

Quality Improvement in Primary Care using the STOPP/START Criteria

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DNP 670 Scholarly Project One

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We have no conflicts of interest to disclose.

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Abstract

Background: Adverse drug reactions (ADRs) in older people is a public health issue and is increasingly a problem in the care of the geriatric population. Polypharmacy and potentially inappropriate medications (PIM) are recognized risk factors for ADRs, which commonly cause adverse clinical outcomes in older people. The goal of this project is to assess if the application of the screening tool of older people's prescriptions (STOPP) and screening tool to alert to right treatment (START) criteria in a primary care practice for all patients age 65 and older will reduce the use of PIM in the geriatric population. The STOPP/START criteria is an evidence-based tool that can be used to facilitate a medication review for older adults.

Methods: Healthcare providers who are treating geriatric patients age 65 years and older in a primary care practice will be the primary population. The principal investigator (PI) will track all patients age 65 and older seen by the participants and screen for use of the STOPP/START criteria and review of PIM for those patients.

Interventions: The PI will provide an educational program for all participants, explaining the history of the STOPP/START criteria and how it is used, as well as avoidance of medications on the PIM list as much as possible. Implementation of the STOPP/START tool and PIM will begin upon completion of the education program and appropriate implementation of the tools will continue to be monitored by the PI for a period of three months. A retrospective review of patient medication lists for patients age 65 and older for the three months prior to implementation of STOPP/START criteria assessment and PIM will be conducted for comparison.

Results: The results of the two-tailed Wilcoxon signed rank test were not significant for PRE_PIM and POST_PIM based on an alpha value of .05, $V = 18.50$, $z = -1.73$, $p = .084$. The results of the two-tailed Wilcoxon signed rank test were significant for PRE_START and POST_START based on an alpha value of .05, $V = 0.00$, $z = -3.49$, $p < .001$.

Conclusions: The use of STOPP/START criteria within primary care increases the amount of START medications applied for patients.

Keywords: *Patient safety, elderly patients, adverse drug event, inappropriate prescribing, STOPP/START criteria, potentially inappropriate medication*

Quality Improvement in Primary Care Using the STOPP/START Criteria

The growth of the geriatric population globally is outpacing the growth of all other population groups. The World Health Organization (WHO) estimates the global geriatric population will almost double between 2015 and 2050, growing from 12% to 22% of the world's population (WHO, 2021). Concurrently, the United States (U.S.) Census Bureau predicts that in the U.S. older adults will outnumber children younger than age 18 by 2034. Looking ahead to the year 2060, one in four adults will be age 65 or older, persons 85 years and older will triple in number and there will be approximately 500,000 centenarians (U.S. Census Bureau, 2021).

As patients age they begin to experience health conditions that are common to aging, such as diminished visual acuity secondary to cataracts and refractive errors, diminished hearing capacity, osteoarthritis and joint pain. Chronic conditions such as diabetes, cardiovascular disease, pulmonary disease, depression and dementia become increasingly common as a person ages. Many older patients experience complex health problems classified as geriatric syndromes, with diagnoses such as frailty, delirium, dementia, falls and urinary incontinence (WHO, 2021).

Geriatric patients often present a complex clinical picture due to having multiple comorbid conditions and requiring various medications to manage these conditions (Lönnbro & Wallerstedt, 2017). As the population ages and advanced technology and treatment extends life expectancy, the need for complex medication regimens have become increasingly prevalent. Multiple medication regimens for the treatment of acute and chronic disease is referred to as polypharmacy and is common in the elderly (Masnoon et al., 2017).

Healthcare providers must be aware of the risks of polypharmacy and avoid potentially inappropriate medication (PIM) prescribing. Research has shown there is a negative correlation between polypharmacy and patient compliance with medications, leading to the risk of confusion about the regimen and added economic burden, as well as increased risk of adverse drug reactions, falls and hospitalization (Milton et al., 2008).

The WHO defines primary care as aim of focusing on a patient's healthcare needs across the lifespan, including promotion of health, prevention of disease, treatment of illness, rehabilitation and palliative care (WHO, 2021). This aligns with the principle that primary care providers are best suited to provide comprehensive care in the management of morbidities and pharmaceutical interventions.

Primary care providers are presented with a unique opportunity to prevent adverse events related to inappropriate medications prescribed for their older patients. The Screening Tool of Older People's Prescriptions (STOPP) and Screening Tool to Alert to Right Treatment (START) criteria was created to help address the issue with geriatric patients. The STOPP/START criteria introduced the concept of including not only drug-drug interactions but also drug-disease interactions when addressing the problem of PIM in the geriatric population (O'Connor et al., 2012).

Deprescribing is another important aspect of care for geriatric patients. One in five prescriptions are thought to be inappropriate for geriatric patients (Reeve et al., 2016). Deprescribing is defined as proactive and systematic process of identifying and discontinuing prescriptions where the potential/actual harm is greater than benefits (Anderson et al., 2017). Recognizing the benefit deprescribing affords geriatric patients is an important role for primary care providers (Reeve et al., 2016).

Maintaining an open and honest relationship with the patient fosters a trusting relationship between the patient and the provider, to include trusting the decisions providers make regarding medications (Anderson et al., 2017). Primary care providers have the responsibility of managing medications for geriatric patients who wish to remain in the community. Remaining within the community is important for many geriatric patients, making mindful medication review extremely important (Steinman & Hanlon, 2010).

Balancing the healing effects of medications with the physiologic changes of aging can be challenging. Older patients may need lower doses of medications due to pharmacodynamics and pharmacokinetic changes that occur as we age. Multi-morbidities and the resulting treatment puts patients at risk for polypharmacy and for PIM, increasing the potential for adverse drug reactions and even death (Milton, 2008).

Background and Review of Literature

A systematic literature review of the Cumulative Index to Nursing and Allied Health Literature (CINAHL) database was conducted to identify studies available regarding polypharmacy in the older adult population, current tools in use to address polypharmacy in the older population and studies reporting the effectiveness of STOPP/START criteria for older patients. Keywords used in the literature search included: patient safety, elderly patients, adverse drug event, inappropriate prescribing, STOPP/START criteria, potentially inappropriate medication.

Epidemiology

Polypharmacy is the simultaneous use of multiple drugs by a single person. Older adults with multimorbidity are at increased risk of harm from medications that are no longer necessary or appropriate as the clinical circumstances and patient priorities change (Anderson et al., 2017). Current research reveals that adults age 65 years and older have 61% higher rates of multiple chronic conditions when compared to the 26% multimorbidity rates of all adults (Quinn & Shah, 2017). Polypharmacy and potentially inappropriate medications prescribed for older adults are growing public health problems in the U.S. One study showed 44.0% of participants were subjected to polypharmacy (Morin et al., 2018).

Potentially inappropriate medications are increasingly found in the medication regimens of older patients. There are multiple concerns when it comes to prescribing medications for the older population such as multiple comorbid conditions, physiologic changes and lack of research to support medication dosage (O'Connor et al., 2012). Prevalence of PIM should be an ongoing concern in the primary care setting. One study showed a prevalence of 68.6% for PIM in the primary care setting ($n = 757$) (Simões et al., 2019).

Complications Related to Polypharmacy

Numerous studies reveal potentially inappropriate prescribing and polypharmacy are common problems among the older population. Quantifying the extent of the problem is compounded by the different settings where older adults encounter healthcare providers, such as acute treatment facilities, long-term care facilities and community dwellers (Bregnhøj et al., 2009). Each additional medication

increases the risk of drug-drug interactions, adverse drug effects or drug-disease reactions. The older population are at risk of impaired renal and hepatic function, decreased lean body mass, hearing and vision impairment and diminished mobility, all factors that contribute to the increased need for careful prescribing and avoidance of polypharmacy. Healthcare providers must be aware that, while a specific drug may be an appropriate treatment for a specific illness, older patients must be treated with a comprehensive analysis of each patient's particularly physiologic and pharmacologic status in order to avoid PIM and polypharmacy (Masnoon, 2017).

Providers are taught to prescribe medication based on evidence-based research. The problem with this instruction is the research does not focus on patients who need more than one medication or have more than one health condition that requires treatment (Molokhia & Majeed, 2017). Complications from polypharmacy can lead to adverse outcomes for patients, including renal failure, falls, fractures and death (Molokhia & Majeed, 2017).

Potentially Inappropriate Medications

Potentially inappropriate medications, or PIM, does not have a standard that is identifiable, rather each patient must be evaluated based on their medical history and morbidities as to the appropriateness of any new prescription. Potentially inappropriate medications generally refers to prescribing a medication whose risks outweighs the benefits for each patient. The term PIM can mean the drug was prescribed with a possible incorrect dosage or indication or it may be prescribed for a prolonged period of use, the interactions with other drugs may be overlooked or the pharmacokinetics of a particular drug for a specific patient may be ignored (Laberge, et al., 2021).

Increased spending is also associated with PIM. One research endeavor calculated that 7.3 billion doses of PIM, at a cost of \$4.4 billion, were prescribed in 2018 in the U.S. (Jungo et al., 2021). Several studies have shown that routine medication reviews by a pharmacist has a positive effect. Laberge et al., (2021) in their systematic review identified only one study that was found to utilize pharmacogenetic testing and the use of a validated decision support tool in making treatment decisions.

Medication reviews are not limited to the primary care provider but can involve a multi-disciplinary team dedicated to avoidance of PIM through the use of a decision support tool such as the STOPP/START or the Good-Palliative-Geriatric Practice (GP-GP). While these were the tools most often mentioned to support avoiding PIM, development of algorithms specific to an organization was also identified (Laberge et al., 2021).

In the U.S. the burden of increasingly complex medication regimens requires thoughtful attention and this attention is likely focused on primary care providers. Sorensen and colleagues (2004) make the point that, from an economic standpoint ongoing medication reviews at each encounter may not be cost-effective, especially if a pharmacist is required for consultation.

STOPP/START Criteria

The STOPP/START criteria were developed to fill a gap in the process of medication prescribing for geriatric patients. Often research and drug studies are conducted without including geriatric patients due to their exclusion secondary to comorbid conditions (O'Connor et al., 2012). The STOPP/START tool was designed to be a comprehensive list of PIM based on current clinical evidence, reflecting the opinion of a multidisciplinary team of experts, drug-drug/drug-disease interaction, and detect frequent prescribing omissions. Creation of STOPP/START led to the first physiological systems-based screening tool for geriatric patients (Gallagher et al., 2008).

The STOPP criteria's intended use is as a screening tool for decisions regarding medications that are possibly inappropriate for geriatric patients based on common conditions. This tool was developed to be user friendly for daily use within the clinical setting. The START criteria was created to complement the STOPP criteria and alert providers to potential prescription treatments which could benefit their patients (Gallagher et al., 2008). The STOPP/START criteria has been extensively validated in the inpatient setting, but has a gap of research within the outpatient setting, including primary care practices. The STOPP consists of 80 criteria that help healthcare personnel systematically identify PIM and START consists of 34 criteria that identify potential prescribing omissions (PPO) (O'Mahony et al., 2015).

A number of the studies compared STOPP/START with other criteria widely utilized to guide medication prescription for older adults such as Beers Criteria, Fit for the aged (FORTA), Medication Appropriateness Index (MAI), European Union PIM list (EU-PIM list) (Awad & Hanna, 2019; Monteiro et al., 2020). The STOPP/START criteria were found to be more sensitive than the Beers criteria for detection of PIM (Bahat et al., 2017; Elliott & Stehlik, 2013; Hill-Taylor et al., 2013). Unlike the Beers criteria, the STOPP/START criteria were made to be used as a checklist, which makes use of the STOPP/START criteria more timely and more likely to be selected for use in practice (Kim & Parish, 2017).

While one systematic review found there is a need for more studies to be conducted on STOPP/START outside of the acute care setting (O'Mahony et al., 2015), a systemic review conducted by Hill-Taylor et al., (2016), found applicability across the care spectrum from community to long-term care. A study conducted over five years at a primary care center in Ireland revealed the potential for long-term benefits of STOPP/START criteria being used regularly. The study showed PIM prevalence to increase over five years from 39.7% to 45.6% when no intervention is in place for geriatric patients (Hansen et al., 2017). Another study in France ($n = 172$), showed 98 patients (57%) had at least one PIM, this number decreased by 37.6% after STOPP/START implementation (Gibert et al., 2018). A Romanian study found 25.80% of their patients ($n = 646$) to have at least one PIM with no intervention in place (Buda et al., 2020). A Swedish study showed 555 PIMs/PPOs for their study subjects ($n = 170$) before any interventions were applied (Lonnbro & Wallerstedt, 2017).

All studies apart from one conducted the STOPP/START research on patients aged 60 and above for best representation of geriatric patients. A study conducted in Turkey was open to all age groups to evaluate polypharmacy prior to intervention, which resulted in the largest study group pool ($n = 1579$). (Unutmaz et al., 2018). Regardless of study group size, all reviewed literature showed a decrease in PIMs with the application of STOPP/START criteria.

Primary care practitioners are in a unique position to implement STOPP/START within their practice to prevent adverse events for their geriatric population. One study showed primary care providers

are prescribing medications 91% of the time they have appointments with their geriatric population (Gibert et al., 2018). Multiple studies cited primary care practitioners as having the most impact on prevention of PIM due to frequent rechecks with patient to gauge adherence and knowledge of patient conditions (Giber et al., 2018; Awad & Hanna, 2019; Simões et al., 2019).

The current literature provides support for the implementation of STOPP/START within the primary care setting for the geriatric population. Primary care providers need to take steps to prevent the use of PIM. This can be through implementation of an electronic health record (EHR) and multidisciplinary collaboration. It must be noted none of the mentioned research was conducted within the U.S., indicating the need for further research involving the use of the STOPP/START tool in primary care in the aging U.S. population is needed.

Theoretical Framework

In 1999, Rosswurm and Larrabee developed a model for evidence-based practice change that includes six steps to promote a change in practice. This model has been widely validated in the acute care setting and has potential for guiding practice change in the primary care setting (White et al., 2019). Acknowledging the “traditional intuition-driven” practice, Rosswurm and Larrabee provided six steps to guide practice change based on current evidence (see Figure 1). This model was used to guide this quality improvement project. This project began with an assessment of the need to improve oversight of polypharmacy and PIM in the older patients cared for in this primary care practice in rural North Carolina. Next, defining how polypharmacy and PIM would impact care of the patients and linking these issues with possible interventions and outcomes. A review of literature summarized the best evidence related to the topic. Implementation and evaluation of the practice change was conducted by the PI for three months. The final step was integration of the use of the STOPP/START tool as a standard of care for older patients seen in the practice (White, 2019; Larrabee, 2010).

Purpose

The use of potentially inappropriate medications in older adults often leads to adverse events in this population. The purpose of this quality improvement project is to assess the impact of the application

of STOPP/START criteria in this rural primary care practice will reduce the use of PIM in the geriatric population.

Methods

This quality improvement project was conducted over a three-month period, implementing the STOPP/START criteria within a primary care practice in a rural community setting. Data collection will occur from October to December. Comparative data will be collected through a retrospective chart review in the EHR. Implementation of the STOPP/START will provide measures of provider use of the tool. Secondary data will be collected regarding the incidence of PIM, discontinuation of PIM and reduction in polypharmacy.

Participants

Healthcare providers who are caring for geriatric patients age 65 years and older in a primary care practice will be the primary population. The PI will track all patients age 65 and older seen by the participants and screen for use of the STOPP/START criteria and review of PIM for those patients.

Procedures

This QI project begins with an educational program describing the history and evidence-based use of the STOPP/START criteria for all prescribing healthcare providers when caring for patients age 65 and older in a rural primary care practice in western North Carolina. The STOPP/START criteria are an internationally recognized intervention with open access for all providers to replicate this intervention. The PI for this project will provide each participant a laminated copy of the STOPP/START criteria for reference during encounters with older patients.

Support staff will be included in this education and will also be provided with a copy of STOPP/START criteria. Following completion of the education on STOPP/START, implementation of a medication review using these criteria will begin for all patients age 65 and older and will continue for a period of three months.

Geriatric patients, age 65 and over, will undergo a medication reconciliation assessment with the application of STOPP/START criteria. The primary outcome will be utilization of the STOPP/START

criteria for each patient age 65 and older seen by the providers in this practice. Secondary outcomes include decreasing the number of PIMs and having change to non-PIMs for each patient evaluated with STOPP/START criteria. Process measure will include the percentage of time the primary care provider applies STOPP/START criteria correctly to an eligible patient. A retrospective chart review will be conducted to evaluate use of the STOPP/START criteria interventions within the practice prior to the implementation of this project.

During the three-month implementation period, the PI will perform a weekly review of charts for all patients age 65 and older seen by the participating providers, evaluating each patient encounter for a review of medications using the STOPP criteria and initiation of any new medications to improve safety and effectiveness using the START criteria. The participants will place a statement within the care plan section stating review of medications have been completed for each qualifying patient.

Measures

PIM Prescriptions

Data on decreasing amount of PIM prescriptions will be obtained with retrospective chart review after implementation of STOPP/START criteria. Pre-intervention numbers will be contrasted with post-intervention numbers to measure improvement. Manual counting of each participant's prescriptions will be logged and compared with data software.

Non-PIM Use

Data on non-PIM use will be evaluated with a retrospective chart review after implementation of STOPP/START criteria. Pre-intervention medication list will be compared with post-intervention list. Manual review will allow for the recording of medication changes and allow for them to be logged and compared with data software.

Process Measures

Percentage of eligible participants who underwent evaluation with STOPP/START criteria by the project participants within the practice will be determined by a chart review.

Analysis

Two-tailed Wilcoxon Signed Rank Test will be performed for pre-intervention and post-intervention mean treatment assessment on participants PIM use and non-PIM use. Descriptive statistics will be used for the reporting of this process. Intellectus Statistics software will be used to perform all statistical computations.

Ethical Considerations

This QI project was reviewed and approved by the Lenoir-Rhyne University Institutional Review Board (IRB) and classified as exempt. Participation in the project was voluntary and participants had the right to withdraw at any time without consequence or prejudice. Research participants were given contact information for faculty advisors in the event they had concerns about the PI or the project. The contact information for the PI was also available, along with the contact information for the Chair of the Lenoir Rhyne University IRB, so any questions or concerns that may have arisen from the project participant could be addressed at any time.

The data was collected and stored using the Intellectus™ Statistics program. A duplicate data set will be stored on a password-protected external drive to ensure safety in the event of damage to the original information. Data will be stored for five years after project completion and then destroyed.

There was no funding for this project. The use of the STOPP/START tool was a system change for this facility. The comprehensive curriculum and training materials will be retained by the facility for use during orientation for all new employees in the future.

Results

Sixty patients age 65 and older were seen during the implementation of the project. A two-tailed Wilcoxon signed rank test was conducted to examine whether there was a significant difference between the use of the STOPP/START tool for PIM prior to the project (PRE_PIM) and during the project (POST_PIM). The results of the two-tailed Wilcoxon signed rank test were not significant based on an alpha value of .05, $V = 18.50$, $z = -1.73$, $p = .084$. This indicates that the differences between PRE_PIM

(*Mdn* = 0.00) and POST_PIM (*Mdn* = 0.00) are explainable by random variation. Figure 2 presents a boxplot of the ranked values of PRE_PIM and POST_PIM.

A two-tailed Wilcoxon signed rank test was conducted to examine whether there was a significant difference between the use of the STOPP/START tool for polypharmacy prior to the project (PRE_START) and during the project (POST_START). The results of the two-tailed Wilcoxon signed rank test were significant based on an alpha value of .05, $V = 0.00$, $z = -3.49$, $p < .001$. This indicates that the differences between PRE_START and POST_START are not likely due to random variation. The median of PRE_START (*Mdn* = 3.00) was significantly lower than the median of POST_START (*Mdn* = 3.00). Figure 3 presents a boxplot of the ranked values of PRE_START and POST_START.

Discussion

This aim of this project was to educate primary care providers in the use of the STOPP/START instrument as a means of prevention of PIM and unnecessary polypharmacy in the older patient population. The project demonstrated the essential but complex issue of medication safety in older patients.

The strengths of the project was the successful integration of an evidence-based tool within the practice and the intent of the practice to continue to use the STOPP/START criteria to avoid PIM and polypharmacy in their practice. The most significant impact of the project was to prevent polypharmacy in the older patient population, resulting in decreased pill burden and economic impact to the patient.

With the current providers in this practice committed to the use of the STOPP/START tool, it would be feasible that the tool could be uploaded to their current EMR platform, which could expedite navigation of the STOPP/START tool for medication review.

Summary

This QI project was able to support the use of STOPP/START criteria within the primary care setting. This project showed improvement from pre-intervention to post-intervention in the amount of START prescriptions ordered for the geriatric patients. While the STOPP criteria did not show a

significant improvement between pre-intervention and post-intervention, there was still very few STOPP prescriptions active from the participating provider.

Interpretations

This project encouraged providers in this rural practice to use an evidence-based tool to perform a comprehensive medication reconciliation at each visit with the older patient population seen in the practice. Providers in the practice developed a deeper understanding of the need to evaluate for polypharmacy and PIM, to include opportunities for deprescribing. This process can often be viewed as too burdensome, given the time constraints of patient visits and in particular, with the patient population who has multi-morbidities and treatment modalities. Having provider commitment to the process improves patient outcomes and quality of care.

Limitations

Limitations within this study include only having one provider contributing to the data collection, collecting data from only one primary care practice, and limited timeframe of data collection. Finally, having the tool and tracking during the project be paper-based made the use of the tool and tracking of data more difficult. Future projects would be facilitated by integration of the STOPP/START tool in the EMR platform.

Conclusions

The use of STOPP/START criteria in primary care has great potential for preventing PIM and increasing safe prescriptions for geriatric patients. Integration of the STOPP/START criteria in primary care as a standard of care serves to improve the care provided. The results found during this project add to the body of evidence supporting the use of the STOPP/START criteria in primary care. The commitment of the provider to this process and this project illustrates the importance of provider buy-in for medication reconciliation. Integration of medication review into routine practice should become a standard of care for all primary care practices, as a means of reducing polypharmacy and avoiding PIM. Further research using the STOPP/START in primary care is needed, however this project showed the potential for improving care for geriatric patients.

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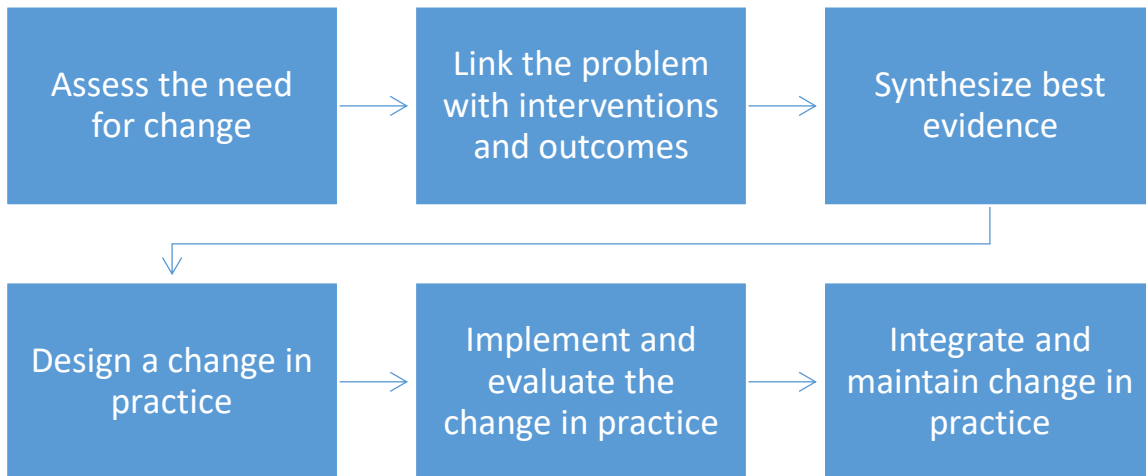
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Figure 1

Model adapted from Rosswurm, M. A., & Larrabee, J. H. (1999). A model for change to evidence-based practice. Journal of Nursing Scholarship, 31(4), 317–322. doi:10.1111/j.1547-5069.1999.tb00510.x.

Figure 2

Ranked values of PRE_PIM and POST_PIM

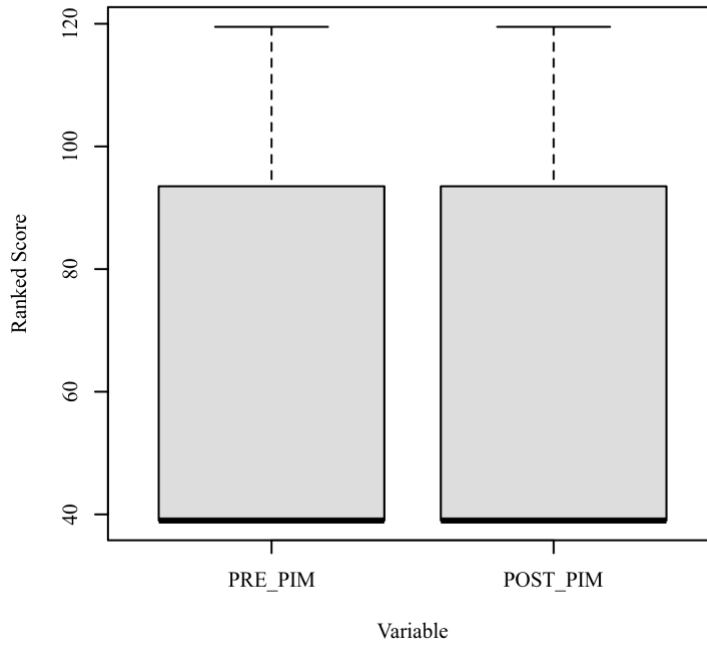


Figure 3

Ranked values of PRE_START and POST_START

