PLATELET-RICH PLASMA AND PAIN MEDICATION REDUCTION

By

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Submitted to the School of Nursing and The Graduate Faculty of the University of Kansas in partial fulfillment of the requirements for the degree of Doctor of Practice.

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March 23, 2018

Date Project Proposal Accepted

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Platelet-Rich Plasma and Pain Medication Reduction

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23 March 2018

Abstract

Problem: Pain is a major health problem that affects patients and families and proves challenging for providers to treat. Large portions of people suffer from pain that can be attributed to musculoskeletal injuries. Providers rely on current first-line recommendations for treating patients with these injuries. Unfortunately, the pain is not being adequately treated, the underlying injury is not being fixed, and many patients develop chronic pain. The solution has been a turn to chronic opioid prescribing that has now become an epidemic.

Project Purpose: Autologous platelet-rich plasma (PRP) is a therapy with little to no risks and proven benefits in surgical procedures and treatment of a variety of injuries. Recently, PRP has been gaining prevalence in research and practice regarding treatment of musculoskeletal injuries. The results have been promising but more support is needed to show PRP can not only reduce pain but also help solve the issues surrounding medication use. By following the Plan-Do-Study-Act cycle, the DNP project aimed to evaluate the effects of PRP on reducing medication consumption with patients being treated for musculoskeletal injuries at a Pain Management and Rehab clinic, specifically Kansas City Bone and Joint Clinic.

Methods: The DNP project used a longitudinal observational quality improvement design that consisted of a convenience sample of patients diagnosed with acute and chronic musculoskeletal injuries who were being treated with PRP as part of their standard care, for musculoskeletal conditions such as knee osteoarthritis, lateral epicondylitis, hip and pelvic pathologies, jumper's knee, and mild to moderate hamstring muscle tears. Candidates needed to be able to speak English, read at a high-school level, give consent, and track medication consumption for follow-up data collection. The primary outcome measure was to evaluate the type, quantity, and frequency of pain medication consumption. The VAS tool and Likert scale assessed pain and

patient satisfaction as secondary outcome measures. An additional document was used to track the PRP injection process. Pre-injection data was collected, with follow-up evaluations occurring at week 2 and 4, and at month 2 post-injections. Descriptive statistics regarding each data point were analyzed to determine if the results either supported or refuted the assumptions of the DNP project.

Conclusions: The data did not afford clear results regarding the primary outcome. However, secondary outcome measures indicated that PRP was at least partly successful in reducing pain and thus led to some degree of patient satisfaction. Despite limitations, the DNP project poses several implications for future research and practice.

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Platelet-Rich Plasma and Pain Medication Reduction

Chronic pain and debility are a major health concern. According to Dhillon, Schwarz, and Maloney (2012), "The World Health Organization has acknowledged that musculoskeletal injuries affect hundreds of millions of people worldwide and are the most common cause of severe long-term pain and physical disability" (p. 1). Soft tissues including muscle and tendon injuries account for 45% of musculoskeletal injuries (Dhillon et al., 2012). With these statistics in mind, musculoskeletal injuries pose a significant burden on patients, families, and providers that lead to increased financial strain, time off work, and compromised active lifestyles (Dhillon et al., 2012).

Unfortunately, most current treatment options for musculoskeletal injuries, such as medications, physical therapy, or corticosteroid injections only offer temporary relief, if any, and rarely fix the underlying injury (Dai et al., 2016). Furthermore, pain management with opioids has become an epidemic, complicating treatment of pain (Dowell, Haegerich, & Chou, 2016). Many patients continue to suffer and develop additional side effects or complications (Dowell et al., 2016).

Due to the high rate of musculoskeletal injuries and major impact on patients and the healthcare system, all possible alternative therapies should be explored that could improve patient care. Platelet-rich plasma (PRP) injections may be a promising therapy that will be defined and evaluated as a possible alternative to the current first-line treatments. Supporting literature will be presented that shows PRP may be an effective treatment option with numerous benefits and few risks. However, PRP needs to be further evaluated to determine its possible role in advancing health care.

Although PRP is now being widely researched, this paper will highlight gaps in the literature. This paper aims to establish the need for research surrounding the use of PRP and the possible benefit of reducing the use of oral pain medications, thus reducing affiliated adverse events. Last, this paper outlines the DNP project designed to evaluate the effectiveness of PRP in treating pain from chronic or sports-related musculoskeletal injuries at a local pain clinic and therefore failure of current first-line treatment options.

The project was designed to evaluate the efficacy of PRP with a specific focus on pain reduction, and thus a reduction in oral medication use. The project took place at the Kansas City Bone and Joint (KCBJ) Pain Management and Rehabilitation (PM&R) clinic that commonly has patients referred by primary care providers for the treatment of protracted musculoskeletal or acute sports injuries. By following patients after PRP injections and tracking medication use, the study aimed to answer this Quality Improvement question: In patients with acute and chronic musculoskeletal injuries referred to a PM&R clinic, does platelet-rich plasma injections reduce oral pain medication use over a two-month period?

Literature Review

The purpose of this literature review is to explore the effects of PRP and its potential for reducing oral pain medication consumption. PRP's mechanism of action, variances of administration and preparation with affiliated efficacy, and compare PRP to conventional medical management (CMM), particularly oral pain medications and intra-articular injectable medications are discussed. Furthermore, the literature review aims to determine the populations that benefit from PRP along with any pitfalls of using PRP. Although PRP is now gaining much attention, its use is still limited due to small-scale or inconsistent studies and therefore a lack of acceptance as a standard treatment practice (Dhillon et al., 2012).

Mechanism of Action

First, it is important to understand what PRP is. Platelet-rich plasma is a portion of an autologous blood sample that is spun down in a centrifuge to become a potent, above baseline concentrate of platelets and bioactive compounds such as cytokines and growth factors (Dhillon et al., 2012; Kraeutler, Garabekyan, & Mei-Dan, 2016; Lana et al., 2016; Shen, Yuan, Chen, Xie, & Zhang, 2017). The prepared PRP is then injected into the site of injury. The introduction of potent plasma enriched with platelets, cytokines, and growth factors has been shown to aid in the healing process, reduce pain, decrease blood loss, increase physical function, and have lasting positive effects (Dai et al., 2016; Dhillon et al., 2012; Gautam et al., 2015; Zavadil, Satterlee, Costigan, Holt, & Shostrom, 2007). Furthermore, because PRP is autologous, there is little to no risk of a transfusion-type reaction (Dhillon et al., 2012; Marx, 2001; Valenti Azcarate et al., 2014; Zavadil et al., 2007). After the injection, patients are recommended to only use ice packs within the first few days and avoid non-steroidal anti-inflammatory drugs (NSAIDS) for at least 5 days (Gautam, Verma, Batra, Bhatnagar, & Arora, 2015; Kraeutler et al., 2016).

Historical Benefits of PRP

PRP has been widely used for over two decades in the dental field as well as some orthopedic, cardiac, and urologic surgical procedures to aid in the healing process (Dhillon et al., 2012; Sampson, Gerhardt, & Mandelbaum, 2008). The first documented use of PRP was in 1987 in cardiac surgery (Dhillon et al., 2012; Ferrari et al., 1987). The PRP was shown to significantly reduce the needs for homologous plasma and platelet transfusions during and after cardiac surgery (Ferrari et al., 1987; Giordano et al., 1988).

As for applications in the dentistry and oral maxillofacial surgery field, Marx (2001) reported PRP as being effective in stimulating and accelerating bone and soft tissue healing.

Specific beneficial uses include site preparation for bone grafting, sinus lifts, osseointegrations, and ridge augmentations. Furthermore, the positive results of PRP with bone grafting and soft tissue healing could be extrapolated to the use of PRP with palatal grafts, gingival flaps, and cosmetic dentistry (Marx, 2001).

Orthopedics has utilized PRP in surgeries such as anterior cruciate ligament (ACL) repair, total shoulder arthroplasty, and Achilles tendon repair (Valenti Azcarate et al., 2014; Zavadil et al., 2007; Zou et al., 2016). Due to PRPs proven long-term benefits and limited adverse effects in these fields, PRP studies have increased dramatically to explore possible uses in treating acute sports-related and chronic musculoskeletal injuries (Dhillon et al., 2012; Kraeutler et al., 2016; Schippinger et al., 2015). However, many gaps exist, particularly, the inherent lack of a standardized method in the PRP treatment process (Dhillon et al., 2012; Kraeutler et al., 2016; Schippinger et al., 2015).

Variances in PRP

Potency. In the literature, several variances in PRP composition, preparation, and administration exist, leading to confusion on a standardized protocol and therefore uncertainty as to which methods are most efficacious in treating musculoskeletal injuries (Dai et al., 2016; Dhillon et al., 2012; Kraeutler et al., 2016; Schippinger et al., 2015). First, studies indicate differing minimum levels of above-baseline platelet concentrations, or potency, necessary when preparing PRP treatments (Hamilton et al., 2015). For example, studies recommended PRP platelet concentrations ranging from a minimum of 5 times baseline, 2- to 8-fold, 2.5- to 5-fold, or 2- to 6-fold increase above baseline concentration to be effective (Dhillon et al., 2012; Gautam et al., 2015; Kraeutler et al., 2016; Valenti Azcarate et al., 2014). However, Dhillon et al. (2012) stated that concentrations much higher than 5 times normal do not further enhance

wound healing and Kraeutler et al. (2016) indicated that higher concentrations might actually have an inhibitory effect on healing.

Quantity of injections. Along with variances of recommended platelet level concentrations, the literature indicates an uncertainty as to the quantity of injections necessary to be therapeutic (Dai, Zhou, Zhang, & Zhang, 2016; Kraeutler et al., 2016; Lana et al., 2016). Current recommendations vary as to whether PRP injections should be performed once, twice, or three times, typically with two weeks between each injection if in a series (Dai, Zhou, Zhang, & Zhang, 2016; Kraeutler et al., 2016; Lana et al., 2016). A meta-analysis of randomized controlled trials (RCTs) that evaluated PRP use in treating knee osteoarthritis, indicated that studies had varying amounts of injections between two treatment groups within studies as well as among all the studies included in the review (Dai et al., 2016). Unfortunately, the authors did not extrapolate any effects of the varying quantity of PRP injections. Shen et al. (2017) completed a meta-analysis to evaluate PRP effects in treating knee osteoarthritis and found that multiple PRP injections is more common and more efficacious than a single injection. Kraeutler et al. (2016) also reported variance of the number of injections among studies evaluating PRP use in hip and pelvic pathologies but stated most studies only used a single PRP injection to treat a variety of hip pathologies.

Seven randomized control trials (RCTs) were included in this literature review. One RCT assessed a single injection for the treatment of recalcitrant lateral epicondylitis (Gautam et al., 2015). RCTs evaluating ACL repair, total shoulder arthroplasty, and Achilles tendon repair surgeries only utilized PRP once at the time of the procedure (Valenti Azcarate et al., 2014; Zavadil et al., 2007; Zou et al., 2016). However, despite positive results with PRP, Valenti Azcarate et al. (2014) discussed that only one application of PRP at the time of surgery may not

be sufficient and repeat injections may result in even longer lasting beneficial effects. Two other RCTs advocated for a series of three PRP injections, each given 2 weeks apart, to treat patellar tendinopathy or osteoarthritis (Filardo et al., 2009; Lana et al., 2016). Finally, one RCT used a single PRP injection to treat hamstring injuries and deemed little to no significant benefits from this treatment, but the discussion portion of the study stated repeated injections could have led to different outcomes (Hamilton et al., 2015).

Composition and preparation. Studies reported multiple variances in the activators used and the composition of PRP. PRP has low risks, but adverse reactions can occur with non-autologous thrombin plasma activators, such as bovine thrombin, so their use should be avoided (Zavadil et al., 2007). Therefore, despite documented decreased efficacy in activation of PRP, the literature advocates autologous thrombin use along with calcium chloride (Dhillon et al., 2012; Valenti Azcarate et al., 2014; Zavadil et al., 2007).

As with any injection, there is an inherent risk of infection. Subsequently, researchers have been evaluating and advocating for a special type of PRP that is enriched with white blood cells (WBC), called platelet-leukocyte-rich plasma (PLRP) (Dhillon et al., 2012; Kraeutler et al., 2016; Lana et al., 2016). With the added antimicrobial proteins, the risk for infection is further reduced and has been studied in particular soft tissue injuries suspected to be at higher risk of infection (Dhillon et al., 2012). The literature is still conflicted on the benefits of increased WBC potency, though, because some studies indicate this can increase inflammation and is therefore counter-productive (Kraeutler et al., 2016; Valenti Azcarate et al., 2014).

PRP versus Conventional Medical Management

Chronic and degenerative musculoskeletal injuries can be exceptionally challenging to treat (Dhillon et al., 2012). As for acute sports injuries, athletes cannot afford to have a

prolonged healing period (Filardo et al., 2009; Hamilton et al., 2015; Schippinger et al., 2015).

Current first-line recommendations typically include conservative treatments like physical

therapy, NSAIDS, analgesia, and intra-articular injections (Filardo et al., 2009; Lana et al., 2016;

Shen et al., 2017). Unfortunately, these therapies are not always effective or without

complications (Dai et al., 2016).

Complications from NSAIDS include increased bleeding risk, nephrotoxicity, and

gastrointestinal issues such as peptic ulcers (Lana et al., 2016). Although not first-line for most

acute musculoskeletal injuries, many patients with chronic pain are prescribed opioids, which

pose several risks for adverse events such as constipation, respiratory depression, dependency,

and overdose (Dowell et al., 2016; Zavadil et al., 2007). Corticosteroid injections, risks include

lipodystrophy, muscle atrophy, tendon rupture, skin pigmentation changes, and blood glucose

alterations (Gautam et al., 2015). Other injections, such as hyaluronic acid have shown to have

only limited benefit, if any (Lana et al., 2016).

Pain Reduction

Evaluating the potential for PRP to reduce the demand for pain medications can have a

significant impact on patients and providers. Based on recent Centers for Disease Control and

Prevention (CDC) recommendations, the Drug Enforcement Administration (DEA) has made a

strong push to reduce opioid use, especially in light of the ever-increasing opioid overdoses, side

effects, and overall complications (Dowell et al., 2016). Along with reducing opioid use,

reducing the need for NSAIDS or corticosteroids can have a major impact on patients' health and

the health care system. Although many of the studies in this literature review utilize similar

outcome measures to evaluate pain reduction, such as the visual analog scale (VAS) or Western

Ontario and McMaster Universities Arthritis Index (WOMAC), few evaluate the use of pain medication as an outcome criterion (Lana et al., 2016; Shen et al., 2017).

Oral Medications

NSAIDS. Kraeutler et al. (2016) and Schippinger et al. (2015) indicated NSAIDS should be reduced in patients treated with PRP in order to ensure a quality product is harvested and to avoid impaired platelet function. However, patients may resume NSAIDS after the series of injections, as this has not been contraindicated in the current literature recommendations beyond 5 days post-injection (Gautam et al., 2015; Kraeutler et al., 2016). It is important, then, to still evaluate if PRP not only reduces opioid intake, but prolonged NSAID intake as well. Although the data may be confounded by the fact that patients must stop NSAIDS initially, if the PRP is effective, the patients may not need to resume the NSAID. Unfortunately, not all studies follow the recommendations of stopping NSAIDS prior to and immediately after PRP injections, thus results may be inaccurate (Kraeutler et al., 2016; Schippinger et al., 2015).

Opioids. One study was identified that measured a reduction in opioid medication in affiliation with PRP. The RCT by Zavadil et al. (2007) examined patients after a total shoulder arthoplasty and found a direct correlation in a reduction of fentanyl requirements in those treated with PRP when compared to the control group. The study also examined differences in the need for oral opioids after hospital discharge, which showed the control group needed more oxycodone, Vicodin, or Darvocet, but the results did not reach statistical significance (Zavadil et al., 2007). The lack of statistical significance may be due to the small sample size of 40. Despite the lack of statistical significance, clinically the findings were significant. Clearly, further research is warranted.

Intra-articular Injections

  Hyaluronic acid. In the quest for alternative treatments for chronic musculoskeletal injuries, particularly degenerative joint pathology, studies have been conducted to evaluate the possible use of hyaluronic acid (HA) injections. HA is a commonly used intra-articular injectable treatment noted for increasing joint lubrication (Lana et al., 2016). Two meta-analyses and one double blind, prospective RCT all came to the same conclusions when evaluating HA versus PRP injections. PRP outperformed HA when assessing outcomes such as pain reduction, functional limitation reduction, and increased physical function (Dai et al., 2016; Lana et al., 2016; Shen et al., 2017).

  Corticosteroids. Corticosteroid injections are a current mainstay in the treatment of chronic musculoskeletal injuries (Lana et al., 2016; Shen et al., 2017). With the risk for complications and need for frequent repeated corticosteroid injections, studies have been conducted to evaluate corticosteroid injections compared to PRP (Gautam et al., 2015; Shen et al., 2017). A meta-analysis and RCT determined PRP as superior to corticosteroid injections in the treatment of recalcitrant lateral epicondylitis and knee osteoarthritis (Gautam et al., 2015; Shen et al., 2017). In fact, corticosteroid injections are contraindicated in certain musculoskeletal injuries, such as hamstring tendinopathy, due to the risk of further tendon weakening and tears (Kraeutler et al., 2016).

Populations that Benefit from PRP

  Chronic musculoskeletal injuries. In this literature review, studies indicate patient populations suffering from chronic musculoskeletal injuries benefit from PRP (Dai et al., 2016; Filardo et al., 2009; Gautam et al., 2015; Kraeutler et al., 2016; Lana et al., 2016; Shen et al., 2017). Most of the studies address a particular benefit in treating knee osteoarthritis (Dai et al.,

2016; Filardo et al., 2009; Lana et al., 2016; Shen et al., 2017). Furthermore, patients with recalcitrant lateral epicondylitis, and hip and pelvic pathologies have shown improvement with PRP (Gautam et al., 2015; Kraeutler et al., 2016).

  Acute sports-related injuries. In the sports-realm, those with jumper's knee, more commonly known as patellar tendonitis, benefit from PRP, but efficacy to treat hamstring tendinopathy is still conflicting (Filardo et al., 2009; Hamilton et al., 2015; Kraeutler et al., 2016). Schippinger et al. (2015) indicated that PRP is commonly used to treat athletes with hamstring muscle tears or to augment surgical reconstructive procedures. According to Kraeutler et al. (2016), "For professional athletes, in-season PRP may be used to reduce pain and improve function as an interim solution until the offseason when the athlete can undergo surgical intervention" (p. 411). Of note, time to return to sport was significantly lower in those athletes treated with PRP (Hamilton et al., 2015; Kraeutler et al., 2016). Research needs to further address medication use in athletes because they commonly take NSAIDs, which as mentioned above, negatively influences PRP efficacy (Schippinger et al., 2015).

Possible Negatives of PRP

  Insurance and cost. Current literature suggests that PRP is cost prohibitive, especially due to a lack of insurance coverage (Dhillon et al., 2012; Kraeutler et al., 2016). Dhillon et al. (2012) reported on the problems with insurance coverage by explaining procedural coding issues. Specifically, at the time the article was published, just one code for PRP existed and could be billed only once, despite the procedure consisting of multiple billable aspects. The procedure includes image guidance, harvesting, and preparation and may be repeated in a series depending on the site and type of injury (Dhillon et al., 2012). Because it is not yet recognized as standard of care, patients pay for PRP out of pocket (Kraeutler et al., 2016).

Inflammation and NSAID effects on quality. Because PRP has an above normal level of platelets, it is important to evaluate the possible systemic effects as well as concomitant effects with NSAIDS. Researchers measured inflammatory markers, particularly C-reactive protein (CRP) and uric acid at baseline and repeated multiple times up to a year after PRP injections (Lana et al., 2016). They determined CRP levels peaked at 90 days post-PRP injections, significantly decreased thereafter, and was less at 1-year compared to baseline levels. Furthermore, CRP was actually lower in the PRP group when compared to the control group and a group treated with hyaluronic acid (Lana et al., 2016). Valenti Azcarate et al. (2014) also measured CRP and deemed treatment with PLRP increased inflammation and swelling compared to leukocyte-poor PRP, thus advocating for avoidance of additional leukocytes.

Schippinger et al. (2015) aimed to determine the quality of PRP harvested from patients using NSAIDS compared to a control group of patients not taking NSAIDS. Although they did not evaluate any related effects of continued NSAID use after the injections of PRP, the authors concluded that the use of NSAIDS within two weeks prior to harvesting the plasma did lead to an inferior quality of PRP. The platelet-inhibiting effect of NSAIDS led to a lower concentration of platelets and therefore less effective form of PRP (Schippinger et al., 2015).

Summary of the Literature

After evaluating the literature, it is apparent that there are many gaps and inconsistencies surrounding PRP preparation, administration, and the potential to reduce medication consumption. However, the existing literature does inform future research and practices to establish more precise protocols and improve healthcare. The DNP project aims to address the potential to reduce oral pain medication consumption by measuring specific data before and after PRP injections in the treatment of musculoskeletal injuries. An initial increase in pain and

inflammation at the site of injury after PRP injections is a possible confounding variable. PRP is a formulation of both inflammatory and anti-inflammatory components that should not lead to this phenomenon, but if this reaction does occur, data must be collected in a manner to take this possibility into account (Lana et al., 2016). Thus, multiple data collection times will occur in this proposed DNP project at baseline, week 2 and 4, as well as month 2 post-PRP injections. Zou et al. (2016) supported the need for more frequent data collection, especially in the early-to-mid time frame post PRP. Furthermore, Zou et al. (2016) proposed that monitoring patient response to PRP more frequently might answer how quickly PRP takes effect and how long this effect could last.

Depending on the site of the injury, the number of injections and method of treatment will follow current literature recommendations and the device guidelines at the KCBJ PM&R clinic. Furthermore, after evaluating the literature, exclusion criteria will consist of the use of anticoagulants, liver disease, clotting disorders, corticosteroid injection within last 6 months, and unable to stop platelet inhibiting medications such as aspirin prior to harvesting plasma. Finally, analysis of cost-benefit should be included, as this has been mentioned in literature as a potential pitfall (Zou et al., 2016).

Methods

This DNP project was a quality improvement project, guided by the Plan-Do-Study-Act (PDSA) framework. Furthermore, the design, sample, sample selection, data collection, and data analysis will be described.

Theoretical Framework

The PDSA cycle served as the theoretical framework for this DNP project. This model consists of four stages: 1) plan the change and observation, 2) implement the change on a small

scale, 3) analyze and evaluate the data, 4) refine the change based on the results and then repeat (Melnyk & Fineout-Overholt, 2014). According to Melnyk and Fineout-Overholt (2014), using the PDSA cycle contributes to the knowledge base of external evidence and enhances the likelihood of success if implemented on a large-scale. Thus, the PDSA cycle is advantageous for this DNP project because it allows for observing any benefits of PRP on a small scale to allow for evaluation and refinement prior to implementing on a wide-scale.

In addition, by observing for the anticipated benefits of PRP in treating musculoskeletal injuries, this project serves as support for future research and possible practice changes (Melnyk & Fineout-Overholt, 2014). Closely looking at the data and determining whether changes need to be made in injection protocols, sample selection, and data collection tools and processes informs and potentially increases success of future studies conducted at the project setting. Furthermore, after following the PDSA cycle, this DNP project provides important information and guidance if changing practices to include PRP injections as a first-line treatment option for musculoskeletal injuries.

Summary of Assumptions

There were several assumptions for the DNP project related to the efficacy of the intervention, PRP, and outcomes, such as pain, satisfaction, and medication consumption. Furthermore, there were presumptions relating to the participants and the data collection process.

First, external evidence shows that PRP injections effectively reduce pain at the site of the musculoskeletal injury being treated, so it was assumed that pain would be reduced in participants of this DNP project. It was also likely that PRP would effectively lower VAS ratings of pain over 2 months. From this, it was assumed that because PRP reduces pain, the intervention would also reduce the need for and consumption of pain medications.

Because pain is subjective, it was assumed that the participants reported a true reflection of their experienced pain at each assessment. Furthermore, the participants were reporting the amount of pain medication consumption, which must also be presumed as accurate. A perceived social stigma of opioid or other medication use could influence patient reporting to err on the side of social desirability, in other words, underreporting. On the other hand, patients may over-report pain in order to continue receiving treatments and medications.

Along with the issue of medication consumption, patients with musculoskeletal injuries seeking PRP treatments have already failed numerous other treatment options. Thus, it was likely that the participants would have chronic pain and therefore would have been taking pain medications for a long period of time. This poses the problem of tolerance, but the DNP project assumed it is possible to wean participants off of these pain medications. Furthermore, it was presumed that although other treatment options failed to alleviate the pain, PRP would be successful. If the PRP proved effective, as hypothesized, participants not only would report reduction of pain and pain medication consumption, but also report satisfaction with the intervention.

The intent was for PRP to safely treat musculoskeletal injuries and reduce the need for other interventions that pose a higher risk of side effects or complications. Being autologous, it was assumed PRP is safe and would not result in any adverse events. In fact, if the participants reduced pain medication consumption as predicted, fewer complications or issues would be reported at the end of the 2-month DNP project than at the beginning.

Finally, past evidence has shown PRP to be cost prohibitive and that it may be difficult to obtain insurance coverage for the treatments. It was assumed that because patients have already exhausted most other treatment options, the patients would be willing to pay the expense for the

PRP injections. The participants selected would come from a pool of patients already being referred, evaluated, and selected for PRP treatment.

Design and Rationale

The DNP project was a quality improvement project, using a longitudinal observational design. According to Fink (2014), an observational study does not introduce new programs or interventions, but instead analyzes already existing conditions and activities. Although this project was longitudinal in design, the duration was brief and therefore the potential for attrition was low. Based on previous research showing a reduction in pain after PRP injections, it was assumed, or hypothesized, that fewer pain medications would be needed post-PRP. Thus, the DNP project was designed to observe for this specific data.

Sample and Setting

Chronic musculoskeletal and acute sports-related musculoskeletal injuries pose a challenge for providers to treat and need improved intervention options (Dhillon et al., 2012). Often, patients are referred to the Kansas City Bone and Joint Clinic (KCBJ) PM&R providers because they specialize in the treatment of refractory pain and debility related to these particular musculoskeletal injuries. Furthermore, KCBJ recently acquired a centrifuge and training on the administration of PRP. The specialization in the population of interest and ability to perform PRP injections made KCBJ an ideal site for a project exploring the possible reduction of pain medication consumption after PRP use.

Sample. Based on the current research, the sample consisted of three patients with acute and chronic musculoskeletal injuries shown to likely benefit when treated with PRP (Dai et al., 2016; Filardo et al., 2009; Gautam et al., 2015; Kraeutler et al., 2016; Lana et al., 2016; Shen et al., 2017). Patients with chronic issues that had knee osteoarthritis, lateral epicondylitis, or hip

and pelvic pathologies or acute injuries that would benefit from PRP, such as jumper's knee and mild to moderate hamstring muscle tears who were going to receive PRP as part of their standard care were evaluated for participating in this project.

Sample selection process. This DNP project aimed to gain a convenience sample of 10 patients who were diagnosed with the specific musculoskeletal injuries listed above, referred to KCBJ clinic for treatment, and had already consented to PRP treatment. According to Hall and Roussel (2014), the sample fits the definition of convenience sample because all patients that fit the predetermined inclusion criteria were invited to participate. Inclusion criteria included over the age of 18, able to give consent, willing to participate in three phone calls or follow-up visit interviews, and track medication usage.

Data Collection

Instruments. The primary outcome measure for the DNP project was the type, quantity, and frequency of pain medication consumption. A basic survey was created to collect these data (see Appendix C: Table C2). The initial survey contained sections to gather demographic data but the subsequent surveys for follow-up data collection focused on the pain medication assessments and a section to gather secondary outcome criteria regarding pain.

To measure secondary outcome criteria, the VAS tool was utilized to assess pain (see Appendix C: Figure C1). The VAS tool has been used in most of the current research surrounding PRP injections (Filardo et al., 2009; Gautam et al., 2015; Lana et al., 2016; Valenti Azcarate et al., 2014). The tool consists of a line with two end-points that usually contain verbal descriptors to mark opposite ends of a spectrum (Reips & Funke, 2008). VAS tools are reliable and valid measurement instruments used particularly in the medical field and especially with

regard to research evaluating pain (Reips & Funke, 2008). In this DNP project, the VAS tool had end points of no pain and worst pain (see Appendix C: Figure C1).

Along with measuring pain and pain medication consumption, it was of benefit to measure patient satisfaction as another secondary outcome criterion. A Likert scale is a common tool used for measuring patient satisfaction that has been established as valid and reliable (Matell & Jacoby, 1971). In this case, the Likert scale ranged from one to five, representing no satisfaction to complete satisfaction, respectively (see Appendix C: Figure C2).

An additional document was used to track the PRP injection process (see Appendix D). Data included the anatomical location of the injection, technique utilized, and if additional ultrasound guidance was used. Furthermore, the volume of PRP injected, and the quantity and frequency of injections were recorded for each participant. If there was a need to deviate from protocol or non-adherence to current literature recommendations, the reasoning needed to be recorded via the PRP injection tracking document. Finally, to address safety, the provider tracking document also kept record of any reported adverse events and if any additional treatments were needed.

Collection process. Pre-injection baseline demographic data were gathered that included age, birth sex, diagnosis, date of injury, and previous treatments (Appendix C: Table C1). Data about medications tried and failed, current medications used, as well as quantity and frequency of consumption were collected. Baseline data included VAS scores (Appendix C: Figure C1) and evaluation of pain frequency and quality. Participants were provided the initial survey prior to the first PRP injection. Follow-up data collection was completed via phone interviews with the investigator to assess pain and medication consumption. Follow-up data was collected at week 2 and 4, as well as month 2 post-PRP injections (see Appendix E).

Human subject protection. Due to the use of human subject data, approval from the University of Kansas Medical Center's (KUMC) Institutional Review Board (IRB) was obtained (see Appendix A). The KUMC IRB study ID number for this DNP project is: 00141647. Potential participants were provided information about the project and then provided written informed consent (Appendix B). According to Hall and Roussel (2014), informed consent is necessary to provide participants with the purpose and requirements of the investigation, particularly the use of collected data.

Data collected was only used for the intended purpose of the DNP project and secured in a locked filing cabinet at the KCBJ office. Only approved providers responsible for patient care had access to information necessary for patient care. Per the IRB's request, Dr. Atul Patel at KCBJ was provided with the Belmont Report and KUMC policies and procedures for protection of human subjects. He also completed an unaffiliated investigator agreement form since he was performing the injections and was part of the project consent process. Data was collected via the investigator interviewing participants and via surveys and phone follow-up interviews. All steps and precautions were taken to ensure patient privacy.

Data Analysis

Descriptive statistics regarding each data point were analyzed. Specifically, mean scores were calculated for VAS pain ratings and Likert satisfaction scores at each time point. Demographics were scrutinized to determine whether the participants are a representative sample of the overall population who could benefit from this therapy at the project setting.

Also, any change in quantity or frequency of pain medication consumption was explored for a possible correlation with PRP. These variances were analyzed to determine the

effectiveness of PRP and influence on patient satisfaction. Additionally, the frequency of data collection was important in informing the time frame of pain relief onset, peak, and duration.

Data from the provider's tracking document was examined to compare the results of this project to current standards of practice, including first-line treatments and studies using PRP. It was important to record the protocols followed and exact intervention methods used, as this will be needed to inform future research, especially since some past studies lacked this detailed reporting. Also, recording adverse events was crucial because the aim of the project is to support PRP as a safer, more effective alternative to current treatment options, and particularly complications affiliated with pain medication consumption.

Results

Sample characteristics. The obtained sample consisted of three participants, two male and one female. Ages ranged from 26 to 65 years old. The location of injury and thus the site of injection all varied. One participant required a left knee injection due to chronic pain after having fissured cartilage. Another had bilateral shoulder injections to treat pain related to degenerative joint disorder. Finally, the third had chronic lateral epicondylitis of the right elbow.

Injection characteristics. The brand of centrifuge and PRP preparation system used was the Zimmer Biomet GPS III Platelet Concentration System. According to the company's brochure regarding the system's characteristics, the platelet concentration produced with this machine is 9.3 times increased over baseline (Zimmer Biomet, 2018). Furthermore, the brochure indicates that the PRP buffy coat layer obtained after centrifugation is leukocyte-rich. The WBC concentration is 5 times above baseline. The activator used in this system is citrate anticoagulant (ACD-A).

The volume per injection ranged from 3.0 to 6.5 mL of PRP per site. Every injection was performed with ultrasound guidance. All injections were well tolerated without any complications or adverse effects.

Pre-injection data. All of the participants reported undergoing multiple varying treatments without success in pain reduction. The three participants all tried NSAIDs, physical therapy, and ice modalities. Another CMM treatment tried by two out of three participants included multiple corticosteroid injections. One participant reported utilizing massage and ultrasound therapies. Another participant had undergone previous arthroscopic surgery. Finally, one participant had already undergone a PRP injection more than 6 months prior to this project. She had reported pain relief with the first PRP injection but her pain had recently come back. Due to her satisfaction with the previous injection, she discussed with her provider and opted to repeat the PRP again. In fact, she reported a terrible response to corticosteroid injections and refused to repeat this treatment option.

None of the patients were taking opiates immediately prior to the PRP injection. Per protocol, for the optimal PRP draw and composition, all three had ceased taking any anti-inflammatories up to 2 weeks prior to the date of the PRP injection. In addition, all three participants reported his or her personal highest VAS pain score prior to the injection.

Medication consumption. Pain medication consumption was the primary outcome of interest, but this project was unable to measure the concept. All of the participants reported little to no medication use prior to the PRP injection, but they did report a history of being on a regimen of NSAIDs, especially around the time of initial pain onset or injury. After the PRP injection, there was a brief increase in consumption of Tylenol Extra Strength by two of the participants within the first 4 weeks after the injection. After the week 4 follow-ups, only one of

the participants reported taking pain medications, specifically ibuprofen, 2-4 tablets at a time, 1-2 times a day, 3 days a week.

Pain level VAS scores. The VAS scores for the knee injury participant were 3/10 pre-injection, 1/10 at week 2, 2/10 at week 4, and 1/10 at the 2-month follow-up. For the bilateral shoulder injury participant, VAS scores were collected for each limb. For the left shoulder, the VAS scores were 5/10 at baseline, 3/10 at week 2, 1/10 at week 4, and 4/10 at month 2. As for the right shoulder, VAS scores were 3/10, 1/10, 0/10, and 0/10 respectively. Finally, the elbow injury participant's VAS scores were 8/10, 8/10, 6/10, and then 4/10. At baseline, the mean VAS score was 4.75/10. Mean VAS scores at week 2, week 4, and month 2 were 3.25/10, 2.25/10, and 2.25/10, respectively (Appendix F: Table F1).

Likert satisfaction scores. The knee injury participant reported 5/5 or "very satisfied" with the PRP injection results at week 2, 4/5 at week 4, and 4/5 at month 2. The shoulder injury participant varied in his satisfaction scoring depending on the shoulder being assessed, but his ratings were the same at each time point. He reported 5/5 satisfaction for the right shoulder but 3/5 for the left at week 2, week 4, and month 2. The elbow injury participant was "very dissatisfied," or 1/5 at week 2. Of note, he was reporting pain scores via the VAS scale as no change from baseline. At week 4 and month 2, he reported 3/5 satisfaction. Mean Likert satisfaction scores were 3.5/5, 3.75/5, and 3.75/5 at weeks 2, 4, and month 2, respectively (Appendix F: Table F2).

Qualitative data. Although the initial project design did not take into account collecting any qualitative data, interestingly, all the participants offered subjective responses during the follow-up phone interviews. Common topics discussed included perceptions of medication consumption, weather influence on symptoms, and word-of-mouth recommendations of PRP.

Due to the small sample size, exploring the qualitative data could afford more valuable information for analysis and extrapolation.

Within a few months prior to the PRP injection, all of the participants had not been taking opiates or frequent dosing of anti-inflammatories. However, all of the participants had a history of chronic anti-inflammatory medication consumption. They each stated that they had tried adhering to a strict regimen of taking NSAID medications such as ibuprofen or naproxen. The reason they no longer were taking the medications regularly was because they had not seen a significant benefit and reported issues such as gastric upset.

Interestingly, two of the participants suggested they felt the weather might be contributing to increased pain symptoms despite initial benefit in relief after the PRP injection. They reported that when the weather was icy or snowing, they felt increased aching symptoms at the location of injury. Those days were most likely ones in which they felt the need to take the prescribed medication for post-injection recovery.

Finally, all of the participants had exhausted most if not all other treatment options and therefore were prime candidates for PRP. They reported that the reason they sought out the treatment, though, was due to word-of-mouth recommendations. Two of the participants stated they had an acquaintance that had PRP injections and had a significantly positive experience with maximal relief of pain symptoms. Therefore, they asked a provider about PRP and were then referred to KCBJ for evaluation and treatment.

Discussion

The results were to be used to either support or refute the assumptions of the DNP project. In addition, the findings were evaluated in comparison to those of previous studies assessed in

the literature review for this project. Overall, the results will serve as a guide for possible future research and practice changes.

All three participants of this DNP project were able and willing to afford the expense of a PRP kit. The sample population of this project came from an affluent community. The providers at KCBJ recommended that for a future wide-scale study, seeking a grant to aid with the cost of PRP kits could assist in capturing a larger sample. In addition, by negating the out-of-pocket expense of the PRP kits, the sample could be more representative of the overall population, and thus provide results that are more likely to be generalizable.

One important implication to discuss is the PRP potency used with participants in this project. In the literature review, most of the studies had used PRP with platelet concentrations averaging around 5 times above baseline. The Zimmer Biomet GPS III system creates a platelet concentration of 9.3 times over baseline in the PRP. The literature was conflicting as to whether potency much higher than 5 times is beneficial or counterproductive. A higher platelet concentration may raise the potential for an increased inflammatory response. This could cause more pain in the initial weeks post-injection. However, the purpose of PRP is to stimulate an inflammatory reaction and therefore could lead to improved healing compared to lower potency PRP solutions.

Along with potency, the composition of the PRP is important to evaluate. The Zimmer Biomet GPS III system creates a leukocyte-rich PRP. As discussed in the literature review, not all previous studies were consistent with using or even stating whether leukocyte-enriched PRP solutions were used. It is still uncertain if the additional leukocytes may provoke an overly inflamed reaction or are more beneficial. For example, studies that were concerned with a risk for bacterial infection advocated for the increased WBC solution. The participants in this project

were not candidates that necessitated the leukocyte-rich PRP, but it is important to note its use when considering standardizing protocols or use in future research.

Furthermore, per KCBJ's current practice standards, PRP injections are only done once and not as a series. Since one of the participants had already received a PRP injection in the knee for the same chronic pain symptoms, it is worth evaluating if it would have been more beneficial to have done a series of three PRP injections, one every two weeks. Again, the literature lacked consistency in recommendations, but when looking specifically at PRP for knee osteoarthritis, most of the studies utilized the 3-injection series. In the future, it should be considered as to whether the practice standards should reflect the previous study recommendations. Regardless, this project is contributing to the pooled data and if a future wide-scale study is being conducted, these factors should all be considered, documented, and evaluated.

When looking at the primary outcome of interest in this project, the data did not generate significant results. The participants in this project were representative of KCBJ's typical patient population in that they tend to avoid opioid medication consumption. The KCBJ PM&R providers acknowledged that it is common practice to not prescribe opioids for pain control and prefer this to be the discretion of the patient's primary care provider. It would be advantageous to evaluate other practices in which the patient population is more likely to consume pain medications to determine the extent of change from pre to post-PRP injection.

Although the data did not generate results that could answer the primary outcome of interest, the results surrounding the secondary outcomes were significant. From baseline to month 2, all of the participants had a reduction in pain via reporting with the VAS scale. This is particularly positive considering all of the patients had little to no benefit with the previous

CMM therapies. It is important to note the shoulder participant reported a significant return of pain in the left shoulder at month 2. He stated that Dr. Patel and himself expected this because previous x-ray imaging indicated the shoulder was "bone-on-bone" and therefore less likely to see prolonged benefit from the PRP injection. This is aligned with other studies that reported PRP is only beneficial in mild to moderate injuries due to the need for remaining tissue in which to evoke an inflammatory response.

When looking at the mean VAS scores, no additional pain reduction was seen between week 4 and month 2. This may indicate that the peak effect occurs at week 4, which is contrary to the literature that found peak effect to usually occur at month 2. However, most of the studies that found a later peak time were utilizing a 3-series injection protocol. Thus, technically the peak was happening within a month after the final injection in the series, which is consistent with the DNP project findings. The 3-injection series protocol is meant to cause inflammatory responses at strategic times in order to maximize results. This is another reason the KCBJ providers should take this approach into consideration. However, when weighing the expense of multiple injections, this cost-benefit analysis still needs to be a deciding factor between a single and 3-series injection protocol.

All three participants varied in the amount of satisfaction via the Likert scale. By month 2, none reported dissatisfaction with PRP. Initially, the elbow injury participant reported a lack of pain reduction and that he was dissatisfied, which correlated with the assumption that pain relief would equate satisfaction. Interestingly, this participant had not tried as many CMM treatments prior to trying PRP as compared to the other two participants. This may reflect that the other participants realized they had exhausted all other measures and therefore were appreciative of the pain relief knowing nothing else worked. On the other hand, the participant

with the lower satisfaction scores offered subjective comments that he had higher expectations for the PRP and maybe that is why he was disappointed with the results.

The KCBJ PM&R providers recommended using function testing as another outcome measure if conducting a similar future study at this setting. They reported that objective data, such as range of motion or activity level, could offer information that may support or refute subjective pain reporting. Although the KCBJ providers aim to reduce pain, they stated function is an important factor that plays a major role in quality of life.

Finally, although not in the original project design, the collected qualitative information added value to the results. The additional narrative gave more depth and understanding of the participants' reasoning for the objective data. Since the qualitative data was helpful in the analysis and synthesis of the results, it is recommended that future studies incorporate this type of evaluation. However, it is understood that numerous phone interviews to collect follow-up data may be cost and time-prohibitive. Depending on the scale of a study and availability of resources, it may be optimal to have participants fill out the surveys.

Limitations. One key limitation of this project was the sample size. The goal was to obtain 10 participants, but due to unexpected delays and time constraints, only three participants were enrolled. Fortunately, despite this limitation, the sample contained a wide variety of musculoskeletal injuries and varied in multiple key demographics.

Another possible limitation was the allotted two-month follow-up time frame. Ideally, the project could have had additional data collection points at month 6 and year 1 post-PRP injection. Per the literature review, participants commonly saw the most benefit at or shortly after the 2-month mark. Gathering later data could shed light on the onset, peak, and length of benefit from PRP. However, this project had time constraints and thus chose to gather data up to

the point in which most PRP recipients usually report significant changes from baseline. Future studies must also consider the balance of use of resources and the risk of attrition when gathering data for up to a year.

It became apparent that patients referred to the KCBJ clinic and those persons most likely to opt for PRP injections are economically stable. The lack of patient diversity in regards to income decreases the likelihood of generalizability to the overall population of patients at this clinic. This project's patient population does not represent persons of lower socio-economic classes.

As mentioned before, another limitation was the inability to gather data surrounding the primary outcome of interest, pain medication consumption. The sample's characteristics reflected the selected location's prescribing practices. Although this is a positive approach, it is not reflective of the population of interest. This led to the inability to answer the PICOT question for this project.

Implications. This DNP project poses several implications for future research and practice. Unfortunately, at this time, insurance does not cover PRP injections. The hope for this project was to show that patients try several CMM treatments before being able to be considered for PRP injections. This is a disheartening and difficult process for patients. It can become more costly and risky, which should be seen as unnecessary.

Between the financial constraints posed by the cost of PRP and the current standards of practice recommending CMM first, providers do not recommend PRP injections until much later in the treatment process, if at all. Many providers do not know about this potential intervention, so another implication from this project is to bring awareness surrounding PRP. If a patient meets assessment criteria that deem them as a candidate that would benefit from PRP, then this

intervention should be a part of the possible treatment plan. Unfortunately, the longer patients suffer from chronic pain, the less likely any treatment will be effective. Thus, the results support the project aim to urge a change in practice toward utilizing PRP sooner in the treatment plan.

The advanced practice nurse (APRN) is specially poised to assist in seeing these implications through. APRNs are equipped with the knowledge and ability to assess a patient's needs, understand important social influences such as financial constraints, and advocate for ideal evaluation and treatment plans. Therefore, it would be especially beneficial for APRNs to be aware of all the treatment options for the musculoskeletal injuries discussed in this paper in order to best detect, educate, refer, and create new treatment strategies for this particular patient population. In addition, the DNP role is specifically aligned with these implications because the DNP has been trained and is expected to stay informed of and contribute to best evidence-based practices.

Conclusion

Musculoskeletal injuries serve as a major contributor to the suffering of patients and families. Providers are challenged with treating the affiliated pain, and often, most standard treatments are exhausted to no avail. With the current fight against the opioid epidemic, pain medication usage has hit the spotlight in the healthcare field and across the nation. Since the current recommended treatments and opioid epidemic are not meeting patient needs, any possible alternatives, especially safe treatments, are worth evaluating.

This report described the safe and beneficial usage of PRP in varying healthcare fields for several decades. Furthermore, evidence was provided regarding promising uses of PRP in the treatment of many common musculoskeletal injuries. The literature was utilized to inform the construction of a plausible DNP project, grounded in the PDSA cycle.

The DNP project helps meet the need to improve healthcare by providing information that may support future research and practice changes. Despite not being able to measure a change in medication consumption, as hypothesized, the DNP project found evidence that supports PRP is a safe and effective method to treat acute and chronic musculoskeletal injuries. This project is crucial because addressing pain while reducing medication-associated complications and side effects could positively affect the lives of millions and change the healthcare field forever.

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Appendix A

IRB Approval Form

KUMC Human Subjects Committee

REQUEST FOR
QUALITY IMPROVEMENT/QUALITY ASSURANCE DETERMINATION

THIS FORM MUST BE TYPED

Principal Investigator: Dr. Moya Peterson		
Department: School of Nursing – Graduate Studies		
Email: MPETERSO@kumc.edu	Phone: 913-588-1908	Mail Stop:
Alternate Contact Person Adriane Arnold		
Email: aarnold2@kumc.edu	Phone: (816) 797-2268	Mail Stop:

Project Title:

Platelet-Rich Plasma and Pain Medication Reduction

Project Number, Version and/or Date:
STUDY00141647

1. **Briefly state the purpose of the proposed project.** *(Attach protocol if available.)*

The proposed project will be designed to evaluate the efficacy of PRP with a specific focus on pain reduction, and thus a reduction in oral medication use. The project will take place at The Kansas City Bone and Joint (KCBJ) Pain Management and Rehabilitation (PM&R) clinic that commonly has patients referred by primary care providers for the treatment of protracted musculoskeletal or acute sports injuries. By following patients after PRP injections and tracking medication use, the study aims to answer this PICOT question: In patients with acute and chronic musculoskeletal injuries referred to a PM&R clinic (P), does platelet-rich plasma (PRP) injections (I) reduce oral pain medication use (O) over a two-month period?

2. **Describe the research that has already demonstrated the effectiveness of your intervention.**
Sentinel research in the field of cardiology utilized PRP to reduce needs for platelet and homologous blood transfusions. Furthermore, dentistry, maxillofacial surgery, orthopedic surgery, and urology have used PRP to aid in healing, decrease pain, expedite healing time, reduce blood loss, and reduce safety risks associated with alternative treatment options. Research surrounding PRP use in the treatment of musculoskeletal injuries has shown benefit in decreasing pain, improving patient satisfaction, and actually leading to resolution of injuries when compared to current first-line treatment options. Specific injuries that have shown benefit include patellar osteoarthritis, lateral epicondylitis, mild to moderate hamstring tears, certain tendinopathies, and hip or pelvic pathologies.

3. **For projects that involve a prospective intervention and post-intervention assessment, which is correct?**
    All patients/providers/units receive the same intervention(s) at the same time
    Patients are individually randomized to one of two or more interventions
    Healthcare providers are randomized to one of two or more interventions
    Units of the hospital are randomized to one of two or more interventions
    ☒ **Not applicable**

4. **What types of data are needed for the project?**
Baseline patient demographics: Sex, age, diagnosis; previous treatments, pain ratings via VAS tool, patient satisfaction, prescribed pain medications and consumption tracking; PRP injection data: volume, quantity of injections, frequency, any adverse events, protocol followed, any equipment or radiological guidance used

5. **Do you need access to identifiable patient records to complete the project?**

    ☐ **NO**
    ☒ **YES**

    If yes, who holds the records? Kansas City Bone and Joint Clinic

    If yes, which patient identifiers or demographics are needed for the project?
    See above, baseline information and confirmation of diagnoses, medications, treatments

6. **Which description best fits your project?**
    Determine if a previously-implemented clinical practice improved the quality of patient care
    ☒**Evaluate the local implementation of widely-accepted clinical standards that have been proven effective at other locations**
    Gather data on hospital or provider performance related to patient care
    Implement a novel approach to clinical care that may hold promise for improving patient outcomes *(if choosing this option, contact the HSC Office for guidance)*
    Other: explain _____

7. Which institutions are involved in the project?
    KUMC only
    Other institutions   List <u>Kansas City Bone and Joint Clinic</u>

_____   _____
Signature   **Date**

_____
Type/Print Name

Appendix B
Research Consent Form
Platelet-Rich Plasma Injections and Pain Medication Usage
Protocol # 141647

Researcher:
Adriane Arnold
aarnold@kcbj.com
(816) 797-2268

INTRODUCTION
You are invited to join this project because you are undergoing platelet-rich plasma (PRP) injections as a way to treat and possibly reduce your pain. The goal of this project is to evaluate the effects of PRP on pain medication needs. Please take whatever time you need to discuss project participation with your family and friends, or anyone else you wish to. The decision to join, or not to join, is up to you.

BACKGROUND
Soft tissues including muscle and tendon injuries account for 45% of musculoskeletal injuries, making them a major health concern, but current therapies, particularly pain medications, are not always curative. PRP is a therapy with little to no risks and proven benefits in surgical procedures and treatment of a variety of injuries. Recently, PRP has been gaining prevalence in research and practice regarding treatment of musculoskeletal injuries. The results have been promising but more support is needed to show PRP can not only reduce pain but also help solve the issues surrounding medication use.

WHAT IS INVOLVED IN THE STUDY?
If you decide to participate, you will be asked to answer some basic questions prior to receiving an injection and then track the amount, type, and frequency of your pain medication consumption, as well as pain scores and treatment satisfaction. We will contact you 2 weeks, 4 weeks, and finally 2 months after the injection to gather this information from you. We think this will take you 5-15 minutes a week to fill out the tracking document and possibly another 15 minutes when contacted to discuss your recordings. You can stop participating at any time. If you stop, your treatment plan with your provider will not be altered or negatively impacted in any way.

RISKS
This study involves minimal risk. Your provider should already have informed you of the risks of PRP and no additional risk is assumed surrounding the injection by participating in this project. A possible risk is distress of the additional time requirements to fill out the tracking document and answer the phone calls to gather data. You might be embarrassed by some of the questions the researcher asks you. You are free not to answer any questions.

BENEFITS TO TAKING PART IN THE STUDY
You may or may not benefit from this study. You may benefit from the additional follow-up calls compared to your provider's plan and from the additional detailed tracking of your response to treatment. It is reasonable to also expect the benefits of contributing to a pool of evidence that supports a safer alternative therapy for the treatment of musculoskeletal injuries, and increasing

evidence in favor of future insurance coverage for PRP. Although we cannot guarantee that you will personally experience benefits from participating in this study, others may benefit in the future from the information we find in this study.

CONFIDENTIALITY

The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

All study information that is sent outside Kansas City Bone and Joint clinic will have your name and other identifying characteristics removed, so that your identity will not be known. Because identifiers will be removed, your health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.

Your permission to use and share your health information remains in effect until the study is complete and the results are analyzed. After that time, researchers will remove personal information from study records.

YOUR RIGHTS AS A RESEARCH PARTICIPANT
Participation in this project is voluntary. You have the right not to participate at all or to leave the project at any time. Deciding not to participate or choosing to leave the project will not result in any penalty or loss of benefits to which you are entitled, and it will not harm your relationship with your medical provider.

CONSENT
Dr. Patel or Adriane Arnold from the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____   _____   _____
Signature of Participant   Time   Date

_____
Print Name of Person Obtaining Consent

_____   _____
Signature of Person Obtaining Consent   Date

Appendix C

Figure C1: VAS Pain Scale
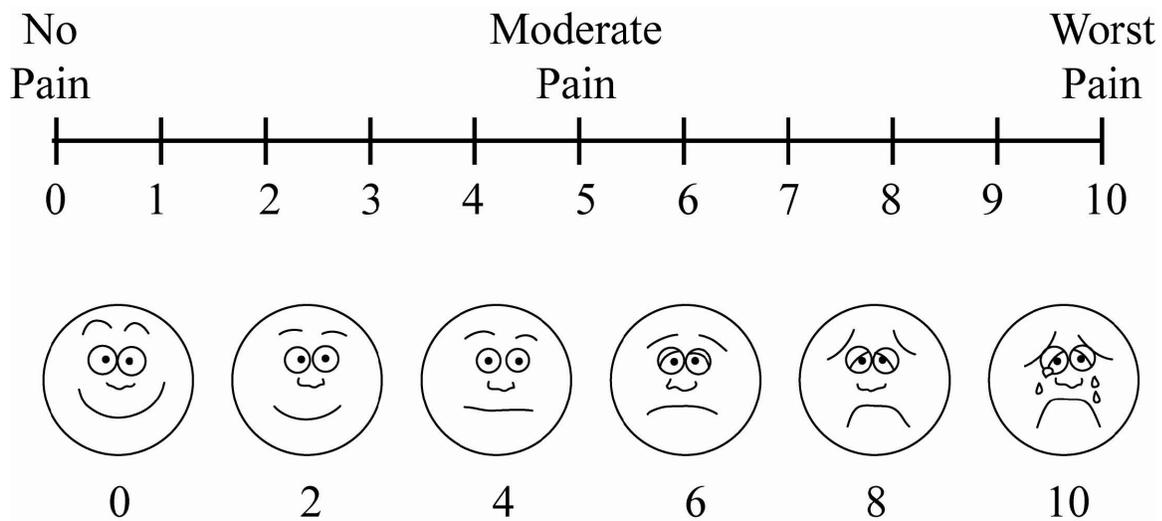
Table C1: Baseline Data Collection Survey

Demographics

Age: _____   ID #: _____

Sex: _____

Diagnosis: _____

Date of Injury: _____

Treatments

Previous treatments: *(circle all applicable)*

Medications – NSAIDS   Aspirin   Tylenol   Opioids   Other:

Injections –   Corticosteroids   Hyaluronic Acid   Other:

Physical Therapy

Ice Packs   Heating Pads   Lidocaine patches   Biofreeze/Topical Ointment

TENS Unit

Current Medications:

Name	Prescribed dose	Amount taken per dose (# of pills)	Amount taken in a day (# of pills)	Frequency in a week

Table C2: Follow-up Data Collection Survey

ID #: _____

Current Medications:

Name	Prescribed dose	Amount taken per dose (# of pills)	Amount taken in a day (# of pills)	Frequency in a week

Adverse Events? List. _____

If so, what treatments received, if any? _____

Figure C2: Patient Satisfaction Likert Scale

Patient Satisfaction with PRP/Pain Relief:

		Neither		
Very		Satisfied nor		Very
Dissatisfied	Dissatisfied	Dissatisfied	Satisfied	Satisfied
(1)	(2)	(3)	(4)	(5)
O	O	O	O	O

Appendix D

Provider PRP Injection Tracking Document

Participant ID #: _____

Location of Injection: _____

Technique/Approach Used: _____

Volume of PRP Injected: _____

Number of Injection if in a series: _____

Planned Number of Injections: _____

Ultrasound Guidance Used? (Circle one)   YES   NO

Other Additional Equipment Utilized? _____

Non-adherence to Protocol? If so, why? _____

Adverse Reactions Noted? If so, treatment applied? _____

Appendix E

Project Timeline

The timeline for the DNP project spanned over two months after approval and sample selection was complete.

Week 0: Baseline data collection prior to injection, provider's injection tracking document, VAS tool

Week 2: Collection of post-injection follow-up data, satisfaction tool, VAS tool

Week 4: Collection of post-injection follow-up data, satisfaction tool, VAS tool

Month 2: Collection of post-injection follow-up data, satisfaction tool, VAS tool

Appendix F

Table F1: VAS Pain Scale Results

	Baseline	Week 2	Week 4	Month 2
Knee	3	1	2	1
Left Shoulder	5	3	1	4
Right Shoulder	3	1	0	0
Elbow	8	8	6	4
Mean scores	4.75	3.25	2.25	2.25

*All results were reported on a scale of 0-10. See Figure C1 for the VAS scale that was provided to all participants and utilized for data collection.

Table F2: Likert Satisfaction Scale Results

	Week 2	Week 4	Month 2
Knee	5	4	4
Left Shoulder	3	3	3
Right Shoulder	5	5	5
Elbow	1	3	3
Mean scores	3.5	3.75	3.75

*All results were reported on a scale of 1-5. See Figure C2 for the Likert satisfaction scale that was provided to all participants and utilized for data collection.