INCREASING ONCOLOGY PATIENT ENGAGEMENT IN TREATMENT DECISIONS: A CNL DRIVEN EDUCATIONAL APPROACH

by

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ABSTRACT

Cancer is the second leading cause of death in Montana affecting 40% of men and 38% of women (MCTR, 2019). In the state of Montana Cancer is attributed to 452 new cancer cases per every 100,000 people, or one in every four persons (MCTR, 2019). Current best practice treatment options for cancer include chemotherapy and biosimilar medications of chemotherapy also known as Biologicals. Biosimilar medication is a product that contains a similar but not identical, version of an active compound of that of the originator medication authorized by the FDA for treatment of cancer (Edwards and Bellinvia, 2020). A literature review was conducted containing fifteen journal articles that included: four systemic reviews, a randomized double-blind study, two observational studies, and one retrospective study. When evaluating the information gathered, it was clear that due to the recent development and lack of public knowledge of biosimilars there is missing and unknown information. The missing information could alter the education needed and topics patients may want to know in an educational program. The plan for this quality improvement project is to create an educational program for biosimilars in oncology offices for providers to use with patients that may need to switch to a biosimilar in their treatment plan and allow for increase patient outcome and safety.

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Introduction

As of 2019, Cancer is the second leading cause of death in Montana affecting 40% of men and 38% of women (MCTR, 2019). In the state of Montana cancer is attributed to 452 new cancer cases per every 100,000 people, or one in every four persons (MCTR, 2019). As such, lifesaving decision making is critical for many Montanans. To make these essential decisions the patient must first understand the current treatment options. Current best practice treatment options for cancer include chemotherapy and biosimilar medications of chemotherapy also known as Biologicals. Biosimilar medication is a product that contains a similar, but not identical, version of an active compound of that of the originator medication authorized by the FDA for treatment of cancer, diabetes, Crohn's disease, colitis, rheumatoid arthritis, and psoriasis. (Edwards & Bellinvia, 2020). Biosimilars are often formulated from living organisms such as animal cells, yeast, and bacteria and are often cheaper to make than generic medication (Edwards & Bellinvia, 2020). With the recent development of cost-effective biosimilars for cancer treatment, there is increasing pressure upon the prescribers to switch their patients to this low-cost option. This results in increasing denials in the preauthorization for generic medications and creates barriers to effective patient care. Sadly, patients are not involved in this treatment decision and are often prescribed or switched to the biosimilar without education or informal consent. These treatment changes and barriers can create anxiety, mistrust, and the possibility of negative outcomes in the oncology patients.

The purpose of this project is to implement a patient education program design to provide a holistic informed patient centered approach to treatment options. This allows for the patients to engage in the informed consent process regarding their course of treatment, clearly outlining cost, risks and benefits, and awareness about upcoming medication changes. Informed consent is the process in which a patient is educated by a medical provider on the benefits, risks, and alternatives to treatment and agrees to the treatment or continuation of the treatment (Shah et al., 2021). Educational programs ensure that the patient is in control of their treatment and engaged in informed consent for their cancer treatment. Since the long-term effect of biosimilars are still unknown providing appropriate education regarding insurance and provider limitations in biosimilar use represents a key gap in cancer treatment.

Definitions

For the purpose of this project the following definitions will be used.

- Cancer: a disease or group of diseases in which abnormal cell growth and division occurs with the potential to destroy body tissue and invade/spread to other parts of the body.
- Biosimilar medication: a pharmacologic product that contains a similar, but not identical, version of active compound of that of the originator medication authorized by the FDA for treatment of cancer, diabetes, Crohn's disease, colitis, RA, and psoriasis (Edwards & Bellinvia, 2020).
- Informed Consent: the process in which a patient makes a competent voluntary decision on treatment, procedures, or interventions based on the education and alternative options provided to them by a health care provider (Hall et al., 2012).

- Autonomy: the legal right of a competent adult to make an informed decision about one's own medical care.

Theoretical Framework

The theoretical framework of Autonomy was utilized in this professional project and is a recognized foundation of ethically delivered healthcare. Autonomy is the right for an adult with mental competency to make a decision on their own medical treatment and care plans voluntarily (BMA, 2020). In order for a decision to be autonomous, the patient must create what is labeled as a self-governed decision free from outside factors compelling the decision. Key practices that may inhibit autonomous decision making are coercion and moral influences affecting the provider and patient. For example, when a cancer patient is no longer wanting to fight their disease with new treatments, coercion from family may present a moral dilemma in future treatment planning. Further, patients who are no longer mentally capable of making that decision due to depression or chemotherapy fog may further this moral imperative.

Research Strategy

An extensive review of the literature was conducted using UpToDate, EBSCO host, Google Literature, and CINHL. The search terms used included biosimilars, informed consent, patient autonomy, education, and insurance prior authorization. Inclusion criteria included articles published within the past five years, topic relevance, and content concerning adult cancer patient who has been switched to biosimilar chemotherapy. Articles related to biosimilar use in patients under 18, or for patients not on biosimilars were excluded. After applying inclusion and exclusion criteria, articles selected included seven journals articles, four systemic reviews, a

randomized double-blind study, two observational studies, and one retrospective study for a total of 15 articles. Remaining articles supported the PICO question. P: Infusion Center Oncology Patients at a single Montana Cancer Clinic, I: Biosimilar educational program C: Patients who were not participants in the educational program on biosimilars O: Patients are well informed on the risks and benefits of the biosimilar chemotherapies in comparison to the generic medication and can make an informed healthcare decision.

Literature Review

The literature highlights that many patients were unaware of changes to medication or awareness of biosimilars approach to cancer treatment. As such, the purpose of this project is to implement a program that supports informed consent for treatment with biosimilars through a quality improvement educational program. The programs support patients' engagement in their treatment plans and ensure informed decision on the choice to continue biosimilars for their cancer therapy. Key sections of the literature review include information regarding current application of an educational programs.

As of 2019, cancer is the second leading cause of death in Montana, affecting 40% of men and 38% of women (MCTR, 2019). In the state of Montana, cancer is attributed to 452 new cancer cases per every 100,000 people, or one in every four persons (MCTR, 2019). Biosimilars are a new addition to chemotherapy treatment options within the last five years in the United States. According to Edwards and Bellinvia (2020), a biosimilar medication is a product that contains a similar, but not identical, version of active compound of that of the originator medication authorized by the FDA for treatment of cancer, diabetes, Chron's disease, colitis, rheumatoid arthiritis, and psoriasis. Biologics or biosimilars are often formulated from living organisms such as animal cells, yeast, and bacteria and are often more difficult to make than the originated medication. The biosimilars must be given at the same dose of the originate, rate, and route (FDA, 2021). Since the first approval of Zarxio in 2015, the US has approved more than 20 biosimilars. Biosimilars have the benefit of cost reduction and patient accessibility with little to no increased side effects, yet long term effects of biosimilars are still unknown (Barbier, 2020). A study found that 20% of 29 participants reported increased serum sickness after switching

from rituximab to the biosimilar Truxima and ultimately lost confidence in their overall treatment (Nisar 2018, as cited in Barbier et al., 2020). These results show the increase in need for an educational program in order to increase patient satisfaction.

Sadly, the influence of the cost reductions related to biosimilars has outweighed the ethics of patient autonomy and informed decision making. While drug substitution for generic or interchangeable medications is a common practice among insurance plans, it is not a legal practice for insurance companies to demand this change in cancer treatment regarding biosimilars. Switching cancer patients from generic to biosimilar has continued to be questioned by physicians with concerns of increased immunogenicity from the exposures of different epitopes, the long-term safe efficacy, and the nocebo affect or negative patient experience (Wiland et al, 2020). Prescribers face increasing pressure to switch patients to low cost biosimilars as evidenced by increasing denials of preauthorization resulting in barriers to effective patientcare (Aronson et al., 2018). Patient autonomy and informed consent are the foundation of ethical healthcare decision making and are commonly facilitated through effective patient education. Despite this ethical standard, the incidence of uninformed patients sustaining a treatment change to a biosimilar is growing (Wiland et al., 2018). This startling statistic raises the concern that patient's autonomy is being violated and their right to informed consent is not being adequately conducted. In order for the patient to make fully informed decisions, educational offerings that discuss benefits, and risk of changing to biosimilars is critical.

Approaches to Informed Consent

Informed consent according to Shah et al., is the "activity of providing education to a patient given by a medical provider discussing the benefits, risks, and alternatives to treatment as

well as a patients' given agreement to this treatment" (2021). They go on to explain that "every state defines the required standard for informed consent and while these may vary by state, they are derived from the same three legal approaches" (Shah et al., 2021). These approaches are as follows; the subjective standard which indicates what the patient needs to know and understand in order to make a decision, the reasonable standard that indicates that information must be given that an average person would need to know to make a decision, and thirdly the reasonable physician standard approach where a physician provides what they would say about this treatment or procedure typically (Shah et al., 2021). The most common approach for informed consent follows the reasonable patient approach (Shah et al., 2021). The prime focus of reasonable patient approach is on patients' ability to understand key information provider by a doctor and make an informed decision based on this information (Shah et al., 2021). The nursing role can support informed consent by ensuring the patient has adequate information and understanding to make an informed consent decision (Strini et al., 2021). We know that while many nurses may be untrained for this role, chemotherapy nurses participate in informed consents daily as a patient advocate.

Exceptions to Informed Consent

Exceptions for obtaining informed consent do occur within the healthcare system. Such exceptions fall under an incapacitated patient, emergent situations without time for consent, and a voluntary waived consent (Shah et al., 2021). In order for a patient to make the informed consent they must be deemed competent to make a voluntary decision about their own health care and treatment. According to Karlawish, "the capacity to make one's own decisions is fundamental to the ethical principle of respect for autonomy" and is a major key in informed

consent for medical treatment (2021). Capacity in the medical world is view as the patient's ability to take given information about a treatment or procedure and make a choice that is in line with their wishes and beliefs. In order to determine one's capacity, their cognition must be evaluated through the conduction of a skillful capacity assessment to determine the level of condition a patient holds and severity of any present impairments that may be present. Capacity is best identified through an interview with the patient by asking questions and viewing the patients' ability to understand, appreciate, reason, and express a choice (Hall et al., 2012). In order for a patient to have intact capacity, one of the four decision making abilities noted above must be identified in this face-to-face interview. Conditions that can impair one's capacity to make a decision include a traumatic brain injury, schizophrenia, bipolar, unipolar major depression, Alzheimer's disease, delirium, cognitive aging, and Parkinson's (Karlawaish, 2021). In the case that a patient lacks the ability to make informed consent, the medical team must turn to an appropriate representative of the patient to make the decision on the patient's behalf.

Patient Outcomes with Informed Consent

With the importance of informed consent and the changes in medication from original to biosimilar, the need for an educational program for these patients changing to biosimilars is highly significant. We know that adult patients report improved understanding and comfort levels when nurses concur about the risks and benefits of biosimilars and deliver consistent patient education (Healio, 2019). By implementing a quality improvement educational program prior to the switch to biosimilars, the patient is better able to make an informed decision.

Methods

Increasing the knowledge and the availability of low cost biosimilars has the potential to entice prescriber pressure for patients to choose to use biosimilars over these lower cost options in cancer treatment and the potential for preauthorization and insurance denials to occur without patient engagement or informed consent. Failure to ensure patient inclusion in treatment decisions leads to mistrust and other negative outcomes (Edwards & Bellinvia, 2020). To address this gap, a quality improvement education program will be used to standardize patient education of biosimilar medications in the treatment of cancer.

Design/ Setting of the Study

A quality improvement patient education project was selected based on literature findings. Many oncology patients are unaware of changes to medication or the approach of biosimilars to cancer treatment (Wiland et al., 2018). The quality improvement educational program was selected for implementation in a Central Montanan cancer infusion center that provides care to 18,000 patients annually. According to Gagnon, the use of a quality improvement project works towards improving both the quality and safety of healthcare delivered to patients by being timely, effective and patient-centered (2022). By increasing quality in healthcare, safety for patients, and increasing patient satisfaction healthcare facilities are seeing a decrease in hospital costs (Gagnon, 2022). The quality improvement education program will include the use of standardized medication education information materials, updated informed consent statements, post educational surveys for patients, and a 90- day analysis of individual patients that made changes from generic to biosimilars or vice versa.

Planning

Upon observation at a Montana based oncology infusion center, patients were visibly confused of changes in treatment courses to biosimilars, and most were unaware biosimilars existed or were an option for cancer treatment. As a result, the need for a quality improvement educational program became evident. The plan for the quality improvement educational program, is to create a process improvement system in which providers and nursing staff in oncology offices educate patients on the use and risks associated with biosimilars products. By creating and implementing the education program, the facility would be allowing patients to be educated and engage in consent on the change prior to any administration of the biosimilar. Challenges identified upon program planning include; varying numbers of patients on biosimilars at any one time, staffs' resistance of change, and lack of knowledge revolving around biosimilars.

Sample

Approximately 30 oncology patients will be randomly selected from the first 30 patients to switch to biosimilars in a one-month period for inclusion in the quality improvement project. The staff will ensure the randomly selected patients meet the educational program criteria and are scheduled for a medication change from a generic medication to a biosimilar or vice versa. All patients involved in the quality improved educational program will be oncology patients diagnosed with cancer, new or reoccurring, who are currently receiving biosimilars and/or original medication forms of Avastin and or Rituximab. Patients must be over the age of 18 and capable of providing consent for their treatment courses. All patients participating in a current

clinical trial will be excluded from the program, due to the uncertainty of the use of drugs or placebo in their cancer treatment.

Protection of Human Subjects

Institutional Review Board (IRB) approval from Montana State University and agency authorization will be obtained prior to project implementation. Registered Nurses (RN), pharmacists, and providers participating in the standardization of chemotherapy teaching were included in IRB approval. Minimal risks of this project to participants were identified and their information was protected. Risks include psychological harm from undesired change in treatment, feelings of stress from a new treatment regimen, invasion of privacy by inclusion in program (UCI Office of Research, 2021). Study information and an informed consent was obtained using the patients' primary language and informed consent obtained prior to inclusion in the project.

Implementations

The quality improvement biosimilar education program team, led by a CNL who will oversee the design, implementation and evaluation of the program will include the following personnel: medical oncology and gynecology oncology providers, pharmacists, RNs (Registered Nurse) in charge of administering biosimilars, CNL in charge of post survey data collection, and one RN assigned as the chart auditor to ensure consent was obtained prior to medication administration.

The implementation of the quality improvement educational program would begin with educational changes oncology patients who meet sampling criteria and are prescribed either biosimilar or generic medications with biosimilar options and effectiveness in patient

education and understanding of their medication switch. During the initial doctor's appointment, the provider would present developed education regarding biosimilars risks and benefits, discuss differences in biosimilars to generic medications, and provide recommendations for cancer treatment.

Once the patient makes an informed decision to use biosimilar treatment, the provider will document the patients' decision for course of treatment and a new consent for the use of a biosimilar for cancer treatment is obtained. After providing education, the primary MD or NP (nurse practitioners) would hold responsibility for obtaining the new consent for the biosimilar medication when a change from generic to biosimilar is being made. Then, the infusion RN would ensure all these steps have taken place prior to the patient's first biosimilar transfusion. On monthly basis an RN would audit the patient's record for completeness prior to start date. The chart audit nurse will use a checklist to follow each patients' path ensuring education, signed consents, and post surveys are being conducted throughout the treatment process of all new biosimilars.

After the patient has received education, signed consent, and completed the first transfusion of biosimilar the CNL will mail the post survey noted in Appendix A regarding patients' trust with the facility, level of understanding about medication education, and areas identified for improvement in patient education. The CNL would also be responsible for filing the surveys returned through the quality improvement educational program and addressing with the program members the issues that need to be addressed as evidence by surveys for improvement within patient education regarding medication changes.

Limitations

Limitations identified within the educational program range vary from patient sample sizes to even effects of staffing. The pilot phase of the educational program has a small sample size of 30 participants. This is due to the varying numbers of patients the facilities may see on Rituxan or Avastin each month depending on the patient schedules. The frequency of the medication administration can alter how many patients are see in the infusion center each month depending on if the frequency is every four weeks or six weeks. Second limitation that facilities may be experiencing is a staffing shortage in both RNs and providers. With this shortage, many facilities are hiring locums and travelers. With this temporary staffing, occasionally educational programs and medication programs for a facility may fall through the cracks to locums who may not be used to this specific practice. Thirdly, is the young age of the biosimilars. Biosimilars are roughly five years of age, meaning that some of the risks and benefits may have not been identified for these medications (Edwards and Bellinvia, 2020). This can lead to failure in educating the patient of all risks and benefits for the medications.

Projected Timeline

Projected timeline for the pilot phase of the quality improvement educational program would be 90 days. This allows for the patients to participate in medication education with a primary care provider, medication infusion, as well as obtain a post evaluation survey on the effectiveness of the educational program. Though active patient appointment time will only take three total days for education, infusion and post survey. The educational program allows for 30 days post infusion for patient completion of post education surveys. From there, the remaining 60 days will allow for CNL evaluation of feedback and implement changes as needed to the

educational program. When surveys are completed and returned, the CNL will assess the post evaluation results and determine how the educational program can improve and work towards implementing improvements to increase patient satisfaction

Estimated Budget

The budget for the educational program is based on the current size and employment status of the facility. For the initial program pilot, a total budget of $1,500 is projected and include printing budget $120 for the survey, $2.50 for mailing stamps, and $4 for the cost of 30 envelopes. It also would include the cost of nursing staff, approximately $1,050, to account for the 30 patient hours noted for education, consent retrieval, as well as survey evaluation. The cost of the infusion nurse administering the medications as well as the oncologist pharmacist would be no extra cost, as they are already part of budget for infusion staffing to cover all patients. The $1,500 budget for the pilot program, which includes a return investment of around a 2.6% increase is the direct result of increased patient satisfaction and patient loyalty, as well as patients cycling back for future health concerns (Betts et al., 2018).

Summary/Research Gaps

This master's in nursing professional project focused on informed consent for biosimilar cancer treatment using current evidence for oncology patient education. Although process change can be difficult in the health care setting, standardizing educational materials and checklists based on current best evidence provides opportunity for effective change at the micro-system level. A review of the literature verified that recent development of biosimilars, are plagued by unknown information that could alter the educational needs of cancer patients. For example, the long-term effects of the biosimilars are unknown and cannot be determined. Further, the insurance company determinations vary and are challenging to predict. Resulting in poor patient satisfaction: thus well planned and timely educational programs is essential to positive patient outcome. Through the implementation of an quality improvement education program, oncology centers can increase patient satisfaction and increase patient autonomy in cancer patients receiving biosimilars.

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APPENDICES

APPENDIX A

POST QUALITY IMPROVEMENT EDUCATIONAL PROGRAM PATIENT SURVEY:

Survey:

This is a voluntary survey on the education and service you received at your recent Oncology visit. We appreciate any and all feedback you may provide us. Thank you for your business and hope you have a wonderful day.

1. Were you pleased with your visit at our facility?
    a. Yes
    b. No
2. Do you feel you received effective education on the risks and benefits of biosimilars, the medication you are receiving? If no, please state how we could improve.
    a. Yes
    b. No

    _____
    _____
3. Do you feel all of your questions of why you are switching to a biosimilar were answered clearly?
    a. Yes
    b. No
4. Do you recall signing a new consent for the use of a biosimilar medication in your cancer treatment and feeling well informed on the decision you were making in changing treatments?
    a. Yes
    b. No

5. Do you feel as though the staff adequately engaged you in the choice of treatment for your cancer. If answer no, how can we improve?
    a. Yes
    b. No

    Please provide areas in which we can improve our education on biosimilars to you and future patients. Thank you.

    _____
    _____
    _____
    _____
    _____