity: 69% over age 65 55.6% female 66.2% married 50.4% employed 96.2 % not enrolled in clinical trial 77.3% solid tumor		form/clinical note.	treatment goals; Rate of discordance found to be 17.3% Logistic regression models applied to determine whether patient characteristics were associated with discordance; Age, gender, marital status, and employment status were not associated with discordance
Citation: https://ascopubs.org/doi/full/10.1200/jop.0866002 Storm, C., Casillas, J., Howard, D. S., McNiff, K., & Neuss, M. M. (2008). Informed consent for chemotherapy: ASCO member resources. Journal of Oncology Practice, 4(6), 289-295. doi: 10.1200/JOP.0866002					Level: VII
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"members of ASCO's Ethics and Quality of Care Committees formed a joint working group to design a consent form template and other resources that provide a framework for consent conversations between oncologists	Nonexperimental - Landmark ASCO Recommendation Standard for Chemotherapy Consent	N/A	N/A	Describes elements of consent for medical treatment: disclosure of patient's diagnosis, nature of proposed intervention, intended benefits, associated risks and adverse effects, and medical alternatives. Provides examples for intended benefits such as: reduction in tumor size, prolonged survival, or reduced discomfort. States consent forms can serve as a guide to ensure all required elements have been addressed and serve as a take-home reference for	N/A

and patients receiving chemotherapy.”				patients. Provided sample consent template which includes goal of treatment.	

Table 2

Evidence Synthesis

Evidence Based Practice Question (PICO): In oncology patients scheduled to receive their first cycle of chemotherapy, does including a goal of treatment statement to the chemotherapy consent form improve patient understanding of the treatment goal?			
Level of Evidence	**# of Studies**	**Summary of Findings**	**Overall Quality**
VI	**2**	Monga el al., found the rate of discordance between physician/patient perception of treatment goals to be 17.3%. None of the patient characteristics measured (age, gender, marital status, or employment status) were found to be associated with discordance. Gumusay et al., found the rate of discordance between physician/patient perception of treatment goals to be 50%. Of the patient characteristics measured (age, gender, marital status, and education), only level of education was found to be associated with discordance with only 55.8% of those with a low level of education accurately perceiving the treatment goal. Patients in Gumusay study received written materials which included the goal of treatment.	Quality B • Utilized convenience sampling which introduces bias as sample may not reflect general population o Both studies included patients with a variety of cancer types o Monga et al. studied included few minority patients while Gumusay et al. studied Turkish patients • Neither study included direct observation of consent conversation which can significantly impact patient understanding • Both studies surveyed patients soon after consent conversation • Studies conducted at single centers
VII	**5**	Standards outlined by Storm et al., Quality Oncology Practice Initiative (QOPI), American Society of Clinical Oncology (ASCO)/Oncology Nursing Society (ONS), the National Chemotherapy Board, and Hall et al. include goal of treatment as a vital element of the informed consent process. Storm et al., QOPI and the National Chemotherapy Board also state patients should be provided with written documentation of goal of treatment. Hall et al. suggest written materials promote understanding.	Quality A • Storm et al. reflects standards for informed consent outlined by Centers for Medicare and Medicaid Services, the Joint Commission, and the American Medical Association • ASCO/ONS standards based on formal systematic review of 97 articles • National Chemotherapy Board references numerous documents regarding the safety and quality of chemotherapy services in England • All standards reflect the same practice regarding patient education of chemotherapy intent • Hall et al. review utilized articles pertaining to informed consent in clinical settings, with a focus on surgery o Authors note findings transferable to other fields of medicine

Appendix A

Goal of Treatment Section of Consent Form

b. The Goal of my treatment is:

_____ Curative – meaning to become free of my cancer with the hope that it will not return.
(provider initials)

_____ Palliative – meaning not to cure my cancer but to improve or maintain my quality of life by relieving or preventing symptoms.
(provider initials)

_____ Palliative and Life-extending – meaning not to cure my cancer but to control the growth of my cancer and to improve or maintain my quality of life.
(provider initials)

_____ Other – meaning treatment of a non-cancer disease.
(provider initials)

Appendix B

Patient Survey

ID # _____

Chemotherapy Consent Quality Improvement Project

The Cancer Center at UMMC is currently working on a project to improve the chemotherapy consent process. Responses to this survey will tell us how we are doing and help us improve the process. The survey will take about 5 minutes. You do not have to answer these questions. If you choose not to answer, it will not change the care you are given.

1. How would you rate the **information** you were given **about your cancer**? This may have included the type of cancer you have, where the cancer is in your body, and whether the cancer had spread from where it started. (*please check one*)

   ☐ Excellent

   ☐ Above Average

   ☐ Average

   ☐ Below Average

   ☐ Poor

2. How would you rate the **information** you were given **about treatments** and the choices you could make? This information may have included names of drugs used to treat your cancer and their side effects. (*please check one*)

   ☐ Excellent

   ☐ Above Average

   ☐ Average

   ☐ Below Average

   ☐ Poor

3. How would you rate the **information** you were given **about the goal of your cancer treatment**? This information may have included whether the treatment is being given to lessen symptoms from your cancer, to help you live longer with your cancer, or to cure you of your cancer. (*please check one*)

☐ Excellent

☐ Above Average

☐ Average

☐ Below Average

☐ Poor

4. Were you given a copy of the signed consent form?

☐ Yes

☐ No

5. Did anyone come with you when you met with the doctor to discuss your cancer treatments?

☐ Yes

☐ No

6. What do you think is the purpose of your chemotherapy treatments?

☐ **Curative** – meaning to become free of my cancer with the hope that it will not return.

☐ **Palliative** – meaning not to cure my cancer but to improve or maintain my quality of life by relieving or preventing symptoms.

☐ **Palliative and Life-extending** – meaning not to cure my cancer but to control the growth of my cancer and to improve or maintain my quality of life.

☐ **I'm not sure**

Thank you for your time. Please place your completed survey in the provided envelop and your nurse will collect before you go home today.

Appendix C

Chart Audit Tool

C1D1 Tx (Patient Name)	ID #	Goal Documented?

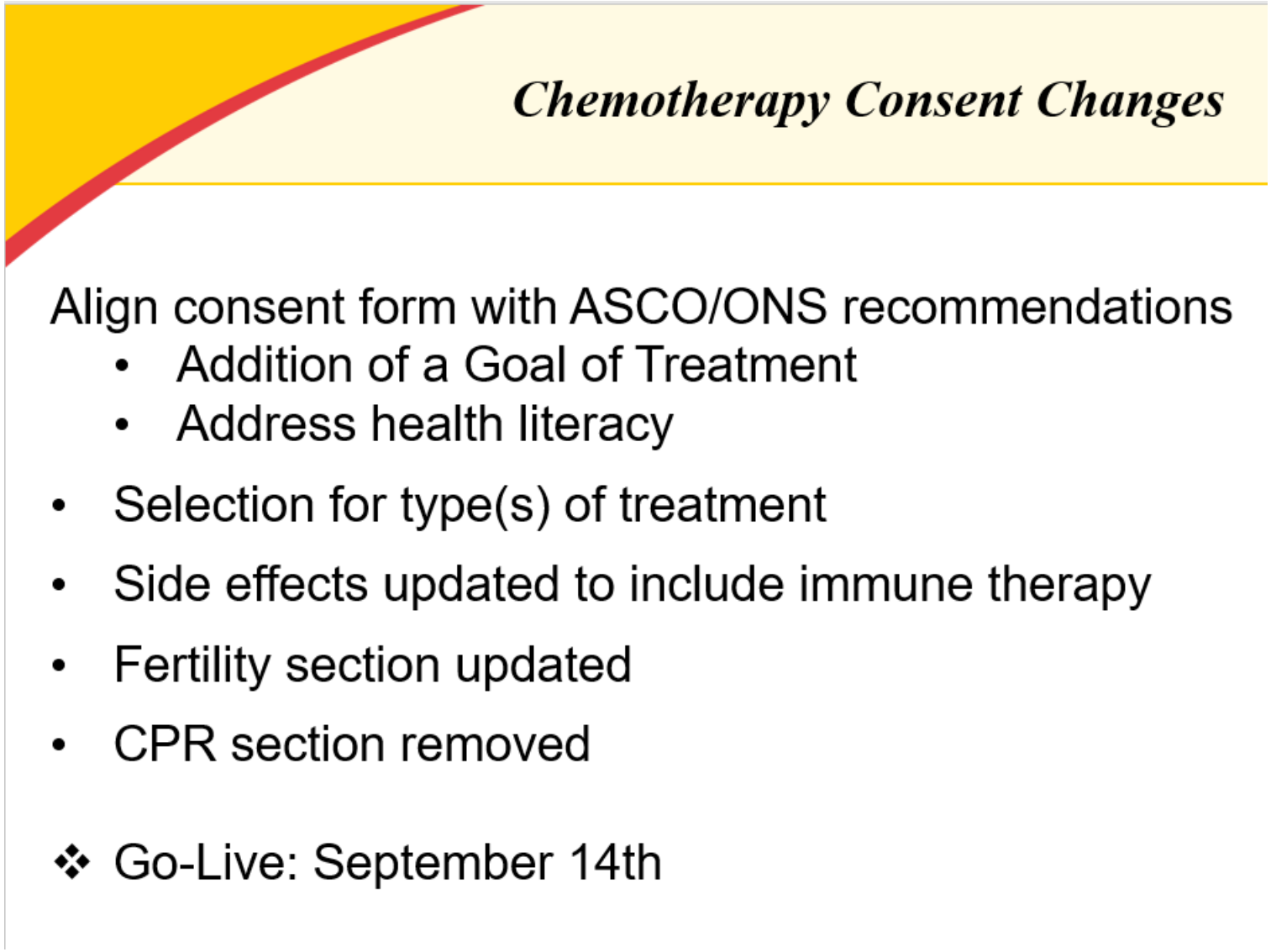
Appendix D

Data Analysis

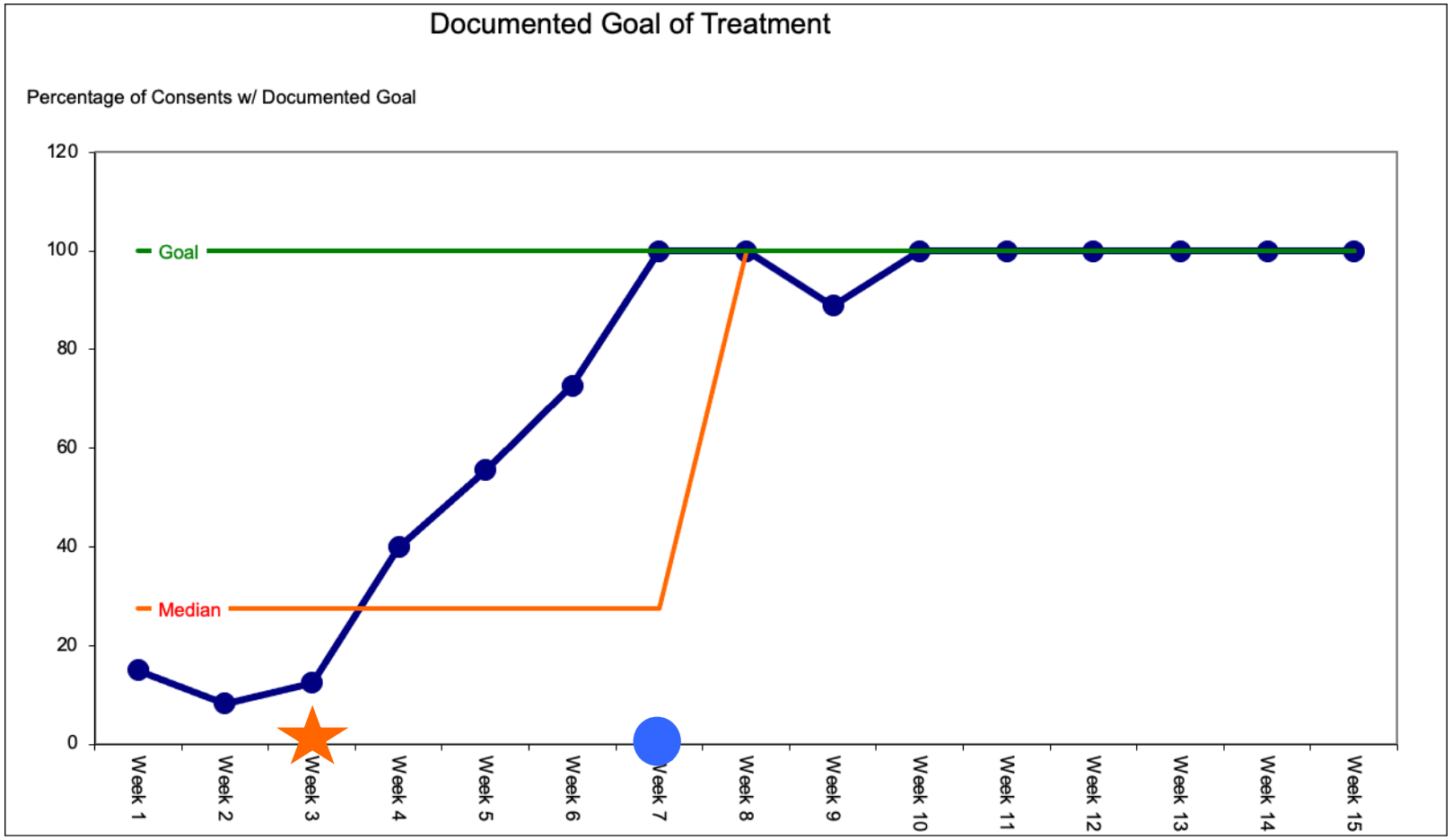
ID #	Doc. Consent Treatment Goal	Type of Malignancy	Attending	Info Quality (Diagnosis)	Info Quality (Treatment)	Info Quality (Goal)	Consent Copy Provided?	Alone at Visit?	Pt. Consent Treatment Goal	Concordance ?

Appendix E

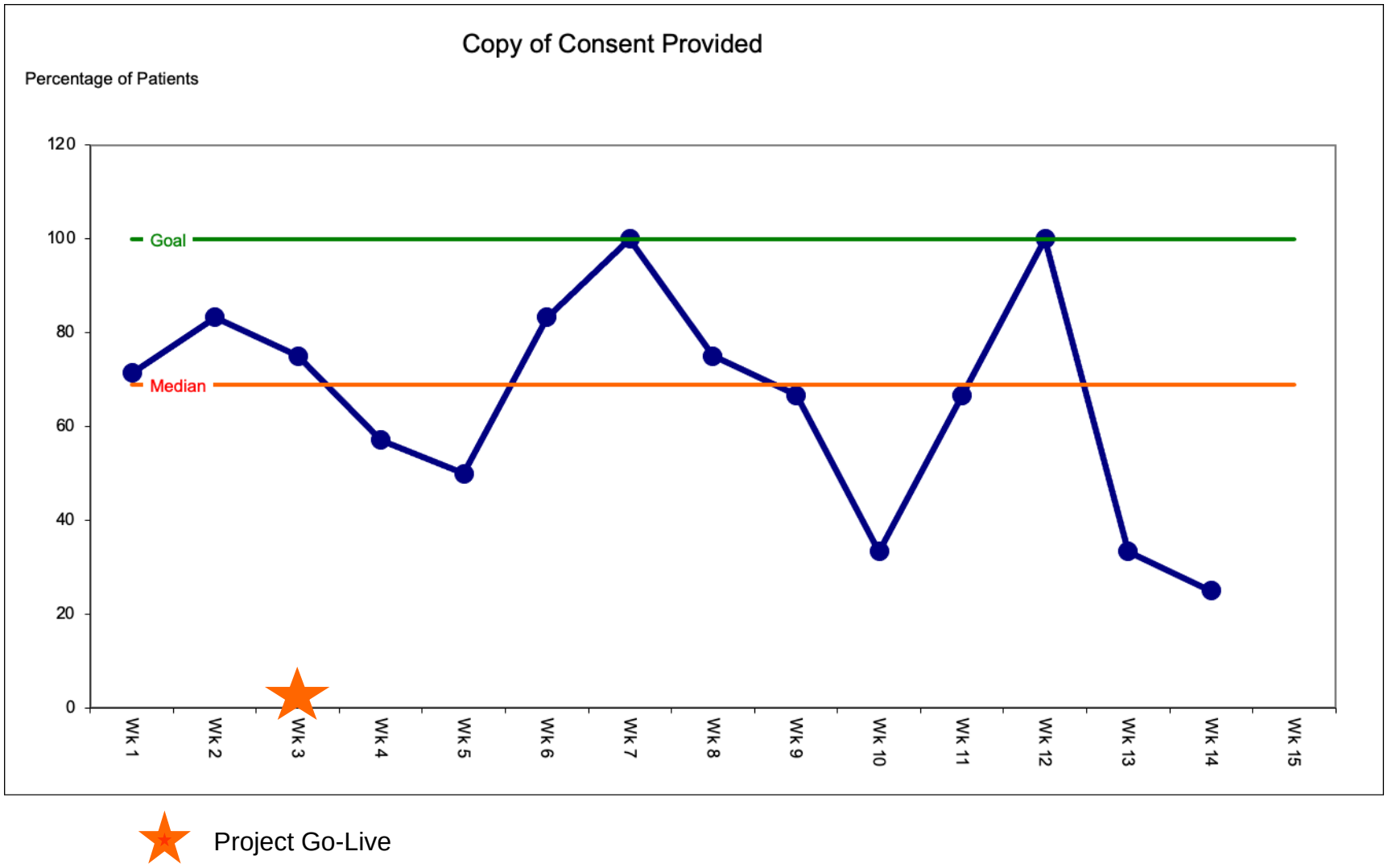
Education Slide



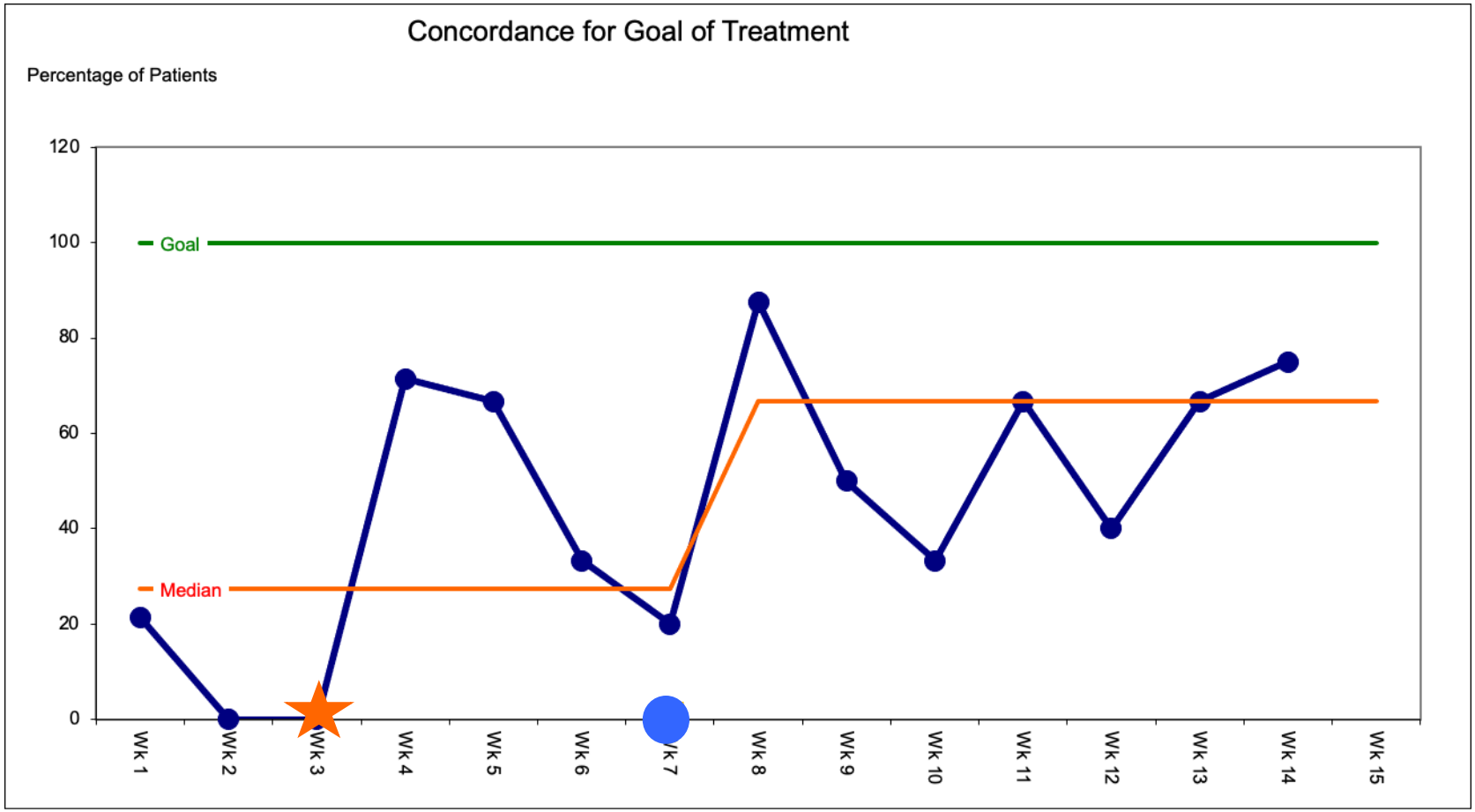
Appendix F


Documented Goal of Treatment
Percentage of Consents w/ Documented Goal
120
100
80
60
40
20
0
Goal
Median
Week 1
Week 2
Week 3
Week 4
Week 5
Week 6
Week 7
Week 8
Week 9
Week 10
Week 11
Week 12
Week 13
Week 14
Week 15
Project Go-Live
Old consents no longer included in survey

Appendix G


Copy of Consent Provided
Percentage of Patients
120
100
80
60
40
20
0
Goal
Median
Wk 1
Wk 2
Wk 3
Wk 4
Wk 5
Wk 6
Wk 7
Wk 8
Wk 9
Wk 10
Wk 11
Wk 12
Wk 13
Wk 14
Wk 15
Project Go-Live

Appendix H



Project Go-Live

Old consents no longer included in survey

Appendix I

Recommended changes shown in red

Goal of Treatment Section of Consent Form

b. The Goal of my treatment is: *(Select One)*

_____ Curative – meaning to become free of my cancer with the hope that it will not return.

_____ Palliative – meaning not to cure my cancer but to improve or maintain my quality of life by relieving or preventing symptoms.

_____ Palliative and Life-extending- meaning not to cure my cancer but to control the growth of cancer and to improve or maintain my quality of life.

_____ Non-cancer diagnosis