SAFETY IMPROVEMENT IN BIOLOGIC THERAPY FOR PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS: A PILOT PROJECT AND QUANTITATIVE ANALYSIS

by

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DEDICATION

I would like to dedicate this work to all psoriatic patients with the hope that treatment methods, research, and safety continue to improve management of care and overall quality of life. I would also like to dedicate this to my family and Tim Chisman who have stuck by my side and supported me through this endeavor. Lastly, I would like to thank my brother Conrad who has shown me meaning of courage, tenacity, and hope.
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Biologic Response Modifier (BRM) medications are indicated for moderate to severe psoriasis and demonstrate high efficacy for disease reduction. Although BRM medications are considered the most effective therapy in the treatment of moderate to severe plaque psoriasis, their side effect profile can be severe. Using BRMs may increase the risk of infections, demyelinating disease, and malignancy (Reich, Burden, Eaton, & Hawkins, 2012). With such established risks, baseline assessments and monitoring have been recommended. However, no standardized guidelines exist for the monitoring of BRM medications (Hanson, Gannon, Khamo, Sodhi, Orr, & Stubbings, 2013). Therefore, the objective of this scholarly project was to implement a BRM monitoring protocol into the Electronic Medical Record (EMR) of a Montana dermatology clinic to improve provider monitoring compliance and therefore improve psoriasis patient outcomes, safety, and education. Monitoring criteria were developed based on recommendations from the University of Illinois Medical Center Clinical Care Guidelines and the American Academy of Dermatologists Biologic Monitoring guidelines. A BRM Electronic Medical Record (EMR) template was then created to utilize such guidelines to improve clinical compliance and patient safety. Seven main criteria were measured for completion including laboratory studies, physical assessment, patient education, follow up, psoriasis severity scale, immunizations, and vital signs. Side effects experienced and patient comorbidities were also recorded. Completion rates of the protocol were analyzed using before and after comparisons, the paired t-test, and McNemar’s test. Before the intervention was implemented, 54% of charts had completion of all seven categories and after the intervention 98% of charts were completed, illustrating a 44% improvement in provider compliance and monitoring. The paired t-test illustrated an average difference of 0.43 with a standard error of .029. The McNemar’s test established a positive association between implementation of the BRM protocol and improvement in provider compliance. 40% of patients experienced co-morbidities associated with psoriasis and 25% of patients experienced side effects related to BRM therapy. These project findings demonstrated the efficacy of a BRM monitoring template for improving provider-monitoring compliance and improving patient safety through early identification of comorbidities and side effects.
CHAPTER ONE

INTRODUCTION

Background

Plaque psoriasis is a chronic autoimmune condition that affects the skin and is characterized by exacerbation and remission of the disease throughout the life span. Psoriasis affects 3-5% of the world’s population and can result in decreased quality of life, chronic pain, depression, and physical and mental disabilities (Van de Kerkhof et al., 2008). In the past, topical treatments were the mainstay of medical therapy for plaque psoriasis. However, many of these medications are difficult to apply, adhere to, or tolerate for patients. In the past few decades, the introduction of Biologic response modifier medications (BRM) has transformed the treatment approach for psoriasis (Esposito et al., 2013). BRMs have become a highly utilized treatment for moderate to severe plaque psoriasis. These medications have significantly reduced disease severity and improved patient outcomes and quality of life (Chan, Hussain, Lawson, & Ormerod 2013). Although BRMs are considered to be the most effective therapy in the treatment of moderate to severe plaque psoriasis, their side effect profile can be severe. Using BRMs may increase the risk of infections, demyelinating disease, and malignancy (Reich et al., 2012). With established risk factors, baseline assessments and monitoring have been recommended; however, no standardized guidelines exist for the monitoring of BRM medications (Hanson et al., 2013). Multiple research studies indicate that routine
clinical monitoring and patient education can reduce adverse events and improve medication adherence (Chan et al., 2013; Esposito et al., 2012; Hanson et al., 2013; Reich et al., 2012; Semble, Davis, & Felman 2014).

Problem and Rationale for the Project

Psoriasis can be an extremely challenging disease to treat, as it is a chronic lifelong disorder that can be managed but not cured. Although psoriasis is a common diagnosis treated in dermatology practices, only 5% of dermatologists prescribe these medications (Bagel, 2011). Many reasons for not prescribing BRM medications range from the concern for side effects to not knowing how to monitor patients effectively on these medications. Such concerns are warranted, as no concrete guidelines exist for monitoring patients on BRM medications (Hanson et al., 2013). Therefore, if providers are not comfortable prescribing these therapies then patients have less treatment options for their psoriasis.

BRM therapies are the most effective treatment for patients with moderate to severe psoriasis (Esposito et al., 2013). If managed appropriately, the risk for side effects remains very low (Menter et al., 2008). Therefore, in order to improve utilization of these therapies and safe monitoring practices, a monitoring guideline must be established. With an evidence-based guideline in place, providers can therefore safely prescribe and monitor psoriasis patients (Hanson et al., 2013). Also, through utilizing monitoring criteria safety outcomes of patients can improve.
Purpose of the Project

The purpose of this study was to create and implement a Biologic Monitoring Electronic Medical Record (EMR) template into a Montana Dermatology clinic to improve provider-monitoring compliance and improve the safety of patients with moderate to severe plaque psoriasis on BMR therapy.
CHAPTER TWO

REVIEW OF LITERATURE

Introduction

In this section the current literature on moderate to severe psoriasis, Biologic Response Modifier medications, and BRM monitoring protocols are reviewed.

Search Methods

Databases

Literature searches were conducted through the use of multiple databases including: PUBMED, CINAHL, CHOCRAN library, UpToDate, Joanna Briggs, Google Scholar, and MEDLINE. Limitations on the year were set from 2000-2016. A total of 52 articles were read and 31 included.

Search Terms

Key words used for the literature search included: adalimumab efficacy and safety; biologic monitoring protocols; biologic response modifiers; BRM side effects; cardiovascular disease and psoriasis; cyclosporine and plaque psoriasis; etanercept efficacy and safety; methotrexate and plaque psoriasis; moderate to severe psoriasis; PASI and PGA scales; phototherapy for moderate to severe plaque psoriasis; psoriasis and TNF inhibitors, insulin resistance, and psoriasis; systemic treatment in plaque
Psoriasis

Psoriasis is a complex inflammatory disease of the immune system that typically manifests itself on the skin but can also affect the joints. Psoriatic lesions can occur anywhere on the body and appear as red, raised, erythematous plaques with a silver scale (Menter et al., 2008). When psoriasis affects the joints, this is called psoriatic arthritis in which chronic inflammation causes dactylitis, disfigurement, degeneration, and pain in the joints. Although the exact pathogenesis of psoriasis is unknown, researchers have established that psoriasis is a genetic condition affected by internal and environmental triggers (Menter et al., 2008). Once the disease is triggered, multiple inflammatory processes occur that increase the production of Tumor necrosis alpha cells, interferon-Y, and certain cytokine cells (Menter, et al., 2008). Severity of psoriasis is individual and can be classified as mild, moderate, or severe. Dermatologists assess and treat patients based off of their disease progression.

Multiple tools exist for the assessment of psoriasis; however, dermatologists utilize the Psoriasis Area and Severity Index scale (PASI) and Physicians Global Assessment (PGA) scale most frequently (Robinson, Kardon, & Kimball, 2011). Researchers use the PASI scale more often due to its extensive evaluation of psoriasis severity, duration, and location (Menter et al., 2008). This scale is calculated before,
during, and after treatment to test the efficacy of different treatment regimens. In research studies, treatments are usually applied to a specific population and a placebo is used as the comparison. Achieving a 75% reduction (PASI 75) is most often used as an end point in medication studies to illustrate efficacy of a treatment (Robinson, Kardon, & Kimball, 2011). Due to the complexity of the PASI, clinicians prefer to use the PGA, which assesses body surface area (BSA) involvement, disease progression, and physical assessment (Menter et al., 2008). With increasing research related to the multiple comorbidities of psoriasis, clinicians are also taking into account cardiac and metabolic risk factors.

Comorbidities of Psoriasis

Historically, psoriasis was regarded as a condition limited only to the skin; however, in the last few decades the systemic effects of psoriasis have become well established. The pathogenesis and occurrence of psoriasis continue to be researched and evaluated for further understanding of the disease. Recent research studies exemplify the substantial relationship between psoriasis and comorbid conditions such as cardiovascular disease, metabolic disease, and depression. Jacobi, Kupke, Behzad, and Hertl (2013) conducted an observation study assessing comorbid conditions associated with moderate to severe psoriasis. Researchers found that 30-40% of subjects had arterial hypertension, depression, and decreased quality of life index scores (2013). Specifically, 30.8% of the population screened positive for depression (Jacobi et al., 2013). Lastly, 10-
20% of patients experienced hypercholesterolemia, inflammatory gastric disease, or diabetes (Jacobi et al., 2013).

Psoriatic patients are at increased risk for these comorbidities due to the systemic inflammation that occurs with psoriatic disease. The abnormally high circulatory inflammation increases patients’ risk for cardiac disease and complications. Tumor necrosis factor alpha, is an inflammatory substance that is overproduced with psoriatic disease (Ryan & Kirby, 2015). Excessive amounts of TNF alpha cause endothelial dysfunction, which predisposes the vessels to artherosclerosis and potential myocardial infarction (Jacobi et al., 2013; Puig, 2012). Although cardiovascular disease has been observed in psoriatic patients for over forty years, the United Kingdom General Practice Research Database (GPRD) study established clinical data in 2006 illustrating psoriasis as an independent risk factor for cardiovascular disease (Gelfand et al., 2006). Multiple studies since the GPRD study have further established increases in cardiovascular events in patients with psoriasis (Puig, 2011; Ryan & Kirby, 2015). In a systemic meta-analysis review, the cardiovascular statuses of 201,239 patients with psoriasis were evaluated (Armstrong, Harskamp, & Armstrong, 2013). Armstrong, Harskamp, and Armstrong (2013) found psoriatic patients experienced an additional 11,500 cardiovascular events yearly compared to the non-psoriatic individuals. Further studies in the literature have demonstrated that individuals with psoriasis have a 5 year decreased life expectancy rate due to cardiovascular disease (Ryan & Kirby, 2015; Gelfand et al., 2006).

Chronic systemic inflammation observed in psoriasis can also cause insulin resistance, which can then lead to metabolic syndrome or diabetes. Metabolic syndrome
is characterized by increased fasting blood glucose, increased blood pressure, elevated lipids, and obesity (Voiculescu et al., 2014). Research studies evaluating the occurrence of metabolic syndrome in psoriatic patients found that patients’ risk of metabolic disease increased after the initial diagnosis of psoriasis (Ryan & Kirby, 2015). Also, patients with increased disease severity had a higher risk of obesity, metabolic syndrome, and diabetes type II (Voiculescu et al., 2014). The insulin resistance in psoriatic patients is increased even in non-obese patients (Voiculescu et al., 2014). Jacobi et al. demonstrated that 11.2% of psoriasis patients in a cross-sectional study had diabetes type II (2013). When insulin resistance occurs, the risk for obesity significantly increases as well. Obesity has been a major factor identified in patients with severe psoriatic disease and is believed to worsen disease progression (Jacobi et al., 2013). Although the research illustrates increased insulin resistance in psoriatic patients, further evidence is needed to establish the exact mechanism of insulin resistance.

With increased risks of cardiovascular disease, insulin resistance, and psychological distress, clinicians need to appropriately assess and monitor psoriatic patients for such risk factors. These patients should be evaluated for cardiac disease throughout their yearly visits and assessed for hyperlipidemia, cardiac inflammatory markers, and clinical symptoms. Metabolic evaluation should also occur once a psoriasis diagnosis has been established. Monitoring fasting blood glucose, weight, blood pressure, and lipid levels will help providers identify metabolic syndrome or onset of diabetes type II. Lastly, depression assessment scales such as the Dermatology Life Quality Index
should be utilized to help identify the physical, mental, and psychological well being of psoriatic patients.

**Biologic Response Modifiers**

Biologic medications are the most effective therapy for treating moderate to severe psoriasis and they significantly reduce disease progression and associated comorbidities. Many treatment options exist for the management of psoriasis; however, the introduction of biologic medications has drastically changed the overall treatment approach to psoriasis. Before the introduction of BRMs, the main classes of therapies utilized included: topical steroids, topical vitamin D analogs, oral steroids, retinoid medications, systemic medications, and light therapy. Individuals with mild to moderate psoriasis responded and continue to respond to these medications. However, the efficacy of topical and light treatments for moderate to severe psoriasis remains low (Chan et al., 2013). Systemic medications such as methotrexate and cyclosporine are frequently used as a first line medication for moderate to severe psoriasis. Efficacy and safety of these medications are variable and the risk of side effects and organ toxicity are high (Mansouri, Y, Goldenberg, G., 2015).

In the last few decades, BRM therapies have significantly reduced disease severity and co-morbidities associated with moderate to severe plaque psoriasis. These medications specifically target immune pathways associated with inflammation. Two main categories of medications are classified as biologic response modifier drugs: tumor necrosis factor alpha inhibitors and IL-12/23p40 inhibitors. TNF inhibitors are
immunosuppressant medications that inhibit the expression TNF alpha, which is an inflammatory pathway in psoriasis. FDA approved TNF inhibitors include etanercept, adalimumab, infliximab, ustekinumab, and efalizumab (Mansouri & Goldenberg, 2015). Ustekinumab is the FDA approved IL-12/23p40 inhibitor. This medications works through inhibiting the subunit p40 of interleukin 12/23 which is a substantial inflammatory factor in psoriasis as well. These medications reduce the inflammatory cycle of psoriasis and therefore decrease disease severity and comorbidities.

Efficacy of Treatments

Over the last two decades, BRMs have been tested through randomized control drug trials, clinical trials, and observational studies to establish efficacy and safety. All of the BRM medications illustrate significant disease reduction when compared to other treatment modalities such as topical, systemic, and light treatment (Chan, Hussain, Lawson, & Ormerod, 2011; Reich, Burden, Eaton, & Hawkins, 2012).

Van de Kerkhof et al. (2008) performed a randomized controlled trial with an open label extension to evaluate the effectiveness and safety of once weekly 50 mg SQ etanercept for 24 weeks compared to placebo in patients with moderate to severe plaque psoriasis. A PASI 75% improvement was noted from baseline over 12 and 24 weeks (Van de Kerkhof et al., 2008). At week 12, 38% of patients in the Etanercept group attained PASI 75 compared to two percent of patients in the placebo population (Van de Kerkhof et al., 2008). At week 24, 71% of subjects in the Etanercept group achieved PASI 75, 64% achieved a clear or almost clear on the PGA score, and a 71%
improvement was noted in the DLQI score from baseline (Van de Kerkhof et al., 2008). Over 57% of subjects in the placebo-Etanercept group achieved a PASI 75 or greater and 42% achieved clear or almost clear on the PGA score after 12 weeks on the medication (Van de Kerkhof et al., 2008). Adverse events recorded were not much different between the two groups: Etanercept group has 2.1% of AEs and the placebo group had 6.5% of AEs. There were no deaths, serious infections, TB, hepatic abnormalities, or malignancies noted in either groups (Van de Kerkhof et al., 2008).

Esposito et al. also established the efficacy and safety of BMR medications. Researcher found that the both etanercept and adalimumab have appropriate efficacy and safety in elderly patients (Esposito et al., 2012). In this study, sixty-one patients were treated with Etanercept and twenty-eight patients were treated with adalimumab. Over eighty-two percent of all subjects reached a PASI score reduction of ≥ 50% by year three. Over seventy-one percent of subjects achieved a PASI score reduction of ≥ 75%. Overall treatment adherence was high in both treatment groups and was illustrated by survival rates after 3 years of 75% (etanercept) and sixty-one percent (adalimumab). In the etanercept group two main adverse events (AEs) were recorded: repeated tachycardia episodes and gastric cancer. In the adalimumab group, three AEs were recorded: dyspnea, atrial fibrillation, and worsening previous glaucoma. The adherence for greater than three years was consistently high; however, slightly better in the etanercept treatment group. The overall safety and tolerability profiles of both etanercept and adalimumab in elderly patients are excellent. Although elderly individuals have many co-morbidities, the use of TNF-inhibitors can be effective, safe, and tolerable if used and monitored appropriately.
The literature shows overall efficacy of BRM medications in comparison to placebo. Multiple research studies also indicate superior efficacy of BRMs over systemic treatments (Barker et al., 2011; Reich et al., 2012). In a RCT assessing efficacy and safety of infliximab versus methotrexate, researchers Barker et al. (2011) illustrated that 78% of infliximab patients achieved a PASI 75 at week 16 in comparison to 42% of methotrexate patients. At week 26, 77% of infliximab patients achieved PASI 75 compared to methotrexate patients at 31%. Considerable improvement in quality of life was noted in the infliximab group at 83% compared to 67% improvement in the methotrexate group. Overall, a significantly higher proportion of infliximab patients achieved PASI 75 in comparison to Methotrexate therapy. Barker et al. emphasize the efficacy of TNF inhibitors in comparison to systemic therapies for moderate to severe psoriasis patients (2011).

**Adherence to Medications**

Researchers frequently use patient medication adherence as an indicator of overall treatment success (Esposito et al., 2013). Biologic medications considerably increase patient adherence and disease improvement. The literature illustrates that the type of psoriatic treatment employed has a significant effect on adherence, disease improvement, and quality of life. Many studies continue to demonstrate that utilization of biologics increases patient adherence and overall disease outcomes.

In an observation study monitoring factors that affect medication adherence, Chan, Hussain, Lawson, & Ormerod (2011) indicated that the major factor affecting
patient adherence was the type of treatment modality they were on. Adherence ranked 100% for patients on biologics, 96% for oral therapy, 93% for phototherapy, and 75% for topical therapy. (Chan, Hussain, Lawson, & Ormerod, 2011). Also, patients who were on biologics had a higher DLQI score than those on other therapies. Other factors affecting adherence to treatment included being too messy, being too busy, being a smoker, and being fed up with treatments (Chan, Hussain, Lawson, & Ormerod, 2011). Lastly, those with mild psoriasis and a DLQI of five or below were less likely to adhere to therapy.

In a multicenter observation study, researchers Esposito et al. (2013) evaluated the long-term efficacy and safety of TNF inhibitor treatment in patients with plaque psoriasis. Researchers also evaluated reasons for discontinuation of TNF inhibitor therapy. Esposito et al. (2013) illustrated that treatment adherence to TNF inhibitors was 72.6% after 2 years of TNF therapy. Etanercept had the highest rate of adherence and long term use (54.1 months) compared to infliximab (36.8 months), and adalimumab (34.7 months) (Esposito et al., 2013). Increased TNF inhibitor adherence was noted in patients with moderate to severe plaque psoriasis. Factors that seemed to improve adherence include: type of biologic treatment, male subject, younger population, and decrease in rescue therapies including IM and oral steroids and hospitalization. Predictors of treatment cessation included female gender, the use of adalimumab or infliximab compared to Etanercept, and lastly concomitant use of other treatments (Esposito et al., 2013). Lastly, reasons for treatment discontinuation included: primary inefficacy (5.2%), secondary inefficacy (14.5%), and adverse events (4.5%) (Esposito et al., 2013). Esposito et al. demonstrated that BRM medications have long-term safety and efficacy in patients
with moderate to severe plaque psoriasis. Also, researchers found that the most common reasons for treatment discontinuation was related to medication type, gender, and multi-therapy use.

**BRM Efficacy on Psoriasis Comorbidities**

BRM medications reduce the risk of cardiovascular disease significantly. This has been confirmed through both the monitoring of MI rates and cardiac biomarkers in psoriasis patients. The literature indicates that the use of BRM medications decreases cardiovascular disease and overall risk factors through reduction of inflammation and disease severity (Puig, 2011). In a retrospective cohort study evaluating 11,475 psoriatic patients on BRM medications, researchers illustrated a 44% reduction in the overall incidence of MIs (Puig, 2011). Other studies have illustrated a significant reduction in cardiac inflammation levels (CRP) in patients being treated with BRMs (Famenini, Sako, & Wu, 2014; Puig, 2011). Researchers continue to evaluate the true efficacy of BRM medications in relation to cardiovascular effects; however, the growing body of evidence indicates overall decreased cardiac inflammatory markers, cardiovascular events, and reduction of cholesterol (Ryan & Kirby, 2015, Puig, 2011).

Lastly, contradictory evidence has been presented on BRM medications reducing the risk of diabetes. Multiple studies have illustrated that BRM therapy can reduce the risk of diabetes; however, other studies have illustrated hyperglycemia in diabetic patients after the onset BRM medication (Famenini, Sako, & Wu, 2014). The majority of research indicates, that BRM medication reduces insulin resistance through blocking the
TNF alpha pathways, which activate insulin resistance (Famenini, Sako, & Wu, 2014; Voiculescu et al., 2014). If the TNF pathway is inhibited, then the overall insulin resistance decreases (Voiculescu et al., 2014).

**Side Effects of Biologic Therapies**

The utilization of biologic therapies in psoriatic patients requires continuous monitoring and evaluation for side effects, adverse events, and disease progress through an established monitoring protocols and trained practitioners. Biologic medications are indicated for moderate to severe psoriasis and demonstrate high efficacy for disease reduction. Although, these medications are effective and tolerable for patients with moderate to severe psoriasis, they can have significant side effects (Semble, Davis, Reldman, 2014). The most common side effects of BRM medications reported include injection site reaction, headache, URI, cellulitis, urticaria, and elevated liver enzymes (Semble, Davis, Reldman, 2014). Adverse side effects include severe infection, demyelinating conditions, hepatic disease, opportunistic infection, reactivation of TB, lupus, malignancy (lymphoma), CHF, increase in non-melanoma skin cancers, and vasculitis (Menter et al., 2008; Semble, Davis, Reldman, 2014). Studies indicate that only two percent of patients experience adverse side effects; however, these side effects can lead to serious morbidities and mortality (Hanson et al., 2013; Semble, Davis, & Reldman, 2014).

Although the potential adverse events can be very detrimental to patients’ health, standardized guidelines for monitoring these medications are lacking and remain unclear.
Different organizations have proposed certain monitoring criteria; however, no consensus has been established (Hanson et al., 2013).

**Monitoring Guidelines**

Biologics have been used for many decades; however, monitoring criteria have been vague and nonspecific. Evidence related to specific monitoring criteria is relatively limited. Clinical monitoring varies due to lack of consensus on criteria to monitor. With initiation of BRM medications, the majority of Dermatology organizations suggest obtaining a baseline tuberculosis PPD test, base line chemistry panel, CBC, hepatitis panel, physical assessment, and vaccines records (Menter et al., 2008; Hanson et al., 2013). No current guidelines exist regarding follow up and maintenance of BRM medications. The Medical Board of the National Psoriasis Foundation suggests patients be periodically evaluated for disease reduction, side effects, and malignancies (Menter et al., 2008). Therefore, the monitoring decision is left to the clinician to establish follow up visits and disease monitoring (Emer, frankel, & Zeichner, 2010). The majority of dermatologists have BRM patients follow up every 3-6 months; however, some practitioners only require a yearly follow up. The advantages of closely monitoring psoriatic patients on these potentially adverse medications include increased medication adherence, decreased side effects, early identification, prevention of side effects, improved patient safety, appropriate assessment for malignancy, and disease evaluation (Emer, frankel, & Zeichner, 2010; Hanson et al., 2013).
Although, BRMs have severe risks of immunosuppression and malignancy, limited research regarding effective monitoring criteria for BRM medication exists. In 2013, Hanson et al., evaluated the efficacy of implementing a safety monitoring protocol. The Clinical Care Guidelines (CCG) for BRM monitoring were created by the University of Illinois Health Science System’s pharmacists, nurses, and physicians. The CCG was constructed from current evidence based recommendations and studies. The CCG was implemented in EHR form for providers to use during psoriatic BRM visits. The CCG required the monitoring of TB tests, Hepatitis B antigen test, CBC, complete blood counts, current vaccinations, pregnancy testing, assessment for malignancies, physical assessment, disease severity, co-morbidities, side effects, and patient education. If criteria were not met, providers were electronically reminded to complete the assessment area. The specialty pharmacy helped to remind and work with the clinicians to improve patient monitoring and drug administration.

In the CCG study, the subject population (n=320) was divided into four different groups: new patients, renewed prescription orders or changes in treatment, patient who filled their prescriptions at UI and patients who filled their prescriptions outside of UI. Researcher gathered data on meeting the CCG guideline before implementation and 6 months after. The implementation of the EHR CCG significantly improved the safety compliance rate for prescribing and monitoring biologics. The CCG monitoring criteria improved clinical compliance and monitoring by 29%. Specifically, 31% monitoring compliance before the intervention was achieved and 60% compliance after the intervention was achieved (Hanson et al., 2013). All of the groups had significant
increases in clinical compliance and monitoring. The new group had the greatest clinical compliance to the guidelines at 83% compliance.

The Hanson and colleagues’ study is one of the first research studies that examined monitoring criteria and compliance related BRM monitoring criteria. Hanson et al., suggest that the use of a standardized monitoring criterion for BRMs should be utilized to improve safety and efficacy of these medications (see Table 1). In the future, further studies evaluating monitoring criteria are essential to eventually create a standardized guideline for safely monitoring BRMs.
**CCG BRM Monitoring Criteria**

<table>
<thead>
<tr>
<th>Initiation of Biologic Response Modifiers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculin test (TB) and negative result</td>
</tr>
<tr>
<td>Baseline labs: Complete Blood Count (CBC), Comprehensive Metabolic Panel (CMP), Hepatitis panel, and Liver panel</td>
</tr>
<tr>
<td>Live and attenuated vaccination updates before utilization of BRM</td>
</tr>
<tr>
<td>Review of medical history</td>
</tr>
<tr>
<td>Physical assessment</td>
</tr>
<tr>
<td>Maintenance criteria for monitoring BRMs</td>
</tr>
<tr>
<td>- Physical assessment</td>
</tr>
<tr>
<td>- Disease assessment</td>
</tr>
<tr>
<td>- Vaccine review: TB test yearly, Influenza vaccine yearly.</td>
</tr>
<tr>
<td>Vaccine administration is up to the provider.</td>
</tr>
<tr>
<td>- CBC and CMP every 3-6 months</td>
</tr>
<tr>
<td>- Follow up every 3-6 month</td>
</tr>
</tbody>
</table>

Table 1. CCG BRM Monitoring Criteria (Adapted from: Emer, frankel, & Zeichner, 2010; Hanson et al., 2013; Menter et al., 2008).
Nursing theory is an integral part of the DNP Scholarly project and DNP practice. Nursing theory provides a framework for both quantitative and qualitative research. Theory “offers a systematic explanation about how phenomena are interrelated” (Polit & Beck, 2012, p.127) and establishes concepts that guide and influence the conduct of the research. Nola Pender’s Health Promotion Theory was chosen as the nursing theory for this scholarly project because of the strong emphasis on health promotion. Although, health promotion is frequently thought of as applying to individuals and populations, her theory can also apply to the health of an organization. In this scholarly project, areas lacking in health promotion were identified and concepts were constructed to promote overall health of the organization at both the macro and microsystems levels.

Pender’s Health Promotion Theory is a middle range nursing theory that focuses on health prevention and can be applicable to many healthcare settings. Middle range theories are “testable theory that contains a limited number of variables, and is limited in scope as well, yet is of sufficient generality to be useful with a variety of clinical research questions” (Current Nursing, 2012, ¶ 3). Pender’s theory focuses on health as an evolving and fluctuating state that is affected by individual’s experiences, behavior, and
environment (Pender, 2011). All of these factors can either promote or discourage health promotion. Four assumptions of the HPM include: individuals regulate their own behavior, individuals affect and are affected by their environment, healthcare professionals can influence health perceptions and interactions, and self-initiation is critical to changing behaviors (Pender, Murdaug, & Parsons, 2011).

With those assumptions made, Pender analyzes the components of the health promotion process through the evaluation and understanding of “individual characteristics and experiences, behavior-specific cognitions and affect, and behavior outcomes” (Current Nursing, 2012, ¶ 2). These three components are the major processes through which health promotion is achieved.

Pender proposes that there are many elements that influence individual experiences, behaviors, and cognitions. Specifically, she reviews fourteen theoretical components that impact how an individual or organization moves through the health promotion process. The ultimate goal of the HPM theory is to help nurses identify and understand health behaviors that will promote healthy lifestyles and decisions (Pender, 2011).

Rationale

For this project, the DNP student employed a change project into a Dermatology organization to promote the health of the organization and patients. The goal of the project was to implement a safety protocol to monitor patients on BRM medications and improve the patient outcomes.
BRM medications have become a highly utilized treatment for moderate to severe plaque psoriasis. These medications have significantly reduced disease severity and improved patient outcomes and quality of life (Chan, Hussain, Lawson, & Ormerod, 2013). Although TNF inhibitors are considered the most effective therapy in the treatment of moderate to severe plaque psoriasis, their side effect profile can be severe. Using TNF inhibitors may increase the risk of infections, demyelinating disease, and malignancy (Reich, Burden, Eaton, & Hawkins, 2012). With such established risk, baseline assessments and monitoring have been recommended. However, no standardized guidelines exist for the monitoring of TNF inhibitor medications (Hanson, Gannon, Khamo, Sodhi, Orr, & Stubbings, 2013). Multiple research studies indicate that routine clinical monitoring and patient education can reduce adverse events and improve medication adherence (Chan et al., 2013; Esposito et al., 2012; Hanson et al., 2013; Reich et al., 2012; Semble, Davis, & Felman 2014).

The Health Promotion Model provides an excellent framework to understand the current health state of the organization and will help provide guidance for change. In the specific organization, the dysfunction was within the prescribing and monitoring of biologic medications for patients. Before the intervention, no specific monitoring or prescribing guidelines existed to help safely monitor clients on these medications. In the last year, the number of medication-induced side effects had significantly increased and patient adherence to these medications continued to decrease (Chan et al., 2013). Therefore, the current system was not promoting health in this area and was, instead, potentially harming the health of the patients. In order to promote health for the
organization, Pender’s model was used to create a monitoring protocol to decrease medication side effects, increase patient adherence and, therefore, promote health of the organization.
CHAPTER FOUR

METHODS

Ethical Issues and Human Rights

In October of 2015, the Montana State University Institutional Review Board approved an exemption for this project. In this study, chart reviews were performed to evaluate for biologic completion criteria before and after the intervention. Data collected included laboratory work, immunization history, physical assessment, psoriasis assessment, psoriasis severity scores, and patient education. Patients were then randomly assigned a number to make sure their data were not used more than once. No identifying factors were used such as name, date, sex, or photos to link the data to the patient. This number list was kept in a locking cabinet within a secure building. At the end of the data collection, this list was shredded. The HIPPA form was used each time the patient checked into the office to ensure patient information protection (Appendix A).

A potential author conflict of interest included that the author worked within the dermatology setting in which the intervention took place. The author also taught the staff how to utilize the biologic EMR template. In order to prevent bias or ethical concerns, the same teaching methods were utilized for all staff though PowerPoint and written instructions.
Sample and Setting

Location of Data Collection

This pilot project took place at a Montana dermatology clinic. This is an outpatient dermatology clinic that treats patients with all types of dermatological conditions including skin cancer, psoriasis, and other skin ailments. This Dermatology clinic has been providing skin care to patients for over 30 years. The practice has 2 Board certified Dermatologists, 3 Dermatology Nurse Practitioners, and 1 Physician Assistant. The clinic has an office manager, nurse manager, billing manager, and multiple Registered Nurses, Licensed Practical Nurses, and Medical Assistants.

Prior to this project, no practice wide monitoring criteria, education, or outcome criteria for patients on biologic medications existed within the clinic. The clinic recently transitioned from paper charts to an EMR called Next Tech. This was a specific dermatology EMR with existing templates and templates that could be created by the providers. There was a biologic template that on which to record where the psoriasis is located on the body, what their treatment is, and what the medication plan is.

Patient Characteristics

The sample assessed in this project were patients in a Montana Dermatology clinic on or starting on BMRs for moderate to severe plaque psoriasis over the age of 18 years old. A total of 48 patient charts were selected for review that met the above criteria. Patient charts were reviewed to collect data on psoriasis medications used, psoriasis severity scores, immunization history, laboratory records, comorbidities, patient follow ups, and
patient education performed. Data on sex, and age were collected; however, no data on race were collected.

![Age distribution of subjects](image1.png)

**Figure 1.** Age distribution of the subjects.

![Biologic Medication](image2.png)

**Figure 2.** Distribution of patient on each BRM medication.
Intervention Design

BRM are highly effective medications for the management of moderate to severe psoriasis; however, their side effects can be severe and possibly life threatening if not monitored appropriately. At Montana Dermatology clinic, no specific monitoring criteria for BRMs existed prior to this project. The literature illustrates the benefits and increased safety of implementing monitoring criteria; however, a consensus has not been finalized to make distinct recommendations. Therefore to improve overall safety with prescribing these medications, the goal of this scholarly project was to improve provider biologic monitoring compliance through the development and implementation of a BRM monitoring Electronic Medical Record template into a Montana Dermatology clinic in December 2015.

BRM Monitoring Criteria

The DNP student and participating staff members researched biologic monitoring criteria recommended by dermatology experts, medical organizations, and drug companies around the world. The most consistent monitoring recommendations identified were from the American Academy of Dermatology (AAD) and from the University of Illinois Medical Center (UIMC) Care Guidelines monitoring criteria. The University of Illinois care guideline study was the only study identified in the literature specifically implementing monitoring criteria for BRM medications. All other research reviewed was based on expert recommendations grounded on experience versus actual data and study design.
The Biologic Response Modifier EMR was then created based on the AAD and UIMC guidelines to improve clinical compliance and patient safety. The BRM template was created by the DNP student in Next Tech, which is a specific dermatology electronic medical record. The template was then edited and approved by the project team for implementation into the clinic in December of 2015.

The template was set up to monitor immunizations, patient laboratory studies, psoriasis severity scores, physical assessment, patient education, and patient follow up. Figure one illustrates the specific data included in the template. The BRM EMR template can be seen in Appendix A.

<table>
<thead>
<tr>
<th>Monitoring criteria BRM therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Physical assessment yearly</td>
</tr>
<tr>
<td>- Vital Signs including blood pressure, pulse, and oxygen saturation.</td>
</tr>
<tr>
<td>- Disease assessment every three to six months.</td>
</tr>
<tr>
<td>This involves record of PGA, side effects, and or body surface area affected.</td>
</tr>
<tr>
<td>- Patient education performed</td>
</tr>
<tr>
<td>- Vaccine review: TB test yearly, Influenza vaccine yearly.</td>
</tr>
<tr>
<td>- CBC, CMP, UA every 3 months</td>
</tr>
<tr>
<td>- Follow up every 3 month</td>
</tr>
</tbody>
</table>

Table 2. Established monitoring criteria for the intervention (Adapted from: Emer, frankel, & Zeichner, 2010; Hanson et al., 2013; Menter et al., 2008).
In-Service Training

After the template was created and approved by the project committee, an in-service to participating staff was given regarding how to use the proposed clinical guidelines and EMR template. Staff members were given hand outs of the template and instructed on appropriate use. See Appendix B and C. Support was provided by the DNP student for questions, concerns, and comments regarding utilization of the BRM template. The BRM monitoring template was then implemented on December 1, 2015 and extended through June 30, 2016.

During the intervention, chart reviews of previous patients were performed to see what patients met the BRM monitoring guidelines before the intervention to compare to after the intervention. Data collected on these patients included the biologic medication utilized, the laboratory tests drawn, the vaccinations given, the side effects experienced, patient comorbidities, patient education performed, physical assessment, evaluation of comorbidities, and the disease severity using the Physicians Global Assessment scale (PGA) (Appendix B) and or Body Surface Area (BSA) assessment. Providers and nurses were responsible for asking the questions, documenting EMR requirements, and following through on monitoring compliance.

Operational Definitions

Specific definitions were used to identify how the information was collected and considered complete or incomplete. Values that were considered incomplete were assigned a value of 0 and values considered complete were assigned a value of 1.
Vital Signs: Blood pressure, pulse, and oxygen saturation are performed.

Physical assessment: The provider has auscultated the patient’s lungs, heart, and abdomen. The cervical and axillary lymph chains are assessed. The patient’s skin and joint assessments are documented.

Immunizations: TB test performed yearly.

Laboratory completion: Laboratory work CBC, CMP, UA, and Mg are ordered and performed every 3-6 months depending on the biologic status of the patient.

Psoriasis scale completion: Body Surface area and or Physician Global Assessment scales are documented. One or more must be documented.

Common side effects: common effects directly associated with a medication including: injection site reactions, upper respiratory tract infection (sinus infection, viral upper respiratory syndrome), and headaches.

Adverse side effects: Uncommon effects directly associated with a biologic medication including: pneumonia, migraine, cellulitis, malignancy, new onset neurological disease, new onset or worsening of congestive heart failure, opportunistic infections or fungal infections. (HumiraSingh, J. A. et al., 2011).

Patient education completion: Documented psoriasis education including subjects on medications, disease process, comorbidities, or any subject related to psoriasis.

Follow up completion: Patient is scheduled for follow up every 3 or 6 months depending on time on biologic medication. If patient has been on biologic <1 year they will have 3 month follow-ups. If patient has been on biologic > 1 year they will have 6 month follow-ups.
Roles

In this specific project, the providers and clinical staff (RNs, LPNs, and MAs) were the supporters and implementers of the monitoring criteria. The providers were responsible for assessing for disease severity utilizing the PGA score system or BSA, recording side effects, and prescribing the medication. The clinical staff were responsible for entering in patient data, printing of lab work, making sure lab work was performed, and updating vaccinations (TB test, Hepatitis B surface antigen, and influenza) as recommended. The recorded data were entered into the BRM EMR template to keep track of events, changes, and patient condition. Reminders were setup in the system to remind the provider or medical staff to order lab work, update immunizations, or come in for follow-ups.

Instruments for Data Collection

The instrument utilized in this project for collecting data was the BRM monitoring template created by the project team at the hosting facility. The instrument was based off of the University of Illinois Care Guidelines. The UIC Biologic Care Guidelines (BCG) were validated in Hanson et al research study. In this study, the UIC BCG established the efficacy of specific guidelines for improving clinical compliance, patient safety, and patient outcomes (2013). The American Academy of Dermatology’s biologics monitoring guidelines were also utilized within the EMR protocol to support and create the intervention.
Budget

The monetary needs for this improvement project were fairly minimal. To create the BRM monitoring protocol and implement it into the EMR did not require any specific funding. The researcher had been trained to edit and create templates within the EMR. EMR support from the Next Tech Company was provided at no additional charge, as a one year support contract was in place with the clinic already.

Staff members were paid their hourly wage for their time and training on the BRM protocol. Project team meetings occurred once a month and took place during designated work hours. Therefore, no additional costs were needed for holding the meeting and reimbursing staff for their time.

This intervention was time intensive for the providers and DNP student involved. Due to the time needed for collecting information, performing physical assessment and educating patients, the visit time changed from 15-minute appointment to 30-minute appointments. Providers were appropriately reimbursed through increased visit charge for spending more time with patients, performing physical assessments, and addressing more patient issues.

Steps of the Intervention

The DNP student was completely responsible for initiation of the project committee and subsequent interventions. The DNP student acknowledges without the support of the clinic, staff, and research team this project would not have been achievable.
1. The preparation for this project began with formulating a project team consisting of the DNP student, one dermatology provider, one LPN, and one MA practicing within the clinic. This team was created based on individual interest for BRMs, experience with BRMs, individual’s ability to identify and solve problems, and individual’s ability to work with a team.

2. Specific aim of the scholarly project was established. The DNP student aimed to improve overall safety with prescribing BRM medications, through improving provider biologic monitoring compliance through development and implementation of a BRM monitoring Electronic Medical Record template into a Montana Dermatology clinic by December 2015. After implementation of the biologic EMR, the goal was that the provider-monitoring compliance would increase 50% by June 2016.

3. The team had multiple meetings to identify appropriate BRM monitoring criteria for the proposed BRM template.

4. Utilizing the UIMC care guidelines and recommendations from the AAD, the BRM monitoring template was created and inserted into Next Tech EMR program by the DNP student.

5. The DNP student taught the project team to appropriately utilize the template through team meetings and guideline handouts. Comments and suggestions were utilized to edit the EMR.
6. Patients 18 years or older with a diagnosis of moderate to severe psoriasis and on a biologic medication (etanercept, adalimumab, and ustekinumab) were selected for chart review before and after the intervention.

7. The EMR was fully implemented and utilized starting December 1, 2015 in the Montana Dermatology clinic.

8. The DNP student collected data including laboratory work, vaccination record, disease severity scale, documented side effects, physical assessment, patient comorbidities, patient education, and medication type before and after the intervention. Data were also collected on patients commencing BRM medications after the initial implementation of the BRM monitoring template.

9. Data were analyzed utilizing before and after comparisons, McNemar’s test, and the paired t-test.

10. Final project presented to staff at Montana Dermatology Clinic and a commitment was made to continue utilization of the BRM monitoring template for all patients on BRM medications within the clinic.

**Expected Outcomes**

Pender’s Health Promotion Model (HPM) was utilized to identify problems within the microsystem and create solutions to solve the acknowledged problems. Pender’s HPM helped to guide evaluation of the microsystem and identify dysfunctions within the system that lead to decrease in health of the organization. If patients on BRM medications were not being appropriately monitoring then a potential decrease in patient
health could occur and therefore failure of the organization to promote health. Thus, the process of monitoring patients on BRM medications was closely evaluated in the clinic to create a health-promoting model of prescribing and monitoring patients on BRM medications.

Both a global aim and specific aim were established for creating and implementing an improvement project to develop and improve biologic safety and monitoring within the microsystem. A global aim is a broad theme identified by the DNP student that clearly states the overall goal for the project. The global aim for this study was to improve the overall assessment, treatment, and patient safety for psoriatic patients on Biologic Response Modifier (BRM) medications at a Montana Dermatology clinic. The process began with assessing the microsystem, identifying specific interventions for improvement, and implementing the interventions. The process ended with evaluating and reflecting on the interventions for maintenance and improvement.

A specific aim describes precise improvements identified with measurable outcomes (Nelson, Batalden, & Godfrey, 2007). In this scholarly project the specific aim was to improve provider biologic monitoring compliance through development and implementation of a BRM monitoring Electronic Medical Record template into a Montana Dermatology clinic by December 2015. After implementation of the biologic EMR, the goal was that provider-monitoring compliance would increase 50% by June 2016.

Through establishing both a global and specific aim, the DNP student and project team were able to guide both the creation of the BRM monitoring EMR template and
advocate implementation within the clinic to improve monitoring practices. Additionally these aims gave the providers and patients outcomes to work for in order to improve gaps in patient care identified.

Analysis

Data Collection

In this study the data collected were quantitative. Data were collected through reviewing 35 patient charts before and after the BRM protocol was implemented. Additionally, data were collected on 12 new patients initiating BRM medications after implementation of the BRM template. Data collected on these patients included the date of visits, biologic medication utilized, physical assessment completion, disease assessment (BSA, PGA score), the laboratory tests drawn, the vaccinations given, the side effects experienced, patient education performed, comorbidities, and record of follow up appointments. Data were collected and organized as complete or incomplete based on operation definitions of data collected. Completed data were assigned the numerical value 1 and incomplete data were assigned the numerical value of 0.

Analytical Methods

The data were then analyzed using retrospective binary comparisons to see what patients charts met BRM monitoring guidelines before and after the intervention. Both the t-test and McNemar’s test were used to evaluate proportion of items completed,
distribution, and association of the data collected. Mr. Flagg and Dr. Lin from the Montana State University Statistic Department performed the statistical analysis.

Effect Size

According to the Center for Evidence Based Intervention, effect size is “a quantitative measure of the difference between two groups” (2016). Effect size can be interpreted using Cohen’s interpretation. If the difference is $\leq 0.2$ = small effect size, if the difference is $\geq 0.5$ = large effect size (CEBI, 2016). Unlike statistical significance effect size takes into account sample size. A large sample may have a greater or less effect depending on the difference of groups in relation to their size. Since this study is a smaller pilot study, the effect size may be less than expected in comparison to a larger sample size.

Quality Assurance

In order to provide quality assurance the data were collected and assigned the correct numerical value for completion by only the DNP student. The DNP student used the operational definitions in each chart review to determine if each category was considered complete or incomplete. With having only one individual performing the data collection, less risk for bias or misunderstanding of the operational definitions occurred.

Additionally, all staff entering and recording the data in the chart had the same training experience and handouts. This helped decrease the potential for mistakes made due to lack of training.
CHAPTER FIVE

RESULTS

Introduction

The purpose of this study was to create and implement a Biologic Monitoring Electronic Medical Record (EMR) template into a Montana Dermatology clinic to improve provider-monitoring compliance and improve the safety of patients with moderate to severe plaque psoriasis on BMR therapy. Seven items were used to compare before and after provider monitoring compliance including vital signs, physical assessment, psoriasis severity score, laboratory work, patient education, immunizations, and follow up. Completion frequencies, the paired t-test, and the McNemar’s test were used to establish data analysis and outcomes. Mr. Flagg and Dr. Lin, PhD, whom were a part of the Montana State University Statics Department, performed statistical consultation and analyses for this pilot project. Mr. Flagg and Dr. Lin were supported by the General Medical Sciences NIH grant for their time.

Findings

Before and After Comparison

The goal of this study was to evaluate provider completion rates of the EMR BRM safety monitoring protocol before and after implementation. Seven categories were established for comparison. A total of 35 patient charts were reviewed before and after
the intervention. Before the intervention 3.83 items (55%) out of 7 items were completed and 6.86 items (98%) were completed after. Figure 3 illustrates comparisons before and after the intervention of each category and Figure 4 shows the distribution of the number of completed items before and after.

**Completion Before and After the BRM Monitoring Protocol**
Figure 3. Completion Before and After the BRM Monitoring Protocol. Plots of the proportion of charts where each item was complete for the before and after periods (Flagg & Lin, 2016).
Figure 4. Distribution of the number of completed items for the 35 participants. After implementation, 31 of the participants had all seven items complete (Flagg & Lin, 2016).

Proportion of Items Completed

The paired t-test was used to evaluate the proportion of items completed before and after the intervention. An average difference of .433 with a standard error of 0.029 was observed resulting in a t statistic of 14.9 on 34 degrees of freedom (p-value <0.0001) was established with a 95% confidence interval. This means that a 37-49% improvement should be seen in item completion after implementation of the intervention. These results illustrate a strong statistical conclusion that the intervention improved overall provider monitoring compliance.
McNemar’s Test

McNemar’s test was used to evaluate for an association between implementation of the BRM safety monitoring protocol and improvement in provider compliance. According to Flagg and Lin, “The McNemar’s test can test for an association between paired binary observations by comparing the proportion of participants where completion status changed between the two visits” (2016). If no change is seen then it can be assumed that there is an equal chance of the item being incomplete or complete. However, if a change is observed, an association between implementation of the intervention and completion of items can be established. The McNemar’s test was performed on each of the seven items as seen in Tables 3-9. The McNemar’s test illustrated that there is strong evidence (p-value < 0.001) that the intervention created a
proportionate difference between before and after completion values of vital signs, physical assessment, psoriasis scale, and patient education. Moderate evidence was established ($p = .0313$) with proportionate difference with improvement of laboratory completion. Lastly, the McNemar’s test was not performed on the follow up item, as this was already 100% completed before and after the intervention.

**McNemar’s Test**

<table>
<thead>
<tr>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Incomplete</td>
</tr>
<tr>
<td>Incomplete</td>
<td>1</td>
</tr>
<tr>
<td>Complete</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 3. Vital Signs. McNemar counts: $b = 24$, $c = 0$, $p$-value < 0.0001 (Flagg & Lin, 2016)

<table>
<thead>
<tr>
<th>Before</th>
<th>After</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Incomplete</td>
</tr>
<tr>
<td>Incomplete</td>
<td>0</td>
</tr>
<tr>
<td>Complete</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 4. Laboratory. McNemar counts: $b = 6$, $c = 0$, $p$-value = 0.0313 (Flagg & Lin, 2016)

<table>
<thead>
<tr>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Incomplete</td>
</tr>
<tr>
<td>Incomplete</td>
<td>1</td>
</tr>
<tr>
<td>Complete</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 5. Immunization. McNemar counts: $b = 3$, $c = 0$, $p$-value = 0.2500 (Flagg & Lin, 2016)
Before | After
---|---
| Incomplete | Complete |
Incomplete | 1 | 23 |
Complete | 0 | 11 |

Table 6. Physical. McNemar counts: $b = 23$, $c = 0$, $p$-value $< 0.0001$ (Flagg & Lin, 2016)

Before | After
---|---
| Incomplete | Complete |
Incomplete | 1 | 19 |
Complete | 0 | 15 |

Table 7. Psoriasis Scale. McNemar counts: $b = 19$, $c = 0$, $p$-value $< 0.0001$ (Flagg & Lin, 2016)

Before | After
---|---
| Incomplete | Complete |
Incomplete | 1 | 31 |
Complete | 0 | 3 |

Table 8. Patient Education. McNemar counts: $b = 31$, $c = 0$, $p$-value $< 0.0001$ (Flagg & Lin, 2016)

Before | After
---|---
| Incomplete | Complete |
Incomplete | 0 | 0 |
Complete | 0 | 35 |

Table 9. Follow Up. McNemar counts: $b = 0$, $c = 0$, $p$-value $= 1.0000$ (Flagg & Lin, 2016)

Completion Status for New Patients

After the intervention was established, 13 new patient charts were analyzed for completion rates. Figure 6 illustrates the proportions of items completed and figure 7 illustrates the distribution of items completed. The proportions for each item are high,
with the lowest being 0.846 for Vital Signs. On average, these charts have 6.69 of the items complete, for an average completion proportion of 0.956. Figure 8 illustrates the distribution of the total completion counts.

![Completion Status for New Patients](image)

**Figure 6.** Proportion of new participant charts where each item is complete (Flagg & Lin, 2016).

![Total Number of Items Completed for New Patients](image)

**Figure 7.** Distribution of the number of completed items for the 13 new participants. Ten participants had all seven items complete (Flagg & Lin, 2016).
Comorbidities

Comorbidities were identified and recorded in each patient chart. Forty percent of all patients had comorbidities associated with Psoriasis. Of those patients: 43% had hypertension, 10% had diabetes, 32% had Obesity, and 14% had depression.

![Comorbidities Identified](image)

Figure 8. Hypertension, diabetes, depression, and obesity were the main comorbidities identified in the project.

Side Effects

A total of 21 side effects were observed in 17 people (35%). A total of 17 of those side effects were considered mild to moderate side effects (URI, injection site reaction, and headache) and 4 were considered adverse side effects including cellulitis, depression, migraine, and pneumonia.
Figure 9. URI, Injection site reaction, migraine, pneumonia, cellulitis, and depression were reported side effects in this project.

**Laboratory Changes**

Lab changes including leukocytosis, urinary tract infections (UTI), glycosuria, elevated liver enzymes, and hyperglycemia were all identified as side effects. Of the 48 patients, 12 patients (25%) had laboratory findings changes that warranted further work up. Of those 12 patients, 58% experienced leukocytosis, which led to the discovery of pneumonia, chronic undiagnosed blood disorder, urinary tract infection, and cellulitis. About 25% of the patients experienced UTIs that were asymptomatic initially and all were treated appropriately with UA and sensitivity. A total of 8% of patients experienced glycosuria. In this case, new onset diabetes was identified and appropriate referrals were made for management.
Figure 10. Laboratory changes identified including leukocytosis, urinary tract infection, and glycosuria.
CHAPTER SIX

DISCUSSION

Introduction

The purpose of this study was to create and implement a Biologic Monitoring Electronic Medical Record (EMR) template into a Montana Dermatology clinic to improve provider-monitoring compliance and improve the safety of patients with moderate to severe plaque psoriasis on BMR therapy. This scholarly project illustrated that the implementation of the BRM safety monitoring protocol increased providers monitoring compliance of patients on BRM medications. Through utilization of the BRM template secondary outcomes of increased patient education, appropriate identification of comorbidities, and early identification of side effects were established.

Pender’s HPM

This scholarly project was guided by Pender’s Health Promotion model, which focuses on health promotion of the individual or organization. In this project, health promotion of the organization was the primary goal. The mission of the Montana dermatology clinic was to provide the best, most effective, and safe dermatology healthcare to all. When analyzing the organization, a major gap in care for patients on BRM medications was identified. At the dermatology clinic, no specific guidelines were in place for monitoring these high-risk medications, therefore, causing possible decline or deterioration of patients’ health. BRM medications provide life-changing therapies to
psoriatic patients; however, if not monitored correctly, they can cause harm and a decrease in the overall health of the patient. With having potential decreased health outcome for patients, this decreased the overall health of the organization.

Therefore, utilizing Pender’s tenants for health promotion, an intervention promoting the health of the patients on BRM medication was identified as a way to actively improve health care at the organization. According to Pender’s theory, “health promoting behaviors should result in improved health, enhanced functional ability and better quality of life at all stages of development” (Gonzalo, 2011). Through implementation of the BRM safety-monitoring template, providers and staff significantly increased their compliance in monitoring BRM patients. Through closely monitoring such patients, infections were identified and treated quickly, WBC counts were monitored more closely for infection and cancerous changes, patients were current on all of their required immunizations, physical and skin assessments were more in depth and performed more regularly, and lastly, increased overall patient education occurred.

The last component of Pender’s HPM involves maintaining the health promotion intervention and preventing competing forces from reversing the intervention. Such forces “can derail an intended health promoting actions (Gonzalo, 2011),” which defeats the success of the intervention. Therefore, to ensure longevity of the BRM safety-monitoring template, the dermatology clinic committed to utilizing only the BRM template for monitoring psoriatic patients on BRM therapy. Also, the project team at the clinic voted to assess the template every 6 months for needed changes depending on new research and changes in evidence-based practice.
Strengths

Multiple factors were identified related to the strengths and success of this intervention including the intervention design, the supportive hosting facility, and the strong committee support of the DNP. Although a small sample size was a limitation in this scholarly project, it was also strength. In order to appropriately test the intervention, performing a pilot project with a small population enabled the DNP student to evaluate the efficacy of the intervention without expending too many resources on an unknown outcome. The intervention was incredibly successful with a 91% increase in provider compliance. With such high compliance rates, this pilot scholarly project was successful in initiating practice change. Therefore, in the future, this intervention can be applied to a larger population to compare further outcomes.

Another strength identified was the support of the hosting facility. The staff and management were all open to evaluating needs within the clinic and strongly supported evidence based practice changes. Although the project was time intensive for the project team and its staff, the staff’s willingness and positivity helped to drive the project forward. There was minimal resistant in learning how to utilize the BRM safety monitoring EMR template. The project team staff participated in creating and evaluating the intervention based on recommended BRM guidelines and with a strong focus of making the template user friendly.

Lastly, the support of the DNP committee was essential for the initiation and completion of this project. The committee helped to culminate ideas related to
intervention creation and establishment. They also served as a guide for the DNP’s continuous progress throughout the intervention.

**Comparison of Outcomes with the Literature**

In the literature to date, there have been minimal studies performed specifically examining the outcomes of monitoring protocols for patients on BRM therapy. The majority of articles and research reviewed suggested further research conduction to establish appropriate monitoring guidelines for patients on BRM medications (Ahn et al., 2015; Huang et al., 2008; Van Lumig et al., 2011; Levine & Strober, 2010; Papp, 2008). In addition to this scholarly project, many research articles support the utilization of laboratory, immunization, and disease severity monitoring (Levin & Strober, 2010; Hanson et al., 2013; Papp, 2008). However, research to evaluate a monitoring protocol for patient co-morbidities and psoriasis patient education is lacking.

**Monitoring Guidelines**

In review of the current literature, there is insufficient evidence to make an overall recommended guideline for monitoring psoriatic patients on BRM due to lack of rigorous quantitative studies. In one study examining current monitoring criteria for biologics, researchers Ahn et al. (2015) found only 26 qualitative articles recommending for or against screening tests including TB tests, laboratory tests, and or comorbidity assessment. The studies reviewed were retrospective without any specific intervention or guideline for monitoring criteria. The utilization of the Tuberculosis test was the only
consistent screening method recommended due to the black box warning of reactivation of latent Tuberculosis. Ahn et al. concluded that due to sparse research studies on monitoring criteria, there was not enough evidence to support or refute specific monitoring criteria (2015). In the UIMC’s BRM study, Hanson et al established that implementing safety guidelines for monitoring BRM medications increased provider compliance and overall patient safety and medication adherence (2013). This study served as a baseline for future studies evaluating the most important monitoring criteria for providers utilizing BRM medications. Additionally, Levine and Strober (2010), supported the use of monitoring criteria stating, “for all biologic therapies it is imperative that the patient undergoes regular surveillance for a range of possible events” (p.32). The authors argued that due to the known risk of immunosuppression, infection, and cancer, BRM patients need to be monitored closely. Although the authors support the use of monitoring criteria, they were still unable to recommend a set criteria based on evidence-based studies.

The BRM safety monitoring scholarly project is one of the first projects examining the impact of establishing monitoring criteria for all psoriatic patients on BRM medications. Although each patient’s background, history, and experiences need to guide the providers monitoring practices, having established guidelines would ensure all BRM patients were receiving appropriate monitoring and care. In this scholarly project, the DNP student found that implementing a safety monitoring protocol increased the providers’ ability to adjust and perform appropriate care for the patient.
The use of laboratory monitoring is controversial in the literature. Some researchers indicate that frequent laboratory monitoring of BRM patients can be a financial burden, waste of healthcare resources, and patient burden due to frequent venipunctures (Van Lumig et al., 2011). Although Van Lumig et al suggested that routine laboratory monitoring is not necessary for BRM patients, their study illustrated that monitoring blood counts overtime illustrated statistically significant declining trends and hematologic abnormalities (2011).

The DNP scholarly project did not specifically analyze patient burden or cost of laboratory testing; however, neither did research studies supporting or refuting use of laboratory monitoring for patients on BRM medications. When performing tests in healthcare the goal of testing should be evaluated. In this scholarly project, the reason for choosing to implement laboratory monitoring within the BRM monitoring template was to screen for and identify potential infection, malignancy, blood disorders, comorbidity identification, and monitor for disease trends. Through performing laboratory monitoring, the DNP student found that 25% of the patient population experienced significant laboratory changes associated with the BRM therapy or disease process. Specifically, lab changes such as leukocytosis, urinary tract infections, glycosuria, elevated liver enzymes, and hyperglycemia were identified and warranted further treatment or work up. Although, the sample size was small (48 patients), a statistically significant number of patients experienced a laboratory change related to their treatment plan. Therefore, this project illustrates the importance of monitoring laboratory function tests on BRM
patients. In the future studies specifically evaluating the risks and benefits of laboratory monitoring on BRM patients should be performed.

Immunizations

Recommendations for immunization monitoring for psoriatic patients on BRM therapy unanimously endorse the utilization of TB testing before initiating BRM therapy. However, performing the TB test just before the initiation of the medication or yearly is contentious whether or not it needs to be performed annually or just before initiation of BRM therapy. Both the AAD and the National Psoriasis Foundation (NPF) suggest the utilization of the TB test before introduction of the BRM therapy and annually (Menter et al., 2008; Sivamani et al., 2013; Ahn et al., 2015).

In the BRM safety monitoring template recommendations were utilized from the AAD and NPF. The template reminded providers to perform yearly TB tests on their BRM patients. In this project, either utilization of the tuberculin skin test (TST) or the QuantiFERON-TB Gold tests were acceptable. Compliance for monitoring TB tests increased from 89% to 98% after the completion of the intervention. Overall, the Montana dermatology clinic was monitoring TB tests routinely for the majority of BRM patients before and after the intervention.

Assessment

Both the AAD and NPF recommend physical assessment and disease assessment at each visit with BRM patients. However, no specific recommendations were used to guide what type of physical assessment should be utilized, what disease assessment score
should be used, or what type of vital signs should be performed. In the literature, utilization of the Physician Global Assessment score and Body Surface Area score are the most commonly used scales for disease assessment. Therefore, in creation of the BRM monitoring protocol, the project team advised physical assessments, disease severity scores, and vital signs to be performed at each visit.

With the onset of new studies and information revealing the significant comorbidities and health risks associated with psoriasis, the advantages of implementing regular assessments was advantageous to both the provider and patient (Yeung et al., 2013). Through performing regular physical assessment and vital sign assessment, the provider was able to identify any respiratory, cardiac, abdominal, or lymph system changes. Specifically, 1 case of pericarditis, 2 cases of pneumonia, 8 cases of URIs, and one case of cellulitis were identified upon physical examination in this project. Also, the use of vital signs helped the provider to identify comorbidities such as hypertension or cardiac related disorders. In this project, 40% of the patients had comorbidities associated with psoriasis. Seven new cases of hypertension, 3 new cases of diabetes, and 1 new case of congestive heart failure were identified through utilization of the BRM protocol.

The employment of disease severity scores increased the ability of the provider and patient to quantify their disease improvement or worsening of their psoriasis. The disease severity scores provided quantitative evidence to suggest continuing or changing the treatment plan. Robinson, Kardos, and Kimball (2012) supported the use of the PGA and recommended its regular use in clinic settings to appropriately evaluate psoriasis patients.
Lastly, in this scholarly project, the provider was responsible for monitoring and documenting side effects experienced by the patient. Over 35% of patients in this study experienced side effects (URI, UTI, headache, and injection site reaction) and of those patients 29% experienced adverse side effects (pneumonia, cellulitis, migraine). The literature supports evaluating patients for side effects, as these are established risks of therapy due to their mechanism of action and FDA side effect report (Sembel, Davis, & Feldman, 2014).

No specific harms could be identified related to employing regular assessment of patients. In the literature, no specific guidelines were recommended for type of assessments to perform or frequency. However, the majority of BRM monitoring articles and studies suggested regular assessment and performance of disease severity scales (Ahn et al., 2015; Emer, Frankel, & Zeichner, 2010; Levine & Strober, 2010; Menter et al., 2008; Papp, 2008).

**Comorbidities**

Within the last decade, research illustrating the systemic effects of psoriasis has become significant and widespread. Cardiac disease, metabolic disorder, stroke, and depression have been identified as major comorbidities associated with psoriatic disease (Armstrong, Harskamp, & Armstrong, 2013). Patients with psoriasis are 30 times more likely to experience a cardiovascular event related to the chronic inflammation induced specifically by psoriasis than the general population (Mehta et al., 2009).
In this project, the DNP student found 40% of the patients had comorbidities associated with psoriasis. Of those patients, 60% of the comorbidities were related to cardiac events, 15% were related to diabetes, and 25% were related to obesity and or depression. This scholarly project illustrates the confirmed prevalence of comorbidities associated with psoriasis. Through screening patients for comorbidities, patients can be better monitored, educated, and managed.

Financial Implications

The cost of implementing the BRM safety monitoring protocol was fairly minimal for the Dermatology clinic. An EMR was already in place and the DNP student was trained on creating and editing templates. The greatest commitment of the intervention was time from staff to learn how to use the BRM safety-monitoring template. The project team was trained and met during work hours, which could be considered a cost to the clinic.

Secondary costs could be related to laboratory expenses for patients and costs of visits. Costs were not specifically monitored in the scholarly project; however, a randomized search was performed on laboratory costs in the region. According to Fair Health, a website committed to providing estimated healthcare costs, the cost of a comprehensive chemistry panel, complete blood count, and urinalysis would cost someone living in Montana with insurance a total of $86.84. Also, the cost of visits every 3 months for the first year and every 6 months thereafter may also have financial implications. Each visit costs a patient without insurance $75-$115. With insurance some
patients have zero co-pay and others have up to $40.00 copays. These estimates could be higher or lower depending on the insurance plan; however, the majority of patients’ deductibles are met from the cost of the BRM therapy and therefore co-payments are the main cost to patients.

Although there are costs associated with monitoring BRM patients, the cost of not monitoring patients could lead to hospitalization for pneumonia, exacerbation of comorbidities, or unidentified blood or carcinoma disorders. According to Thomas et al., for a Medicare client, the average cost of a hospitalization and follow up for pneumonia would be $15,682 (2012). It would take over 180 lab draws or 90 years of lab draws to equal the cost of pneumonia. Therefore evaluating the cost of prevention practices versus disease treatment must further be evaluated and assessed when considering financial implications of this intervention.

**Limitations**

This was a pilot project to evaluate the efficacy of a BRM safety-monitoring template in relation to provider compliance. Although sufficient for a pilot project, the sample size was small and therefore a limitation. However, this pilot project helped to validate the use of the BRM template and illustrated the effect of augmented provider compliance of monitoring. Therefore, in order to strengthen the statistical and clinical significance, performing the study on a large population would be advantageous.

Another limitation of this project was the setting of a rural Montana dermatology clinic. Due to the rural setting, this project may not be generalizable to larger academic
practices or urban practices. Implementing this project in a larger setting would illustrate if there were differences in provider compliance between urban, rural, or academic settings.

Bias is also a potential limitation identified within this scholarly project. Potential biases identified include training of staff, and DNP student participation-and experience. Although all participating staff were provided with the same teaching materials, some staff were stronger at navigating and using the EMR. Information could have been missed or entered incorrectly due to user error; therefore potentially confounding the results. Also, the DNP student participated as a provider with the project, potentially causing bias in monitoring patients. However, measures were taken to try and prevent such bias. All staff and providers received the same training and used the same monitoring template for assessment of patient on BRM medications. Also, patients followed up with the same provider for each visit to prevent provider assessment bias. Lastly, documentation of the practitioner providing care was not disclosed or compared to prevent breech of privacy and respect.

Lastly external validity and reliability must be examined. These results can be generalized to rural or private dermatology clinics providing care to psoriasis patients on BRM medications. If the clinic does not have an EMR then the template can be utilized on paper making the utilization flexible for use. Due to the size of the sample and location, the results may not be generalizable to larger practices or academic settings. Generalizability of the results could be examined through replication in a larger institution or academic setting. Since psoriasis patients in all locations and settings have
the same risks for comorbidities and utilize similar medications, the EMR safety-monitoring template should be easily employed in any setting.

Medications and drugs will change overtime for psoriasis. With these changes and further research, monitoring criteria will need to be adjusted and addressed as research changes. There will need to be a monitoring system in place to make sure the appropriate data are gathered and documented to improve overall patient care and outcomes. At the hosting Montana dermatology clinic, the providers and staff are committed to using this template for all patients on BRM therapies. Also, utilizing this template will help providers who do not yet prescribe BRM medications, to have an area to start and learn about monitoring. In order to maintain the efficacy of provider monitoring, the project team will assess the BRM safety-monitoring template every 6 months for needed changes and will perform training and education updates for staff with necessary changes.
CHAPTER SEVEN

CONCLUSION

Implications and Suggestions for Future Studies

This scholarly project illustrates the significant impact a BRM safety-monitoring template can have on improving provider compliance and provision of patient care. This specific project focused on creation of an effective monitoring guideline and implementation to improve provider compliance for monitoring patients on BRM medications. A major secondary endpoint was improvement in patient safety through close monitoring for side effects, comorbidities, and infections. Lastly, another secondary endpoint was to increase patient education, through employing a patient education section in the BRM monitoring template. This was measured indirectly by monitoring if patient education was executed or not.

Although BRM medications have been around for over 20 years, a standardized monitoring criterion still does not exist for assessing psoriatic patients on BRM medications. Minimal research has been performed specifically evaluating safety-monitoring guidelines within dermatology practices. The majority of studies focus on retrospective data evaluating patient data without particular interventions. Therefore, performing specific research studies assessing the effectiveness of a BRM monitoring protocol would add to the significance of this project’s findings. Also, future studies evaluating whether BRM monitoring protocols help to improve patient safety and reduce
side effects would also support utilization of standard monitoring guidelines. Studies specifically examining whether a standardized BRM monitoring protocol would improve patient medication adherence and patient satisfaction would provide strong evidence for or against making generalized guidelines for managing BRM patients. Lastly, executing studies appraising different monitoring criteria to make standardized recommendations would help to suggest generalized monitoring criteria for all psoriasis patients on BRM medications.

**Practical Application and Dissemination**

The complexity and chronicity of psoriasis can be challenging to appropriately manage and treat. The introduction of BRM medications has revolutionized efficacy of psoriasis treatments and has significantly reduced disease severity and disease associated comorbidities. BRM medications are associated with 75-100% disease reduction for patient with plaque psoriasis (Van de Kerkhof et al., 2008; Esposito et al., 2012). Although BRM medications are incredibly effective, they have a severe side effect profile of potential malignancy, tuberculosis reactivation, severe infections, and a trigger for demyelinating disease (Menter et al, 2008; Semble, Davis, Reldman, 2014). This project illustrated that close monitoring of laboratory work, vaccinations, physical observation, and disease reduction can potentially improve the adherence to BRM medications (Chan, Hussain, Lawson, & Ormerod, 2011; Esposito et al., 2013). With the increased utilization of BRM therapy for moderate to severe plaque psoriasis and their serious potential side effects, a standardized monitoring guideline should be established.
to prevent side effects and improve overall monitoring of the patient. With standardized monitoring of patients on BRM medications, overall provider compliance and patient safety profiles improved in this study. Essential monitoring criteria for biologics include laboratory work, physical assessment, disease severity assessment, reported side effects, comorbidity identification, and patient education. In this pilot project, the BRM safety-monitoring protocol improved overall monitoring compliance and patient safety.

This project was implemented in a Montana dermatology clinic in December of 2015 and data collection was performed through June 2016. However, the utilization of the BRM safety-monitoring protocol continues to be utilized at the clinic as it is supported by and illustrates evidence based practice. The DNP student disseminated the results of this project during her scholarly defense and will also present the scholarly project in Orlando, Florida for the Dermatology Nurses Association 2017 conference. In the future creating standardized guidelines for BRM medication will help the safety and efficacy of BRM in the use of plaque psoriasis.
REFERENCES CITED


APPENDICES
APPENDIX A

BIOLOGIC RESPONSE MODIFIER SAFETY
MONITORING ELECTRONIC MEDICAL
RECORD TEMPLE
<table>
<thead>
<tr>
<th>Chief complaint (What patient is here for, psoriasis medications, skin/joint response, side effects, and any other concerns)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medications/Allergies:</td>
</tr>
<tr>
<td>Past medical history</td>
</tr>
<tr>
<td>Family history</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Review of Systems: (drop down menus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constitutional</td>
</tr>
<tr>
<td>Skin</td>
</tr>
<tr>
<td>Joints</td>
</tr>
<tr>
<td>HEENT</td>
</tr>
<tr>
<td>Lymph system/Immunologic</td>
</tr>
<tr>
<td>Respiratory</td>
</tr>
<tr>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Gastrointestinal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Past psoriasis History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Onset</td>
</tr>
<tr>
<td>Type of psoriasis</td>
</tr>
<tr>
<td>Past topical treatments used</td>
</tr>
<tr>
<td>Past systemic medications used</td>
</tr>
<tr>
<td>Past biologic treatments</td>
</tr>
<tr>
<td>Current treatment</td>
</tr>
</tbody>
</table>
Body map (Stamp areas of psoriasis: each area stamped will represent 1% of BSA making the BSA easy to calculate) and the recorded areas affected with psoriasis.

<table>
<thead>
<tr>
<th>Laboratory test</th>
<th>Date</th>
<th>Next test due</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMP with platelets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinalysis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunizations</th>
<th>Date</th>
<th>Next test due</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB test</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical Assessment</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joints</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HEENT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymph system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdomen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vital Signs</td>
<td></td>
<td></td>
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<tr>
<td>---------------------</td>
<td>------------------------</td>
<td></td>
</tr>
<tr>
<td>Blood Pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxygen Saturation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Body Surface Area</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Global Assessment Score</td>
<td></td>
</tr>
<tr>
<td>Side effects Experienced</td>
<td>Drop down menu (Injection site reaction, Upper respiratory tract infection, urinary tract infection, headaches, pneumonia, cellulitis, migraine, malignancy, neurological disease, worsening Congestive heart failure)</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>Drop down menu: Hypertension, cardiac disease, diabetes type II, depression, or obesity</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Plaque Psoriasis (696.1) and or Psoriatic arthritis (696.0)</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>Assessment</td>
<td>Drop down menu: Mild, Moderate, Severe</td>
</tr>
<tr>
<td>Medications</td>
<td></td>
</tr>
<tr>
<td>Plan</td>
<td></td>
</tr>
<tr>
<td>Patient education</td>
<td>Drop down menu (patient education on diagnosis, treatment options, and long term treatment plan; patient education on risks, side effects, and appropriate use of medications, patient educated on the comorbidities of psoriasis, general psoriasis patient education performed)</td>
</tr>
<tr>
<td>Labs ordered</td>
<td>Drop down menu (CBC, CMP, Magnesium, UA)</td>
</tr>
<tr>
<td>Next Vaccines due</td>
<td></td>
</tr>
<tr>
<td>Follow up appointment</td>
<td>Drop down menu (1 month, 3 months, 6 months)</td>
</tr>
</tbody>
</table>
APPENDIX B

BIOLOGIC RESPONSE MODIFIER SAFTEY EMR
TEMPLATE FOR INSTRUCTION USE
Objective

- The objective of this scholarly project is to implement a BRM monitoring protocol into the Electronic Medical Record (EMR) of a Montana dermatology clinic to improve provider monitoring compliance and therefore improve psoriasis patient outcomes, safety, and education. Monitoring criteria were developed based on recommendations from the University of Illinois Medical Center Clinical Care Guidelines and the American Academy of Dermatologists Biologic Monitoring guidelines.
- Learn to understand and appropriately utilize the BRM EMR template for patients with psoriasis.

Rationale

- BRM medications are the most effective treatment for moderate to severe psoriasis.
- BRM medications can have severe side effects such as pneumonia, malignancy, worsening CHF, and opportunistic infection.
- BRM side effects can be significantly reduced if appropriate monitoring criteria are put in place.
- Proposed monitoring criteria include completion of: laboratory studies, physical assessment, patient education, follow up, psoriasis severity scale, immunizations, and vital signs. Side effects experienced and patient comorbidities will also be recorded.

Definitions

- Adverse side effects: Uncommon effects directly due to a biologic medication including: pneumonia, migraine, cellulitis, malignancy, depression, new onset neurological disease new onset or worsening of congestive heart failure, opportunistic infections or fungal infections.
- Common side effects: common effects directly due to a medication including: injection site reactions, upper respiratory tract infection (sinus infection, viral upper respiratory syndrome), and headaches (HumiraSingh, J. A. et al., 2011).
Follow up completion: Patient is scheduled for follow up every 3 or 6 months depending on time on biologic medication. If patient has been on biologic <1 year they will have 3 month follow-ups. If patient has been on biologic > 1 year they will have 6 month follow-ups.

Immunizations: TB test performed yearly.

Laboratory completion: Laboratory work CBC, CMP, UA, and Mg are ordered and performed every 3-6 months depending on the biologic status of the patient.

Psoriasis scale completion: Body Surface area and or Physician Global Assessment scales are documented. One or more must be documented.

Patient education completion: Documented psoriasis education including subjects on medications, disease process, comorbidities, or any subject related to psoriasis.

Physical assessment: The provider has auscultated the patient’s lungs, heart, and abdomen. The cervical and axillary lymph chains are assessed. The patient’s skin and joint assessments are documented.

Vital Signs: Blood pressure, pulse, and oxygen saturation are performed.

Roles

Providers: responsible for assessing for disease severity utilizing the PGA score system or BSA, recording side effects, and prescribing the medication.

Medical staff (RNs, LPNs, and MAs): responsible for entering in patient data, printing of lab work, making sure lab work was performed, and updating vaccinations (TB test, Hbsag, and influenza) as recommended.

Procedure

All medical staff at the meeting will be given a copy of the EMR template to make notes and write tips as a guide throughout this presentation.

Each visit all seven criteria will be reviewed and documented by the appropriate medical staff.

Specific times will be designated to seek help or answer questions related to the template.

The recorded data will be entered into the BRM EMR template to keep track of events, changes, and patient condition.

Reminders will be setup in the system to remind the provider or medical staff to order lab work, update immunizations, or come in for follow-ups.
Evaluation

- After June 30, 2016 all data will be collected and analyzed to evaluate:
  - Provider completion and compliance
  - Side effects associated with BRM medications
  - Co-morbidities associated with BRM medications
APPENDIX C

BRM CHECKLIST FOR CLINICAL STAFF
<table>
<thead>
<tr>
<th>Check List</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chief complaint complete (Medication dose and frequency, patient response, review of systems)</td>
</tr>
<tr>
<td></td>
<td>Medications and allergies reviewed</td>
</tr>
<tr>
<td></td>
<td>Psoriasis history documented</td>
</tr>
<tr>
<td></td>
<td>Laboratory function test performed every 3 months or 6 months (CBC, CMP, Mag, UA; 3 months if have been on a BRM for &lt;1 year, 6 months if &gt; 1 year)</td>
</tr>
<tr>
<td></td>
<td>Immunization (TB test yearly)</td>
</tr>
<tr>
<td></td>
<td>Physical assessment performed (Skin, joints, lymph, cardiac, respiratory, and abdomen)</td>
</tr>
<tr>
<td></td>
<td>Vital signs (BP, Pulse, Pulse ox)</td>
</tr>
<tr>
<td></td>
<td>Psoriasis scale (PGA and BSA)</td>
</tr>
<tr>
<td></td>
<td>Side effects experienced</td>
</tr>
<tr>
<td></td>
<td>Comorbidities</td>
</tr>
<tr>
<td></td>
<td>Patient education</td>
</tr>
<tr>
<td></td>
<td>Follow up scheduled for 3 or 6 months (3 months if have been on a BRM for &lt;1 year, 6 months if &gt; 1 year)</td>
</tr>
</tbody>
</table>