THE EFFECT OF A SCREENING PROTOCOL ON OPIOID USE: AN INTEGRATIVE REVIEW

A Scholarly Project Proposal

Submitted to the

Faculty of Liberty University

In partial fulfillment of

The requirements for the degree

Of Doctor of Nursing Practice

By

Stephen Wright

Liberty University

Lynchburg, VA

April, 2021
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Scholarly Project Chair Approval:

Dr. Kenneth Thompson, PharmD, RPh April, 2020
ABSTRACT

The opioid crisis is a pervasive and social problem in the United States. Since 2001 several hundred thousand people have died from the misuse of prescription and illicit opioids. On average nearly 130 Americans perish every day due to opioid abuse while millions annually struggle with morbidity derived from opioid abuse disorders. This crisis causes tremendous physical and emotional suffering and death and is likely the most profound public health crisis our nation has faced. In 2015 alone, 52,000 people died of drug overdoses, with over 30,000 of those dying from opioid drugs. If left unchecked, the epidemic will continue to increase, and more of the population will continue to be affected by the opioid abuse. Literature related to opioid abuse is vast and expansive. However, the literature is lacking in the area of screening during the initial assessment to indicate the abuse potential. Findings derived from the literature show consistent support in the need for methodologies and interventions that prompt intervention or assist providers in the assessment of patients requiring opioids for management of chronic pain with the result to stalemate the opioid abuse in society. With this in mind, the purpose of this project is to determine whether the use of an opioid screening tool at the time of initial assessment of patients with chronic non-cancer pain will decrease the use of opioid use.

Keywords: Opioid, abuse, overdose prevention, screening tools, therapeutic opioid use, pain management, chronic pain, and opioid crisis
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List of Abbreviations

Chronic Non-cancer Pain (CNCP)

The Critical Appraisal Skills Program (CASP)

Integrative Review (IR)

Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA)

World Health Organization (WHO)

Current Opioid Misuse Measure (COMM)

Opioid Risk Tool (ORT)

Screener and Opioid Assessment for Patients with Pain (SOAPP)

Prescription Opioid Misuse Index (POMI)

Opioid Related Behaviors in Treatment (ORBIT)

Rapid Opioid Dependence Screen (RODS)

Opioid Use Disorder (OUD)
SECTION ONE: FORMULATING THE REVIEW QUESTION

Introduction

The opioid crisis is a pervasive and social problem in the United States. Since 2001 several hundred thousand people have died from the misuse of prescription and illicit opioids. On average nearly 130 Americans perish every day abusing opioids and millions more struggle annually with morbidity arising from their opioid use disorders (Hodge, et. al., 2019). This crisis causes tremendous physical and emotional suffering and death and is likely the most profound public health crisis our nation has faced. In 2015 alone, 52,000 people died of drug overdoses, with over 30,000 of those people dying from opioid drugs (Vadivelu, Kai, Kodumudi, Srancik & Kaye, 2018). If left unchecked the epidemic will continue to increase, and more of the population will continue to be affected by the abuse of opioids.

Background

Opioid medications and their derivatives have, for centuries, been viewed as a viable and legitimate option for the management of pain. However, with approximately 100 million people suffering from both chronic and acute pain in the United States, opiates will continue to remain a prominent class of medication in healthcare facilities and homes. Across the United States over 66% of total overdose episodes in 2016 were opioid-related (Stoicea, et. al., 2019). This figure attests to the severity and wide-spread nature of this issue.

Although providers have complied with the appropriate management of acute and chronic pain, the short or long-term opioid exposure provides opportunities for long-term opioid misuse and abuse (Stoicea, et. al., 2019). This then leads to addiction of patients who receive an opioid prescription. Alarmingly, the overwhelming majority of opioid abusers begin their addiction with
prescription medications, primarily for chronic pain (Vadivelu, Kai, Kodumudi, Sramcik & Kaye, 2018).

**Defining Concepts and Variables**

To minimize any ambiguity, it is important to the process of the Integrative Review (IR) to appropriately articulate the defining concepts and variables associated with the project. For the purpose of this project and to understand the intricacy of the problem, there are terms that need to be defined: opioid addiction, and opioid abuse. West and Brown in their book *Theory of Addiction*, defined addiction as a chronic condition in which there is a repeated powerful motivation to engage in a rewarding behavior, acquired as a result of engaging in that behavior, that has significant potential for unintended harm. It is not all-or-none, but a matter of degree (West & Brown, 2013).

The second term is opioid abuse. In general, substance abuse is an initial step toward addiction and dependence. The World Health Organization (WHO) defines substance abuse as “the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs” (World Health Organization, 2017). Some attributes that characterize substance abuse are failure to fulfill social or work obligations, continued use of a substance in hazardous situations, legal problems related to substance abuse, and persistent use despite continued and recurrent problems (Alzeer, Jones & Bair, 2018).

**Rationale for Conducting the Review**

Literature related to opioid abuse is vast and expansive. However, the literature seems to be lacking in the area of screening during the initial assessment to indicate the potential for abuse. Findings derived from the literature, in context of the clinical question, demonstrates consistent support in the need for methodologies and interventions to stalemate the opioid abuse
in society. In addition, data from the articles show the need for elements that prompt intervention or assist providers in the assessment of patients requiring opioids for management of chronic pain.

**Purpose and/or Review Question**

With this in mind, the intent of this project is to determine whether the use of an opioid screening tool at the initial assessment of patients with chronic non-cancer pain will decrease the use of opioid use. This not only supports optimal outcomes in the pain management setting of chronic non-cancer pain (CNCP) patients, but also increases awareness of screening for opioid abuse among health providers in both acute care and community environments.

**Clinical Question**

This integrative review will address the following clinical question: In patients with chronic non-cancer pain, does the use of a screening tool at initial assessment compared to those not screened, influence the reduction of opiate medication use?

**Formulate Inclusion and Exclusion Criteria**

To further reduce and control data, strict parameters were set via inclusion and exclusion criteria. These criteria are listed in table 1 and include original studies or systematic reviews in peer reviewed journals that examined chronic pain. Articles of evidence prior to the year 2016 were excluded to include only more recent studies.

**Table 1**

*Inclusion and Exclusion Criteria:*

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Articles written in English</td>
<td>Articles written in any language other than English</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Articles written between 2016-2021</th>
<th>Articles written prior to 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full text article</td>
<td>Unpublished manuscripts, letter to editor, short article, abstract only, uncompleted clinical trials, podium speeches</td>
</tr>
<tr>
<td>Addressing screening tools for substance abuse</td>
<td>Articles that do not address the intervention of screening for substance abuse, or screen for other conditions</td>
</tr>
<tr>
<td>Peer reviewed article</td>
<td>Articles that have not gone through peer review process</td>
</tr>
<tr>
<td>Studies with focus of Chronic non-cancer pain</td>
<td>Studies that have a primary focus of acute pain, or cancer related pain</td>
</tr>
</tbody>
</table>

**Conceptual Framework**

Integrative reviews require methodological thoroughness supported by framework.

Whittemore and Knafl (2005) note that the integrative review method is the only approach that allows for the combination of diverse methodologies. It further states, through enhancing its rigor, this method has the potential to allow for findings from diverse methodologies to be applied to clinical practice and evidence-based practice initiatives (Whittemore, & Knafl 2005). The conceptual framework used to guide the project is drawn from Whittemore & Knafl’s (2005) methodology for critiquing evidence. This was accomplished through synthesis of published literature that supports the subject matter of interest.
SECTION TWO: COMPREHENSIVE AND SYSTEMATIC SEARCH

Search Organization and Reporting Strategies

The assistance of a professional librarian was utilized and incorporated in the development of a search strategy for this integrative review. This allowed for the incorporation of multiple databases to be utilized along with the prevention of potential bias on the part of the researcher.

For the purpose of research evidence for the project the use of multiple databases was employed. The databases utilized include Pub Med, CINAHL Plus with Full Text, Health Source: Nursing/Academic Edition, Medline, and Nursing & Allied Health Database from the year 2016-2020. This was completed for referencing studies related to opioids and screening tools utilized in treatment of chronic pain. The research evidence was drawn from the databases using key words. The key words utilized were, opioid, abuse, overdose prevention, screening tools, analgesics, opioid therapeutic use, pain management, chronic pain, and opioid crisis. The key words were then used in the database search engines in exactly the same order.

Terminology

The databases utilized were a compendium of peer-reviewed scientific works published by various academic journals. The aforementioned databases were accessed with the rights and privileges owned by Liberty University. The platforms utilized by these databases were ProQuest and EBSCO. In addition, the project leader also utilized two software programs that efforted the categorization and reduction of data. These programs were RefWorks and Covidence. RefWorks is a citation manager capable of article retention, identification of duplicates and bibliographical citation. RefWorks was utilized for its ability of data reduction through the incorporation of Prisma guidelines.
SECTION THREE: MANAGING THE COLLECTED DATA

Once the articles had been selected from the various databases the selected articles were then uploaded into RefWorks and then to Covidence where the articles were manually sorted and duplicates removed along with further data reduction utilizing the Prisma guidelines. The resulting information can be seen in figure 1. As a result of the large number of articles from the resulting database search, the project leader made the decision that further databases did not need to be incorporated into the project.

Figure 1

Prisma 2020 Flow Diagram
Note: Prisma flow diagram depicting data search and reduction process

Of the 1809 articles screened for the review, 1544 were deemed irrelevant. The resulting 265 articles formed the base and provided the project leader a point at which to begin the screening process. 215 articles were excluded through inclusion/exclusion criteria resulting in 50 articles that were then deemed eligible for full text review. 38 of which were excluded for either wrong setting, patient population, intervention, or study design.

SECTION FOUR: QUALITY APPRAISAL

The process of data analysis is integral to a strong, viable project. Evaluating quality of primary sources in the integrative review method where diverse primary sources are included.
increases the complexity (Whittemore & Knafl, 2005). The Data analysis stage involves thematic: coding, categorizing, ordering, and summarizing data found in the articles selected (Whittemore & Knafl, 2005). In addition, records are kept during the entire data analysis process to ensure that analytical integrity, as well as process clarity were consistently applied (Whittemore & Knafl, 2005). Reducing the enormous data to a manageable amount of information requires various techniques and serves to extract the most important information, then organize it where the project leader can sort for substance and applicability ensuring that rigor is maintained (Whittemore & Knafl, 2003).

Sources of Bias

The minimalization of bias is necessary to ensure rigor and applicability to any project. This project utilized the Prisma guidelines in this regard. The incorporation of these guidelines helped place specific criteria to minimize the scope of the data. The project leader does acknowledge that there is the potential of selection bias on the part of the researcher as there is only one person involved in the procuring of articles. This is inherent to the definition of the project and all efforts have been made to minimize this bias. As stated previously, this was mitigated by the utilization of the professional librarian.

Internal Validity

Each article selected for this IR utilized a scientific approach to reach its own individual conclusion and results. This approach minimized the potential for bias and increased its individual validity. Thus, due to the use of randomizations, standardized review questions and cohort studies each was deemed credible and applicable for use.
Appraisal Tools

Articles in this study were identified, critically appraised, and critiqued for validity individually and based on Melnyk’s level of evidence and the CASP checklist (Centre for Evidence-Based Medicine, 2020). A table of evidence is provided in Appendix A. The table categorically incorporated title, author, study design, method, Melnyk level of evidence, along with strength and limitation of the study. The CASP checklist was additionally utilized as it is specifically designed to evaluate qualitative research. It contains 10 questions what were answered in the affirmative for each article to determine if they presented statistical merit.

Applicability of Results

The literature matrix (Appendix A) served to establish the applicability of each article. As previously stated, each article was appraised to ensure that each had conclusions and recommendations that paired with the design, ethical issues, limitations, and discussion of the study.

Reporting Guidelines

To appropriately recount the structure, bias, and recommendation for this IR, the 2020 PRISMA checklist for systematic reviews was utilized. The identification of this IR was presented in the title of the manuscript. Structure pertaining to the manuscript are title, abstract, introduction, methods, results, and discussion. Components incorporated into the body of work are objectives, synthesis of results, and discussion of bias and recommendations are distinctly examined within the body of work per PRISMA guidelines.
SECTION FIVE: DATA ANALYSIS AND SYNTHESIS

Data Analysis Methods: Thematic Analysis

Once the data was appropriately reduced, the next stage was the display and comparison of common themes within the articles. This process of data visualization and comparison provides some clarity to the empirical and/or theoretical support emerging from early interpretive effort and involves an iterative process of examining data displays of primary source data to identify patterns, themes, or relationships (Whittemore & Knafl, 2005). As previously stated, the thematic analysis stage involves thematic: coding, categorizing, ordering, and summarizing data found in the articles selected (Whittemore & Knafl, 2005).

Braun and Clarke (2006) proposed a six step process that enables the identification of patterns and themes through a collection of literature. The project leader became profoundly acquainted with each article evaluating each with critical analysis and evaluation. The project leader then produced initial codes that signified relative information from the data. These codes were then sorted into potential themes along with creation of a visual representation to better correlate each. The themes were refined and reviewed with the collection of articles to ensure they represented that data as a whole. They were then further refined and defined to identify the overall themes articulated. There were four main themes that emerged throughout the analysis of the articles.

1. Screening tools are an effective method that offer predictive value with the provider patient relationship.

2. Screening tools have little effect in managing opioid abuse and are no better than chance in determining future OUD.

3. Screening tools are not utilized consistently.
4. There is a lack of consensus as to which screening tool is most effaceable.

**Descriptive Results**

The articles included in this IR were distributed between qualitative and quantitative evidence with four articles being ranked level four and the remaining eight being ranked between level five and six in Melnyk level of evidence. It is notable that there are no articles raking higher that level four indicating the literature gap and further indication of need of study.

**Systematic Review**

There were six systematic reviews identified. Lawrence et al., was the first review and had the purpose to identify validated measurement tools for risk assessment and monitoring of chronic non-cancer pain patients being considered for, or currently prescribed, analgesic drugs with abuse potential. The results were that for predicting prescription opioid misuse, the pain medication questionnaire and the screener and opioid assessment for patients with pain (SOAPP) had the relevant evidence.

Picco et al., was the second systematic review and had the purpose to confirm the optimal wording, scoring methods, and cutoff for the OWLS. This review demonstrated that OWLS is a time-efficient, simple scoring method, allowing for quick and accurate screening for opioid use disorder to occur.

Greene, et al., was a review that utilized 2014 INSPECT (Indiana's PDMP) data to identify factors that increase patients' likelihood to engage in opioid-related risk behaviors. While not a strict screening tool in the same manner as others the project leader felt that this was still a method of screening that provided strength to the concept. The results concluded that about one-fourth of all patients consuming opioids engaged in one or more risk behaviors; higher number of opioid prescriptions and addition of even a small number of benzodiazepine
prescriptions dramatically increased these odds. PDMPs can be helpful in identifying opioid users at high-risk for misuse. The strength of this study lies in its size. It consisted of large sample size, \( n = 1,538,120 \) opioid patients.

Nielsen et al., was a review with the intent to develop a short, patient-administered screening tool that will allow for earlier assessment of prescription opioid dependence (often referred to as addiction) in primary care settings. This study was able to identify sixty-four variables associated with criteria for prescription opioid dependence.

Klimas et al., was a systematic review initiated to review the evidence examining factors associated with opioid addiction and screening tools for identifying adult patients at high vs low risk of developing symptoms of prescription opioid addiction when initiating prescription opioids for pain. The results of the study were that while a history of substance use disorder, certain mental health diagnoses, and concomitant prescription of certain psychiatric medications appeared useful for identifying patients at higher risk, few quality studies were available and no symptoms, signs, or screening tools were particularly useful for identifying those at lower risk.

Chaudry et al., was a review with the purpose of to investigate the opioid prescription patterns of FNPs and their utilization of RMPs in caring for patients with CNMP. The results derived from the study showed with respect to risk mitigation practices, 50 of the 86 opioid-prescribing FNPs reported using treatment contracts with their CNMP patients. Far fewer (20.9%) used formal screening tools to gauge the risk of opioid abuse and misuse.

**Qualitative Study**

The IR also identified one qualitative study. Strand et al., is a Qualitative Study of participating pharmacists who provided screening for 107 patients. The intent of the study is to design the Opioid Misuse Risk Prevention Toolkit and then evaluate the utility of the toolkit by
implementing it in community pharmacy practice sites. The project demonstrated the utility and feasibility of screening for opioid misuse risk at the community pharmacy level.

Cohort Studies

The IR contained five cohort studies included in the IR. Clarke et al, was a study consisting of 225 consecutive new patients. Its purpose was to analyze the validity of the Opioid Risk Tool (ORT) in a large diverse population. It should be noted that this was the only study that did not, in some manner validate the effectiveness of a screening tool for prediction of future OUD. The results from this study show self-report ORT was not a valid test for the prediction of future aberrant behaviors in this academic pain management population.

Lee et al., was a study undertaken to evaluate Opioid use disorder using the Korean version of the CAGE-Adapted to Include Drugs, and to investigate clinical predictors that might be useful to screen for OUD. The results derived from the study were that Opioid questionnaires did not discriminate OUD effectively on their own. Only when combined with other patient variables such as sex, comorbid NPD, and CHAI, were the CAGE-AID/Opioid questionnaires feasible and valid to screen for OUD in clinical practice.

Glanz et al., initiated a study to develop and validate an overdose predictive model which could be used in primary care settings to assess the need for naloxone. This study consisted of a cohort of 42,828 patients taking chronic opioid therapy and externally validated the model in 10,708 patients. The results derived from the study were that among patients on chronic opioid therapy, the predictive model identified 66–82% of all subsequent opioid overdoses.

Black et al., was a cohort study that incorporated 555 patients recruited from pain clinics. The purpose of the study was to develop a short form of the SOAPP-R by retaining as few items as possible while maximizing predictive accuracy. The results provide strong preliminary
support for the SOAPP-8 as a brief screening tool of aberrant opioid-related behavior in chronic pain patients.

Cheatle et al., was a study with a cohort of 180 patients at the time of initiating opioids for chronic noncancer pain. The purpose of the study was to examine the risk of developing aberrant behaviors that might lead to a substance use disorder (addiction) when prescribing opioids for the relief of chronic noncancer pain in primary care settings. The resulting findings supported the importance of prescreening patients being considered for opioid therapy and that prescription of opioids for noncancer pain may carry a lower risk of abuse in selected populations such as in private, community-based practices.

**Synthesis**

The consensus of the review is that screening protocols are an effective method and do offer predictive values in the clinical setting. With this consensus in mind a total of four themes emerged throughout the course of the review. These can be viewed in a visual representation in figure 2. The effectiveness and predictive value of screening protocols was noted in 11 of the 12 studies included (Picco, et al., 2020; Greene, et al. 2017; Lawrence, et al., 2017; Lee, et al., 2019; Nielsen, et al., 202; Chaudhary, et al., 2017; Klimas, et al., 2019; Glanz, et al., 2018; Strand, et al., 2019; Black, et al., 2018; Cheatle, et al., 2018). The determination that screening protocols has little effect on opioid use was noted in one article (Clark, et al., 2018). The inconsistent use of the screening protocol was noted in one article (Chaudhary, et al., 2017). The lack of consensus as to which screening protocol to use was noted in five articles (Black, et al., 2018, Nielsen, et al., 2020; Lee, et al, 2019; Lawrence, et al., 2017; Picco, et al., 2020).

**Figure 2**

*Synthesis of Literature*
Ethical Considerations

Ethical considerations are of utmost importance. To comply with ethical standards and to ensure the protection of human subjects, the DNP project team (student and project Chair) completed research ethics training to ensure protection of human subjects. The project is appropriately linked to DNP essentials and submitted for review and approval by the Institutional Review Board (IRB). In addition, a copy of the student’s Collaborative Institutional Training Initiative (CITI) Certificate is provided in the appendix A.

TIMELINE

This integrative review was completed from May of 2020 through April of 2021. The clinical question was formulated and approved by the project chair in June of 2020. Once the
clinical question was approved the project leader initiated the proposal phase of the project which was completed March 5, 2021. The project leader initiated a detailed literature review and analysis which was completed April 2, 2021. The first draft of the manuscript was given to the project chair April 9, 2021. Revisions to the first draft, submission to a third-part editor and submission of final draft were completed by beginning of May 2021

**SECTION SIX: DISCUSSION**

This proposed study contributes to the growing body of syntheses encompassing the opioid epidemic and its implications. It suggests that the utilization of a screening tool at the initial assessment translates to decreased use of opioids. Data from the articles show the need for elements that prompt intervention or assists providers in the assessment of patients requiring opioids for management of chronic pain. This study makes a new contribution to the existing literature and highlights the targeted and future methodologies to mitigate opioid abuse in society.

**Implications for Practice/ Future Work**

The current body of obtained literature supports raised awareness of the subject matter. The literature demonstrates that a problem exists related to the high percentage of opioid abuse. Through synthesis of the acquired articles, the project leader was able to identify factors and indicators supporting the need for consistent screening assessment of potential abuse in the administration of opioids. No significant gaps or conflicting evidence was identified in the review of material. The potential for future work derived from this IR is tremendous. As previously noted, the fact that no articles ranked higher than level four within the Melnyk level of evidence is disappointing and demonstrates the continued need for research in this area.
Dissemination

Dissemination will be accomplished through mediums that include but are not limited to: peer-reviewed publications, poster presentations, and seminars. The project leader envisions the presentation could be on a macro and micro level and seeks the information available to a broad audience of professionals by having the findings published in a recognized medical journal. In addition, the power point developed for this project will be presented at a local symposium for internal medicine and primary care providers.
References


Appendix A

Literature matrix

In patients with chronic non-cancer pain, how does the use of a screening tool at the initial assessment compared to those not screened influence the reduction of opiate medication use?

<table>
<thead>
<tr>
<th>Title, Author, Year</th>
<th>Study Objective</th>
<th>Design, Sampling Method, &amp; Subjects</th>
<th>Level of Evidence</th>
<th>Intervention</th>
<th>Results</th>
<th>Strengths and Limitations of Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation of the OWLS, a Screening Tool for Measuring Prescription Opioid Use Disorder in Primary Care, Picco, L., Middleton, M., Bruno, R., Kowalski, M., &amp; Nielsen, S. (2020).</td>
<td>To confirm the optimal wording, scoring methods, and cutoff for the OWLS</td>
<td>Cross-sectional analysis of an online sample Participants comprised those with chronic noncancer pain who regularly used prescription opioids</td>
<td>Level 5</td>
<td>Participants self-completed an online version of the OWLS prescription opioid use disorder screening tool and the Composite International Diagnostic Interview Substance Abuse module</td>
<td>A time-efficient, simple scoring method, allowing for quick and accurate screening for opioid use disorder to occur.</td>
<td>Strengths: validity in a broader, more generalizable sample Limitations: Participants did not receive detailed information about the study until after they had been screened and identified as eligible, which may explain the low conversion rate due to the online self-complete method, meeting eligibility was determined by self-report,</td>
</tr>
<tr>
<td>Assessment of risk behaviors in patients with opioid prescriptions: A study of Indiana’s inspect data, Greene, M.</td>
<td>To utilize 2014 INSPECT (Indiana’s PDMP) data to identify factors that increase patients' likelihood to engage in</td>
<td>Literature review</td>
<td>Level 5</td>
<td>Four risk behaviors were identified: Receiving &gt;90 morphine milligram equivalents (MME), having &gt;4 opioid prescribers, obtaining opioids from &gt;4 pharmacies,</td>
<td>About one-fourth of all patients consuming opioids engaged in one or more risk behaviors; higher number of opioid prescriptions and addition of even a small number of benzodiazepine</td>
<td>Strengths: large sample size (n = 1,538,120 unique opioid patients) and completeness of the dataset Limitations: Concurrent use of opioids and benzodiazepines was one of the study’s outcomes.</td>
</tr>
<tr>
<td>Source</td>
<td>Opioid-related risk behaviors</td>
<td>Analysis</td>
<td>Level</td>
<td>Strengths</td>
<td>Limitations</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------</td>
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<td>-------</td>
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</tr>
<tr>
<td>S., Chambers, R. A., Yiannoutsos, C. T., Wright, E. R., Steele, G. K., &amp; Zollinger, T. W. (2017).</td>
<td>and concurrent use of opioids and benzodiazepines. Two binary logistic regression analyses (engaging in at least one risk behaviors; engaging in all four risk behaviors) and an ordinal regression analysis (engaging in 0-4 risk behaviors) were conducted to identify factors associated with these opioid-related risk behaviors. Prescriptions dramatically increased these odds. PDMPs can be helpful in identifying opioid users at high-risk for misuse.</td>
<td></td>
<td></td>
<td>PDMPs identify prescribers by their individual DEA number. Patients who see multiple providers at the same clinic may be inappropriately marked as doctor-shoppers, because the database is unable to recognize when providers are working together</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-assessing the Validity of the Opioid Risk Tool in a Tertiary Academic Pain Management Center Population, Clark, M. R., Hurley, R. W., &amp; Adams, M. C. B. (2018).</td>
<td>To analyze the validity of the Opioid Risk Tool (ORT) in a large, diverse population. A cross-sectional descriptive study. A total of 225 consecutive new patients, aged 18 years or older.</td>
<td>Data collection included demographics, ORT scores, aberrant behaviors, pain intensity scores, opioid type and dose, smoking status, employment, and marital status. The self-report ORT was not a valid test for the prediction of future aberrant behaviors in this academic pain management population.</td>
<td>Level 4</td>
<td>Strengths: likely that EHR data are not complete in the domains relevant to misuse stratification/ the team member had ample time to review the EHR and collect objective data, unlike a clinician actively seeing patients with a limited time window to review patients’ past medical history to obtain an accurate ORT score. Limitations:</td>
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<td>Systematic review to determine</td>
<td>To identify validated measurement</td>
<td>Systematic review</td>
<td>Level 5</td>
<td>Strengths: the wide range of databases searched</td>
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which validated measurement tools can be used to assess risk of problematic analgesic use in patients with chronic pain, Lawrence, R., Mogford, D., Colvin, L., & Hardman, J. G. (2017).

| Tools for risk assessment and monitoring of chronic non-cancer pain patients being considered for, or currently prescribed, analgesic drugs with abuse potential. | Evaluating tools for risk of analgesic misuse, either before, or during, analgesic therapy for chronic pain, using predetermined inclusion/exclusion criteria. Two independent reviewers assessed abstracts, selected full texts, extracted data and assessed quality. | Medication questionnaire and the screener and opioid assessment for patients with pain (SOAPP) had the best evidence. | Limitations: The lack of literature regarding screening tools for non-opioid medication abuse and our inability to do a meta-analysis because of heterogeneity of studies. |

<p>| Usefulness of the Korean Version of the CAGE-Adapted to Include Drugs Combined With Clinical Predictors to Screen for Opioid-Related Aberrant Behavior, Lee, C.-S., Kim, D., Park, S.-Y., Lee, S. C., Kim, Y.-C., (2017). | To evaluate Opioid use disorder using the Korean version of the CAGE-Adapted to Include Drugs, and to investigate clinical predictors that might be useful to screen for OUD in conjunction with the CAGE-AID/Opioid questionnaires. | A single-center, prospective, observational study. | Level 4 | Assessed OUD in patients with chronic opioid treatment. Multivariable logistic models of the CAGE-AID/Opioid questionnaires combined with relevant clinical predictors were established. Then, the receiver operating characteristic curve analysis of the multivariable CAGE-AID/Opioid models was used to classify patients as having or not having OUD. The multivariable models of the CAGE-AID/Opioid with sex, comorbid neuropsychiatric disorder, and current heavy drinking were valid parameters to screen for OUD, with the cutoff scores of the CAGE-AID/Opioid questionnaires ranging from 0 to 3 depending on the presence of the clinical variables. | Limitations: this is a single-center study. Therefore, there would be biases for generalizing our results to a national level. |</p>
<table>
<thead>
<tr>
<th>Reference</th>
<th>Methodology</th>
<th>Study Details</th>
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<tr>
<td>&amp; Moon, J. Y. (2019).</td>
<td>Opioid questionnaires</td>
<td>Conducted to assess diagnostic accuracy to screen for OUD. Next, we calculated predicted probability with &gt;85% sensitivity and &gt;50% specificity in each CAGE-AID and CAGE-Opioid model. Using the optimal value of the predicted probability, a cutoff score of the CAGE-AID/Opioid questionnaires combined with the relevant clinical factors was suggested to screen for OUD.</td>
</tr>
<tr>
<td>Development of a Brief Patient-Administered Screening Tool for Prescription Opioid Dependence for Primary Care Settings, Nielsen, S., Picco, L., Campbell,</td>
<td>To develop a short, patient-administered screening tool that will allow for earlier assessment of prescription opioid dependence (often referred to as addiction) in primary care settings.</td>
<td>Cross-sectional analysis</td>
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<td>Level 5</td>
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<td>Identification of individual items that were significantly associated with meeting ICD-11 criteria for prescription opioid dependence. Exploratory and confirmatory factor analysis were conducted, and items were reduced to identify a small item</td>
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<td>Sixty-four variables associated with criteria for prescription opioid dependence were initially identified.</td>
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<td>Limitations: The existing data set comprised a sample of CNCP patients who were prescribed strong opioids. As such, it is not clear how findings relate to those who have been prescribed weaker opioids, those who have been taking opioids for shorter periods of time, or those using opioids for acute pain.</td>
</tr>
<tr>
<td>Strategies to Identify Patient Risks of Prescription Opioid Addiction When Initiating Opioids for Pain: A Systematic Review, Klimas, J., Gorfinkel, L., Fairbairn, N., Amato, L., Ahamad, K., Nolan, S., Simel, D. L., &amp; Wood, E. (2019).</td>
<td>To review the evidence examining factors associated with opioid addiction and screening tools for identifying adult patients at high vs low risk of developing symptoms of prescription opioid addiction when initiating prescription opioids for pain</td>
<td>A Systematic Review</td>
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<td>Prediction Model for Two-Year Risk of Opioid Overdose Among Patients</td>
<td>To develop and validate an overdose predictive model which could be used in primary care settings to</td>
<td>Retrospective cohort. A cohort of 42,828 patients taking chronic opioid therapy</td>
</tr>
<tr>
<td>Prescribed Chronic Opioid Therapy, Glanz, J. M., Narwaney, K. J., Mueller, S. R., Gardner, E. M., Calcatera, S. L., Xu, S., Breslin, K., &amp; Binswanger, I. A. (2018).</td>
<td>assess the need for naloxone and externally validated the model in 10,708 patients records. Fatal overdose outcomes were identified from state vital records. To match the approximate shelf-life of naloxone, we used Cox proportional hazards regression to model the 2-year risk of overdose. Calibration and discrimination were assessed</td>
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<td>Use of risk mitigation practices by family nurse practitioners prescribing opioids for the management of chronic nonmalignant pain, Chaudhary, S., &amp; Compton, P. (2017).</td>
<td>To investigate the opioid prescription patterns of FNPs and their utilization of RMPs in caring for patients with CNMP</td>
<td>Online survey A national sample of 856 FNPs</td>
</tr>
</tbody>
</table>

| Development and Validation of an Eight-Item Brief Form of the SOAPP-R | To design the Opioid Misuse Risk Prevention Toolkit and then evaluate the utility of the toolkit by implementing it in community pharmacy practice sites | Qualitative Study participating pharmacists provided screening for 107 patients | Level 6 | Pharmacists were trained in the use of the toolkit, which they implemented within their community pharmacy for all patients receiving opioid prescriptions. A triage tool was used to guide the process of screening patients for opioid use disorder, red flags, risk of accidental overdose, and misuse of opioids through the prescription drug monitoring program (PDMP) | This pilot project demonstrated the utility and the feasibility of screening for opioid misuse risk at the community pharmacy level. | Limitations: This pilot project lacks statistical power, and thus the results should be viewed from a qualitative perspective |

<p>| Development and Validation of an Eight-Item Brief Form of the SOAPP-R | To develop a short form of the SOAPP-R by retaining as few items as possible while | Cohort Study, Participants (N = 555), recruited from pain clinics. | Level 4 | completed the 24-item SOAPP-R and participated in a five-month follow-up visit to evaluate aberrant drug-related | These results provide strong preliminary support for the SOAPP-8 as a brief screening tool of aberrant opioid-related | Limitations: the predictive accuracy of the SOAPP-8 with other populations, such as teenagers or cancer patients, is unknown |</p>
<table>
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<tr>
<th>Study Title</th>
<th>Research Question</th>
<th>Study Design</th>
<th>Outcome Measures</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| Maximizing Predictive Accuracy (SOAPP-8), Black, R. A., Mccaffrey, S. A., Villapiano, A. J., Jamison, R. N., & Butler, S. F. (2018). | To examine the risk of developing aberrant behaviors that might lead to a substance use disorder (addiction) when prescribing opioids for the relief of chronic noncancer pain in primary care settings | Longitudinal, prospective, descriptive design with repeated measures             | Level 4
Standardized measures of patient status and treatments provided, urine drug monitoring, and medical chart audits were obtained at the time of initiating opioids for chronic noncancer pain in primary care settings and at three, six, and 12 months thereafter. | Supports the importance of prescreening patients being considered for opioid therapy and that prescription of opioids for noncancer pain may carry a lower risk of abuse in selected populations such as in private, community-based practices. | Limitations: potential for selection bias and the effect of being monitored both in the subjects and the prescribing physicians. |
Appendix B

To: Thompson, Ken (Nursing); Wright, Stephen (Nursing)

March 8, 2021


Dear Stephen Wright and Kenneth Thompson,

The Liberty University Institutional Review Board (IRB) has reviewed your application in accordance with the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) regulations and finds your study does not classify as human subjects research. This means you may begin your research with the data safeguarding methods mentioned in your IRB application.

Decision: No Human Subjects Research

Explanation: Your study is not considered human subjects research for the following reason:

“Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected,” are not considered research according to 45 CFR 46.102(l)(1).

Please note that this decision only applies to your current research application, and any modifications to your protocol must be reported to the Liberty University IRB for verification of continued non-human subjects research status. You may report these changes by completing a modification submission through your Cayuse IRB account.

Also, although you are welcome to use our recruitment and consent templates, you are not required to do so. If you choose to use our documents, please replace the word research with the word project throughout both documents.

If you have any questions about this determination or need assistance in determining whether possible modifications to your protocol would change your application's status, please email us at irb@liberty.edu.
Sincerely,

G. Michele Baker, MA, CIP  
*Administrative Chair of Institutional Research*  
*Research Ethics Office*
Appendix C

This is to certify that:

**Stephen Wright**

Has completed the following CITI Program course:

**Biomedical Research - Basic/Refresher**  
(Curriculum Group)

**Biomedical & Health Science Researchers**  
(Course Learner Group)

**1 - Basic Course**  
(Stage)

Under requirements set by:

**Liberty University**

Verify at [www.citiprogram.org/verify/?wf3fccc611-08a2-494d-847f-ded14b476772-37502070](http://www.citiprogram.org/verify/?wf3fccc611-08a2-494d-847f-ded14b476772-37502070)