The **PICK** Study

Parkinson's Disease **I**npatient **C**linical **K**nowledge and Management

Co-Principal Investigators
Hooman Azmi, MD
Claudia Douglas, DNP, RN, APN.C
Mohammed Quadri, MD

Sub-Investigators
Francine DeLuise, MSN, RN
Rose Williams BSMT, MSCRA, CCRP
Lisa Cocoziello, MSN, RN, APN, CNRN
Jewell Thomas, Pharm.D.
Blessy Jacob, Pharm.D

Study Sponsor
Hackensack University Medical Center
Hackensack, NJ

Table of Contents

Protocol Synopsis	
PROTOCOL NAME	**P**arkinson's Disease **I**npatient **C**linical **K**nowledge and Management
PROTOCOL NO:	PICK Study: Pro00006159
CO-PRINCIPAL INVESTIGATORS	Hooman Azmi, MD Claudia Douglas, DNP, RN, APN.C Mohammed Quadri, MD
SUB-INVESTIGATORS	Francine DeLuise, MSN, RN Rose Williams, BSMT, MSCRA, CCRP Lisa Cocoziello, MSN, RN, APN, CNRN Jewell Thomas, Pharm.D. Blessy Jacob, Pharm.D
SITE AND SPONSOR	Hackensack University Medical Center Hackensack, NJ
RESEARCH QUESTION	Does Parkinson's Disease Inpatient Clinical Knowledge and Management Program and the WatchRx System make a difference in the clinician knowledge, customized PD order time and PD medication administration time, complications (administered contraindicated medication, falls, positive delirium scores, and positive confusion), medication error and length of stay during hospitalization?
HYPOTHESIS	Ho1: Parkinson's Disease Inpatient Clinical Knowledge and Management Program will not make a difference in the clinician knowledge. Ha1: Parkinson's Disease Inpatient Clinical Knowledge and Management Program will make a difference in the clinician knowledge. Ho2: Parkinson's Disease Inpatient Clinical Knowledge and Management Program will not make a difference in the customized PD order time and PD medication administration time, complications (administered contraindicated medication, falls, positive delirium scores, and positive confusion), medication error and length of stay during hospitalization. Ha2: Parkinson's Disease Inpatient Clinical Knowledge and Management Program will make a difference in the customized PD order time and

Protocol Synopsis	
	PD medication administration time, complications (administered contraindicated medication, falls, positive delirium scores, and positive confusion), medication error and length of stay during hospitalization. Ho3: WatchRx System will not make a difference in the customized PD order time and PD medication administration time, complications (administered contraindicated medication, falls, positive delirium scores, and positive confusion), medication error and length of stay during hospitalization. Ha3: WatchRx System will make a difference in the customized PD order time and PD medication administration time, complications (administered contraindicated medication, falls, positive delirium scores, and positive confusion), medication error and length of stay during hospitalization.
STUDY DESIGN	Two Part Study Design • **Part 1:** Retrospective Phase • **Part 2:** Prospective Phase
INTERVENTION	Clinician Education Program, WatchRx system, and enrollment in PD registry.
SAMPLE SIZE	Patients - 300 in total 150 - retrospective phase 150 - prospective phase
PRIMARY OBJECTIVES	To measure the difference in knowledge of the clinicians before and after completing the Parkinson's Disease Inpatient Clinical Knowledge and Management Program.
PRIMARY ENDPOINTS	Difference in PD Knowledge assessment score before and after Parkinson's Disease Inpatient Clinical Knowledge and Management Program (Appendix I A PD Knowledge assessment score)

Protocol Synopsis	
SECONDARY OBJECTIVES	1. To measure the difference that the Parkinson's Disease Inpatient Clinical Knowledge and Management Program has on PD medication administration time, administered contraindicated medication, PD medication errors, falls, positive confusion, positive delirium scores, and length of stay for PD patients. 2. To measure the difference that the WatchRx system has on PD medication administration time, administered contraindicated medication, PD medication errors, falls, positive confusion, positive delirium scores, and length of stay for PD patients.
SECONDARY ENDPOINTS	• Difference in scheduled versus actual PD medication administration time • Number of medication errors • Number of contraindicated medications administered • Number of falls • Number of positive confusion scores • Number of positive delirium scores • Length of stay
STUDY PERIOD	**Retrospective Data Period**: January – June 2015 **Prospective Data Period:** After the clinicians have completed the Parkinson's disease Inpatient Clinical Knowledge and Management Program and the WatchRx Smartwatch is integrated in the medication administration for PD medications.
SPONSOR	Hackensack University Medical Center
STATISTICAL ANALYSIS PLAN, DATABASE, DATA ENTRY & ANALYSES	Themba Nyirenda, PhD Hackensack University Medical Center Research Biostatistician Department of Research Office: 551-996-8210 Fax: 201-457-1882 Email: TNyirenda@HackensackUMC.org

Statement of Investigator

Parkinson's Disease **I**npatient **C**linical **K**nowledge and management

An observational, quasi-experimental retrospective and prospective study.

PROTOCOL: PICK VERSION 5 – MAY 9, 2019

STATEMENT OF INVESTIGATOR(S):

The Study Site Principal Investigator's Signature signifies acceptance of the Parkinson's Disease Inpatient Clinical Knowledge and Management (PICK) Study and agrees to participate in the study in accordance with the protocol, applicable regulations including informed consent requirements, Health Insurance Portability and Accountability Act (1996) and Principal Investigator requirements stated in this protocol:

_____ _____

Hooman Azmi, MD Date
Principal Investigator

_____ _____

Claudia Douglas, DNP, RN, APN.C Date
Co-Investigator

_____ _____

Mohammed Quadri, MD Date
Co-Investigator

Hackensack University Medical Center
30 Prospect Avenue
Hackensack, NJ 07601

Study Contacts

CO-PRINCIPAL INVESTIGATORS

Hooman Azmi, MD
Chief Division of Functional and Restorative Neurosurgery Chief Division of Neurotrauma
Department of Neurosurgery Hackensack University
Office: 201-342-2550
Fax: 201-342-7171
Cell: 917-406-6914
Email: HAzmi@hackensackUMC.org

Claudia Douglas, DNP, RN, , APN.C
Director, Institute of EBP & Nursing Research
Patient Care Services
Office: 551-996-2730
Cell: 201-913-8591
Email: CDouglas@HackensackUMC.org

Mohammed Quadri, MD, MBA
Title: Director, Epidemiological Strategy
Department of Patient Care
Office: 551-996-2421
Fax: 551-996-8824
Cell: 201-310-0477
Email: mquadri@hackensackUMC.org

SUB-INVESTIGATORS

Francine DeLuise, MSN, RN
Rose Williams BSMT, MSCRA, CCRP
Lisa Cocoziello, MSN, RN, APN, CNRN
Jewell Thomas, Pharm.D
Blessy Jacob, Pharm.D

STATISTICAL ANALYSIS PLAN AND STATISTICAL ANALYSES

Themba Nyirenda, PhD
Hackensack University Medical Center
Research Biostatistician
Department of Research
Office: 551-996-8210
Fax: 201-457-1882
Email: TNyirenda@HackensackUMC.org

STUDY SPONSOR

Hackensack University Medical Center
30 Prospect Avenue
Hackensack, NJ 07601

	Definitions
Discrete data	Data with numerical value that is distinct and separate
MDR	The Multidisciplinary (MDR) is the clinical infrastructure supporting a multidisciplinary/interdisciplinary framework for clinical practice promoting a patient-centered, evidence- and value-based care within a managed care environment
Dementia Assessment Method	Standardized examination used to detect dementia (Mini-Cog)
Delirium Assessment	Standardized examination used to detect delirium (CAM).
Unstructured data	**Unstructured Data** (or **unstructured** information) refers to information that either does not have a pre-defined **data** model or is not organized in a pre-defined manner. **Unstructured** information is typically text-heavy, but may contain **data** such as dates, numbers, and facts.

Introduction and Background

Parkinson's Disease (PD), the second-most common neurodegenerative disorder after Alzheimer's disease is a progressive disorder of the central nervous system affecting movement resulting in tremor of the hands, arms, legs, jaw, face, bradykinesia, rigidity of limb, trunk/ postural instability, impaired balance and coordination (Kowal, Dall, Chakrabarti, Storm, and Jelin, 2013).

PD prevalence rate in the United States is estimated to be approximately 0.3% (Kowal et al., 2013) and is ranked the fourteenth leading cause of death (CDC, 2013). Depending on the methodology, the national prevalence data on PD is varied and insufficient (McLaughlin, Piryatinsky, Epstein-Lubow, Marino, and Friedman, 2014). PD is projected to increase by 4% to 5% in age 65 and over 85 years respectively (Weintraub, Comella, and Horn, 2008), and is associated with high economic burden exceeding $14.4 billion per year (Kowal et al. 2013). Admission to the hospital is identified as a major risk factor due to imprecise timing of medication administration, disruption of sleep pattern, dietary changes, and unfamiliarity of the hospital environment, which all contribute to exacerbation of PD symptoms (Oguh & Videnovic, 2012; Parkinson’s disease Foundation, 2015). Exacerbation of PD symptoms is also associated with higher risk for falls and falls with injury during hospitalization. A study by Chou et al., (2011) involving 51 worldwide National Parkinson Foundation Centers found 94% of centers were not confident in the care and knowledge hospital professionals provided specific to: PD medications, complex drug interactions, contraindications and precise timing of medication administration. A survey on medication administration in PD patients found 75% of hospitalized patients failed to receive their medications on time (Okun, 2010), thus compromising patient care. According to Chou et al. (2011), Martignoni et al. (2004), Michigan Parkinson Foundation

(2013) hospital co-morbidities could be improved or prevented by adjustment of PD medication and medication adherence, critical in decreasing hospital length of stay. In general, the length of stay for patient with PD is 1.45 times higher (Dorsey et al., 2005; McLaughlin et al., 2014) in comparison to non- PD patients.

PD prevalence is projected to double over the next few decades as the size of the elderly population increases. This projected growth and anticipated demographic burden has created the impetus for Hackensack University Medical Center PD Management Team to create new innovative strategies incorporating current best practices and protocols for delivering care and treatment during hospitalization in this subset of patient population.

Study Purpose and Rationale

It is documented that PD patients are more likely to experience complications during hospitalization (Chou et al., 2011; Gerlach et al., 2012). A preponderance of the evidence indicate decrease motor function increases the risk for falls and falls with injury, decline in mental capacity, the failure to detect depression, and lack of knowledge and expertise on the care of PD patients by health care professionals are all contributors leading to the exacerbation of complications during acute hospitalization (Ashslok, 2014; Gerlach, Broen, Dombury, Vermeij, & Weber 2012; Mondolo, Jahanshahi, Grania, Biasutti, Cacciatori & Benedetto,2006). The root cause of the failure to meet the specific therapeutic requirements and overall care needs of PD patients during hospital stay is related to failure of health care clinicians to implement current evidence-based Parkinson's specific disease care guidelines (Gerlach et al., 2012; Skelly et al., 2014).

The complexity of PD coupled with the absence of Parkinson specific core knowledge on the care of these patients by frontline clinicians (Gerlach et al, 2012; Thompson, 2015) has led to the status quo of prolonged length of stay (Braga, Pederzoli, Antonini, Beretta, Crespi, 2014; Ramirez et al. 2015) , deterioration of PD disease symptoms (Ahlskog, 2014; Gerlach, 2012), increased psychological and physical morbidity (Soundy, Stubbs, and Roskell, 2014) and subsequent reduction in quality of life (Duncan et. al (2014). Timely administration of PD improves morbidity, mortality and length of stay (CMS 2014).

While the goal during hospitalization is to provide, safe and effective high quality care. 74% of PD patients receive incorrect medications (Martinez-Ramirez et al, 2015 and are at increased risk for developing complications related to medication administration. According to the Institute for Safe Medication Practices [ISMP] (2015 p. 19) "patients with PD require strict adherence to an individualized timed medication regimen of anti-parkinsonian agents." Medications must be administered on time, based on the patient's unique schedule. A comprehensive search of the literature from 2009 – 2015 found few studies evaluating the impact of focused integrated inter and multidisciplinary approach to managing PD patients during hospitalization. In another survey, PD patients' perceptions is that hospital staff lacked understanding of PD, the importance of medication timeliness, and appreciation of valuable insights from patients, families and caregivers (Oguh & Videnovic, 2012).

A paradox of the U. S. healthcare system is that it leads the world in medical science and technology, yet there is limited application of technology to enhance patient-centered care in the hospital setting. In accordance with the Institute of Medicine's (2001) quality performance goals, safety, effectiveness, timeliness, patient-centeredness, efficacy and equity, this study will integrate WatchRx system, a medication reminder system. The WatchRx system includes a

smartwatch, caregiver app and online web interface which allows clinicians to customize the medication administration time and alerts the patient and the nurse when the medication to due to be administered.

This study will conduct research on establishing multidisciplinary clinical guidelines in management of PD across the acute care setting. We will further explore the impact of PD medication management on patients hospital length of stay and complications associated with mismanagement. We intend to create a PD registry for Hackensack University Medical Center, and possibly expand across the Hackensack Meridian Health Network in the future. According to the New Jersey Assembly Bill 2955, December 2014, patients and/or their designated caregiver must receive discharge instructions prior to discharge from the hospital and appropriate referrals for follow-up care. This study aligns New Jersey Bill 2955 (2014) mandating the education and preparation of designated caregiver in the discharge plan of care of hospitalized PD patients.

Research Question

Does Parkinson's Disease Inpatient Clinical Knowledge and Management Program and the WatchRx System make a difference in the clinician knowledge, customized PD order time and PD medication administration time, complications (administered contraindicated medicationfalls, positive delirium scores, and positive confusion), medication error and length of stay during hospitalization?

Hypothesis

Ho1:

Parkinson's Disease Inpatient Clinical Knowledge and Management Program will not make a difference in the clinician knowledge.

Ha1:

Parkinson's Disease Inpatient Clinical Knowledge and Management Program will make a difference in the clinician knowledge.

Parkinson's Disease Inpatient Clinical Knowledge and Management Program will not make a difference in the customized PD order time and PD medication administration time, complications (administered contraindicated medication, falls, positive delirium scores, and positive confusion), medication error and length of stay during hospitalization.

Ha2:

Parkinson's Disease Inpatient Clinical Knowledge and Management Program will make a difference in the customized PD order time and PD medication administration time, complications (administered contraindicated medication, falls, positive delirium scores, and positive confusion), medication error and length of stay during hospitalization.

Ho3:

WatchRx System will not make a difference in the customized PD order time and PD medication administration time, complications (administered contraindicated medication, falls, positive delirium scores, and positive confusion), medication error and length of stay during hospitalization.

Ha3:

WatchRx System will make a difference in the customized PD order time and PD medication administration time, complications (administered contraindicated medication, falls, positive

delirium scores, and positive confusion), medication error and length of stay during hospitalization.

Primary Objective

To measure the difference in knowledge of the clinicians before and after completing the Parkinson's Disease Inpatient Clinical Knowledge and Management Program.

Primary Endpoints

Difference in PD Knowledge assessment score before and after Parkinson's Disease Inpatient Clinical Knowledge and Management Program (Appendix A- PD Knowledge assessment score).

Secondary Objectives

1. To measure the difference that the Parkinson's Disease Inpatient Clinical Knowledge and Management Program has on PD medication administration time, administered contraindicated medication, PD medication errors, falls, positive confusion, positive delirium scores, and length of stay for PD patients.
2. To measure the difference that the WatchRx system has on PD medication administration time, administered contraindicated medication, PD medication errors, falls, positive confusion, positive delirium scores, and length of stay for PD patients.

Secondary Endpoints

- Difference in scheduled versus actual PD medication administration time
- Number of medication errors

- Number of contraindicated medications administered
- Number of falls
- Number of positive confusion scores
- Number of positive delirium scores
- Length of Stay

Inclusion Criteria

1. Adult patients diagnosed with primary and secondary diagnosis of Parkinson's disease
2. Patient 22 years old and older
3. Patients admitted to inpatient units and Center for Ambulatory Surgery
4. Alert and able to follow commands
5. Patient who agree to participate in the study

Exclusion Criteria

1. Patients less than or equal to 21 years of age

2. Patients who refuse or unable to wear the WatchRx smartwatch

3. Disoriented and unable to follow commands

4. Patients who are allergic to silicone, stainless steel and/or latex

5. Patients positive for Clostridium difficile and/or Candida auris

Study Period

Retrospective Data Period: January 2015 – June 2015

Prospective Data Period: After the clinicians have completed the Parkinson's Disease Inpatient Clinical Knowledge and Management Program and the WatchRx Smartwatch is integrated within medication administration for PD medications

Retrospective Study Period

Data collection of adult patients admitted with a primary and secondary diagnosis of Parkinson's disease during January – June 2015.

- Data will be extracted from the EPIC (current EMR system at Hackensack University Medical Center).
- Business intelligence will run the data and create reports with the specific data points mentioned above prior to providing it to the study team for further statistical analysis.

Data collected from the automatic dispensing cabinet barcoding database will verify accuracy and timeliness of medication.

Prospective Study Period

Data collection starting after completion of the Parkinson's Disease Inpatient Clinical Knowledge and Management Program for staff nurses, advanced practice nurses (APN), nursing assistants, patient care technicians, case managers, adult inpatient physician assistants, pharmacists, occupational therapists, physical therapists, nurse educators, and dietitians.

- Data will be extracted from EPIC and WatchRx records from the Watch Rx Web Interface.

Data collected from the automatic dispensing cabinet barcoding database will verify accuracy and timeliness of medication.

- Unstructured data will be collected by the principle investigator (PI), designees inclusive of study staff through focused chart review on 150 patients.
- Data will be analyzed for objectives and endpoints.

This data will compare prevalence of medication errors, complications associated with administration of contraindicated medications and timing of medications, falls and falls with

injury, positive CAM and Mini-Cog Scores, length of stay and cost per case in the study population. This phase will also assess the knowledge of the clinicians regarding the basic aspects of Parkinson's Disease inpatient management, the Parkinson's Disease Inpatient Clinical Knowledge and management program and integration of the smartwatch into the PD medication management.

- Parkinson's Disease Knowledge Assessment Survey (Appendix A)
- Parkinson's Disease Inpatient Clinical Knowledge and Management Program (Appendix B)

Study Enrollment Procedure

Patients with Parkinson's disease (PD) who meet inclusion criteria will be offered the opportunity to participate in the study. After obtaining informed consent, the patient will be enrolled in the study.

PD Medication Reconciliation:

The Principal Investigator (PI) and Transitions of Care (TC) Pharmacists (sub-investigator(s) will complete the admission medication reconciliation.

WatchRx System Enrollment:

Using Internet Explorer web browser, the Principal Investigator and the TC Pharmacist (sub investigator(s) will complete the following:

- Enter the patient's information into the WatchRx Inc. Website interface to create the patient profile and PD medication regimen
- Register the patient into WatchRx web interface via website URL by entering the PD patient's name, unit number and room number.

- Enter the patient PD medication administration schedule as ordered
- Assign the WatchRx Smartwatch to the patient
- Review the WatchRx Smartwatch functions with the patient
- Review the Aware in Care Kit with the PD patient

The primary nurse will be asked to wear the WatchRx smartwatch. After obtaining verbal consent, the Principal Investigator and TC Pharmacist will review the patient's PD medication schedule in WatchRx smartwatch with the primary nurse.

The WatchRx web interface will activate reminder alerts from the patient's WatchRx Smartwatch to the primary nurse WatchRx smartwatch. Alerts reminders will send fifteen minutes before the PD medication is due. Medication reminder alerts will continue to be sent from WatchRx smartwatch worn by the patient to the WatchRx Smartwatch worn by primary nurse at 3-minute intervals for a period of 10 minutes or until the PD medication is administered.

At each end-of-shift and/or at handoff, the WatchRx smartwatch will be cleaned using Super SaniClothTM and the nurses will document completion of the WatchRx smartwatch cleaning procedure on the WatchRx Smartwatch cleaning log and verify by signing their names (Appendix F).

Sample Size Calculation

A total of 433 patients were admitted to Hackensack University Medical Center with a diagnosis of PD in the year 2014. A convenience sample of 300 patients, 150 patients in the prospective phase and 150 patients in the retrospective phase, and approximately 346 clinicians, before and after implementing the Parkinson's Disease Inpatient Clinical Knowledge and Management education program will be enrolled in the study.

The sample of clinicians will include physician's assistant, advanced practice nurses, staff nurses, nurse educators, case managers, dietitians, pharmacists, physical therapist and occupational therapist. (Table 1)

Categories	Overall population	Sample population	Percentage (Sample size)
Staff Nurses Adult (Inpatient Units)	1931	100	5 %
Nursing Assistants	277	N/A	
Patient Care Technicians	165	N/A	
Advanced Practice Nurses (Adult Inpatient Units)	107	87	81%
Case Managers(Adult Inpatient Units)	48	48	100%
Nurse Educator Adult Inpatient	20	19	95%
Physician's Assistant Adult Inpatient	73	40	54%
Dietitians	17	17	100%
Pharmacists	119	12	11%
Physical Therapist	17	17	100%
Occupational Therapists	6	6	100%

Table 1

Data Analysis

The summary of the demographic characteristics will be presented. Continuous variables will be summarized using mean (SD) or median (interquartile range) depending on whether or not the data follow the normal distribution. Categorical variables will be summarized by frequency (percentage). Comparison of continuous variables between any independent groups will be examined using two-sided t-test or two-sided Wilcoxon rank sum test, analysis of variance (ANOVA) or Kruskal-Wallis test followed by pairwise tests, as appropriate. Categorical variables will be examined using Fisher's exact test or Pearson's Chi-square test, as appropriate.

Measurements

The following will be documented on a case report form:, demographics (age, sex, and race), comorbidities and complications, date of discharge, length of stay, and number of medication discrepancies.

- Subject ID (coded de-identified patient identifier)
- Demographics (age race, gender)
- Primary Diagnosis
- Comorbidities
- Medication list at admission (Admission Medication Reconciliation)
    - Number of medications at admission
- Prescribed Medication List (Medication Administration Record)
    - Number of medications during hospitalization
- Medication list at discharge (Discharge Medication Reconciliation)
- Complications associated with medication administration
- Medication Administration Schedule
    - Order Time
    - Patient Falls
    - Number of falls
    - Time of patient falls
    - Injury
- Length of Stay

Data Management

All data in this study will be obtained from multiple sources: EPIC Hyperspace for medical record number. A database in Microsoft Office Excel (Microsoft Corporation, Redmond, WA,

USA) will be created based on a case report form. Data from the WatchRx smartwatch and the WatchRx app will be stored in real time within a secure database. All study data will be imported into SAS software where data management programming will be utilized to flag and generate queries on out of range data issues until they are resolved. All analysis will be performed using SAS version 9.4 (SAS Institute Inc. Cary, NC, USA).

Discomforts and Risks

This study involves no more than minimal risks No medical intervention is included as part of this study. All patients will be provided and treated as per physician order.

Benefits

This study will improve timely administration of medications to PD patients. Patients enrolled in the study will have direct monitoring of their medication compliance and adherence. This study will improve knowledge of Parkinson's disease amongst clinicians and better medication management of PD patients.

Limitations

Limitation 1: Single site

Limitation 2: Convenience sample

Confidentiality

Data will be handled in a confidential manner to meet mandated IT Security standards and to prevent loss of privacy.

All electronic files will be stored in an encrypted and password-protected database on a secure medical center server. Only co-investigators, advanced practice nurses and the data coordinator who contact the subjects will have access to information linked to subject identifiers.

- Each eligible patient will be assigned a study specific identification number (ID#) to separate patient information from their specific study data and responses. Any research data extracted from participants' medical records will be recorded in a study specific electronic spreadsheet and coded with participants' ID#'s. The electronic spreadsheet will be kept on a password protected computer.
- The key linking ID numbers to patients' identifier will be kept on a password-protected computer.
- Publication resulting from this research will not contain any information that could potentially identify participants either directly or indirectly.

References

Ashslok,J.R. (2014). Parkinson disease treatment in hospitals and nursing facilities: Avoiding pitfalls. *Mayo Clinic Proceedings, 89*(7), 997-1003. doi:10.1016/j.mayocp.2014.02.018

Braga, M., Pederzoli, M., Antonini, A., Beretta, F., and Crespi, V. (2014). Reasons for hospitalization in PD: A case-control study. *Parkinsonism & Relate Disorders*, 20(5), 488-492. doi:10.1016/j.parkreldis.2014.01.022

Brown MT, Bussell JK. Medication Adherence: WHO Cares? Mayo Clinic Proceedings. 2011;86(4):304-314.

Centers for Disease Control. National Vital Statistics Reports: Deaths: Final Data for 2010. May 2013. Retrieved from: http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_04.pdf

Centers for Medicare and Medicaid. (2011). Interpretative Guidelines for Hospitals 42

CFR 482.23C

https://www.cms.gov/RegulationsandGuidance/Guidance/Transmittals/downloads/R77SOMA.pdf

Chou, K.l., Zamudio, J., Schmidt, P., Price, CC., Oarashos, SA., Bloem, Okun, M.S. (2011). Hospitalization in parkinson disease: A survey of national parkinson foundation centers. *Parkinsonism & Related Disorder*, 17(6), 440-445. doi:10.1016/j.parkreldis.2011.03.002

Dayer, Lindsey, et al. "Smartphone medication adherence apps: Potential benefits to patients and providers: Response to Aungst." *Journal of the American Pharmacists Association*, vol. 53, no. 4, 2013, p. 345., doi:10.1331/japha.2013.13121.

Dorsey, E.R., Constantinescu, R., Thompson, J.P., Biglan, K.M., Holloway, R.G., Kieburtz. K., Marshall, F.J., Ravina, B.M., Schifitto, G., Sideowf, A., & Tanner, C.M. (2007). Projected number of people with parkinson disease in the most populous nations *Neurology*, 68(5), 384-386.

Duncan, GW.,Khoo, TK., Yarnall, AJ. O'Brien, JT., Coleman, SY., Brooks, RA., & Burn, DJ. (2014). Health-related quality of life in early PD: The impact of nonmotor symptoms. *Movement Disorder*, 29(2) 195-202. DOI: 10.1002/mds.25664

Gerlach, O H.H., Winogrodzka, A., Weber, W. E. J. (2011). Clinical Problems in Hospitalized Parkinson's Disease Patients: Systematic Review. *Movement Disorders 26(2)*. 197 -208. Retrieved from:

Gerlach, O., Broen, M., van Dombury, P., Vermeij, Ad., & Weber, W. (2012). Deterioration of parkinson'lyPDs disease during hospitalization:Survey of 684 patients. *BioMed Central Neurology* 12(3). doi: 10.1186/1471-2377-12-13

Institute for Safe Medication Practices [ISMP].(2015 Mar12). Delayed administration and contraindicated drugs place hospitalized PD patients at risk. *ISMP Acute Care Newsletter.*

Kowal, S.L, Dall, T.M., Chakrabarti. R., Storm, M.V., and Jain, A. (2013). The current and projected economic burden of Parkinson's disease in the United States. *Mov Disord., 28*(3), 311-8. doi: 10.1002/mds.25292.

Martignoni, E., Godi, L., Citterio, A., Zangaglia, R., Riboldazzi, G., Calandrella, D., Pacchetti, C., Nappi, G. and the Parkinson's Disease Comorbidity Study Group. (2004). Comorbid

disorders and hospitalization in parkinson's disease: A prospective study. *Neurological Sciences*, 25(2), 66-71. Doi: 10.1007/s10072-004-0232-5

Martinez-Ramirez, D., JGiugni, J. C., Little, C. S., Chapman, J. O., Ahmed, B. Monari., Okun, M. S. , E. (2015) Missing Dosages and Neuroleptic Usage May Prolong Length of Stay in Hospitalized Parkinson's Disease Patients. *PLOS One.*10(4) 1- 12. doi:10.1371/journal.pone.0124356.

McLaughlin, N., Piryatinsky, I., Epstein-Lubow, G., Marino, L., & Friedman, J. (2014). Neuropsychiatric Symptoms in an Inpatient Parkinson's Disease Sample. Hindawi Publishing Corporation Parkinson's Disease. Retrieved from http://dx.doi/10.1155/2014/420240.

Michigan Parkinson Foundation. (2013). Diet and Parkinson's Disease. Medication Administration in the Management of Parkinson's Disease. 1- 5. Retrieved from https://www.parkinsonsmi.org/parkinsons-facts/managing-pd

Mondolo, F., Jahanshahi, M.,Grania, A.,Biasutti, E.,Cacciatori E., & Benedetto, (2006). The validity of the anxiety and depression scale and the geriatric depression scale in PD. Behavioral Neurology, 17, 109-115

New Jersey Assembly Bill 2955, December 2014

Oguh, O., & Videnovi,, A., (2012). Inpatient management of PD. *Neurohospitalist*, 2(1), 28-35.

Okun, M. S. (2010). Poor Medication Management of Parkinson's Disease DuringHospital Admissions: Patients

http://www.parkinson.org/Patients/Patients---On-The-Blog/July-2010/Poor-Medication-Management-of-Parkinson-s-Disease-

Parkinson's Disease Foundation (2015). Going to the hospital with Parkinson's: How to Be prepared. Retrieved from: http://www.pdf.org/fall12_going_hospital

Prizer, L. P., & Browner, N. (2012). The integrative care of PD: A systematic review. Journal of Parkinson's Disease, 2(2) 79-86.doi: 10.3233/JPD-2012-12075

http://www.researchgate.net/publication/49801019_Clinical_Problems_in_the_Hospitalized_Parkinson's_Disease_Patient_Systematic_Review

Skelly, R., Brown, L., Fakis, A., Kimber, L., Downes, C., Lindop, F., Johnson, C., Bartliff, C., & Bajaj, N.(2014). Does a specialist unit improve outcomes for hospitalized patients with PD?, 20, 1242-1247.

Soundy, A., Stubbs, B., & Roskell, C.(2014). The experience of PD: A systematic review and meta-ethnography. The Scientific World Journal, ID 613592, 1-19.

Thompson, T. (2015). Parkinson's Action Network Applauds Advancing Research for Neurological Diseases Act of 2015 Parkinson's Action Network. Retrieved from: http://parkinsonsaction.org/pan-applauds-advancing-research-for-neurological-diseases-act-of-2015/

Weintraub, D., Comella, C. & Horn, S. (2008). PD Part I: Pathophysiology, symptoms,burden, diagnosis, and assessment. AmJ Manag Care, 14 (2) 40-48

Appendix A – PD Knowledge Assessment Survey

HackensackUMC
Where medicine meets innovation

The PICK Study

Parkinson's Disease **I**npatient **C**linical **K**nowledge and Management

Role:
□ APN □ Physician Ad
□ Staff Nurse □ Case Manage
□ Physician □ Pharmacist
□ PA □ Other, specify
_____

Parkinson's Disease Knowledge Assessment

01.
- Please select the correct answer.

In most cases PD is caused by:
☐ a. There is no known cause
☐ b. Smoking
☐ c. Genetics
☐ b. Environmental toxins

02. Which is not a cardinal sign in the motor aspect of PD?
☐ a. Slowness of movement
☐ b. Tremor
☐ c. Rigidity of muscles
☐ d. Muscle weakness

03. Select the incorrect statement.
PD is found:
☐ a. In all ages
☐ b. In all races
☐ c. In both genders
☐ d. In males only

04. Please select the correct answer.
Which neurotransmitter is depleted in patients with PD?
☐ a. Serotonin
☐ b. Acetylcholine
☐ c. Dopamine
☐ d. Norepinephrine

05. Which of the following brand name drugs contain levodopa, the precursor to dopamine?
☐ a. Comtan
☐ b. Sinemet
☐ c. Symmetrel

06. What type of food can interact with the adsorption of PD medication?
☐ a. Fats
☐ b. Carbohydrates
☐ c. Protein
☐ d. Sugars

07. Select the drug which is contraindicated in PD patients:
☐ a. Quetiapine (Seroquel)
☐ b. Haloperidol (Haldol)
☐ c. Trimethobenzamide (Tigan)
☐ d. Ibuprofen (Motrin)

08. Select the correct answer.
Tremor in PD is most commonly seen in patients:
☐ a. On action
☐ b. On posture
☐ c. At rest
☐ d. When asleep

09. Please select all the correct answers which can apply to PD patients:
☐ a. Anxiety
☐ b. Constipation
☐ c. Sexual dysfunction
☐ d. Postural hypotension

10. Select the incorrect answer.
Nursing care of a patient with PD includes:
☐ a. Ensuring contraindicated medications are avoided
☐ b. Sitting patient upright for meals

☐ d. Requip

☐ c. Restraints for patients with severe tremors
☐ d. Ensuring medications are given on time

Parkinson's Disease Knowledge Assessment

11. Please select the term which does not apply.
PD is a disease which is:
☐ a. Degenerative
☐ b. Reversible
☐ c. Progressive
☐ d. Made worse by stress

12. Select the correct answer (s).
Dyskinesia describes involuntary chorea-like movements of the head, shoulders, trunk or limbs. In PD it:
☐ a. is a side effect of medication
☐ b. is a symptom of the condition
☐ c. requires patient restraint
☐ d. it is a precursor to seizures

13. Bradyphrenia refers to:
☐ a. Hallucinations in PD
☐ b. Depression in PD
☐ c. Slowness in thinking in PD
☐ d. Psychosis in PD

14. Patients with PD can tolerate missing their medications:
☐ a. up to 30 minutes
☐ b. One hour or more
☐ c. No more than fifteen minutes
☐ d. can take two doses on the next schedule

15. Select the incorrect statement.
☐ a. The presence of tremor is necessary for the diagnosis of PD
☐ b. PD can affect any age ☐ c. PD can be hereditary
☐ d. PD medications slow down the disease progression

16. Select the drug which is contraindicated in PD patients:
☐ a. Metoclopramide (Reglan)
☐ b. Acetaminophen
☐ c. Ondansetron (Zofran)
☐ d. Oxycodone

17. Select the incorrect answer
☐ a. PD is a form of dementia
☐ b. Cognitive slowing can be a side effect of PD meds
☐ c. Vivid dreams can occur for patients with PD
☐ d. Response to PD meds can be affected by type of food

18. Delay in PD medication administration can lead to all the following except:
☐ a. falls
☐ b. confusion
☐ c. seizures
☐ d. dysphagia

19. Please select the correct answer(s)
☐ a. All PD patients have dementia
☐ b. PD patients may have both motor and non-motor symptoms
☐ c. Strict adherence to medication timing is not crucial for PD patients
☐ d. PD can be diagnosed by a blood test

20. Please select which medication is safe in PD
☐ a. Meperidine (Demerol) put an R sign for registered trademark
☐ b. Prochlorperazine (Compazine)
☐ c. Clonazepam (Klonopin)
☐ d. Promethazine (Phenergan)

Appendix B – PD Inpatient Clinical Knowledge and Management Study (PICK)

Education Plan Overview

Prior to launch of the educational plan, there will be Nursing Grand Rounds. The curriculum will also be introduced to case managers, pharmacists, physical and occupational therapists and dieticians. Clinical Level III and IV registered nurses on each unit will be designated with the responsibility of steering the education on the unit. They will be directly supported by Nurse Educators and the Department of Neurosurgery clinicians.

The educational plan will be rolled out by direct testing, education and retesting to each nursing unit with distribution via print material and electronic material. Contact hours will be awarded for those completing the pre-test, webinar and post-test.

Step 1: Administration of a Parkinson's disease knowledge base assessment test to the target audience via HOLA.

Step 2: Introduction of the PD webinar through HOLA. During this step, there will also be posters and other educational material available to the units.

Step 3: Re-administer the Parkinson's disease knowledge base assessment test to determine retention.

Knowledge Assessment Methodology

1. Administer Parkinson's Disease (PD) Pre-test to target audience via HOLA (HackensackUMC Online Learning Academy) Learning Management System. Time frame for completion: 4 weeks.
2. Administer PD Webinar to target audience via HOLA followed by Post-test. Time frame for completion: 4 weeks.

3. Administer a follow-up Post-test to target audience via HOLA 4 months after completion of PD webinar. (Time Frame for completion: 4 weeks)
4. Award contact hours to those completing the pre-test, webinar and post-test.
5. Develop educational poster on PD to display on all in-patient nursing units.
6. Coordinate Nursing Grand Rounds on Parkinson's Disease to include contact hours.
7. Additional Educational Resources:
    a. PD Nurse Champions
    b. Unit Based Council Chairs
    c. PD Best Practice Alert - EPIC

Objectives:

After participating in educational offerings, the (HackensackUMC employed) target audience will be able to:

1. Describe the pathophysiology of Parkinson's Disease (PD).
2. Discuss the signs and symptoms of PD.
3. Identify the treatment options and medications used to manage patients with PD.
4. Explain the medication contraindications for patients with PD.
5. Explain the importance of administration of PD medications "On Time Every Time."
6. Recognize the complications of not giving PD medications on time

Target Audience:

1. Advanced Practice Nurses
2. Physician's Assistant (PA)
3. In-patient registered nurses practicing on:
    a. Medical/Surgical units

   b. Critical Care units/PACU
   c. Emergency & Trauma Center
   d. Surgical Admission Suite (SAS)
   e. Center for Ambulatory Surgery (CAS).
4. Case Managers
5. Pharmacists
6. Dietitians
7. Physical Therapist
8. Occupational Therapist

Appendix C – Aware in Care Kit

A kit containing useful tools and information for helping PD patients during their hospital visits. Includes the following:

- Parkinson's Disease ID Wrist Bracelet
- Medical Alert Card
- Medication Form
- PD Fact Sheet

PD ID Wrist Bracelet

Designation to be worn at all times in the event of emergency situations and for hospital tracking purposes.

Medical Alert Card

Includes emergency information.

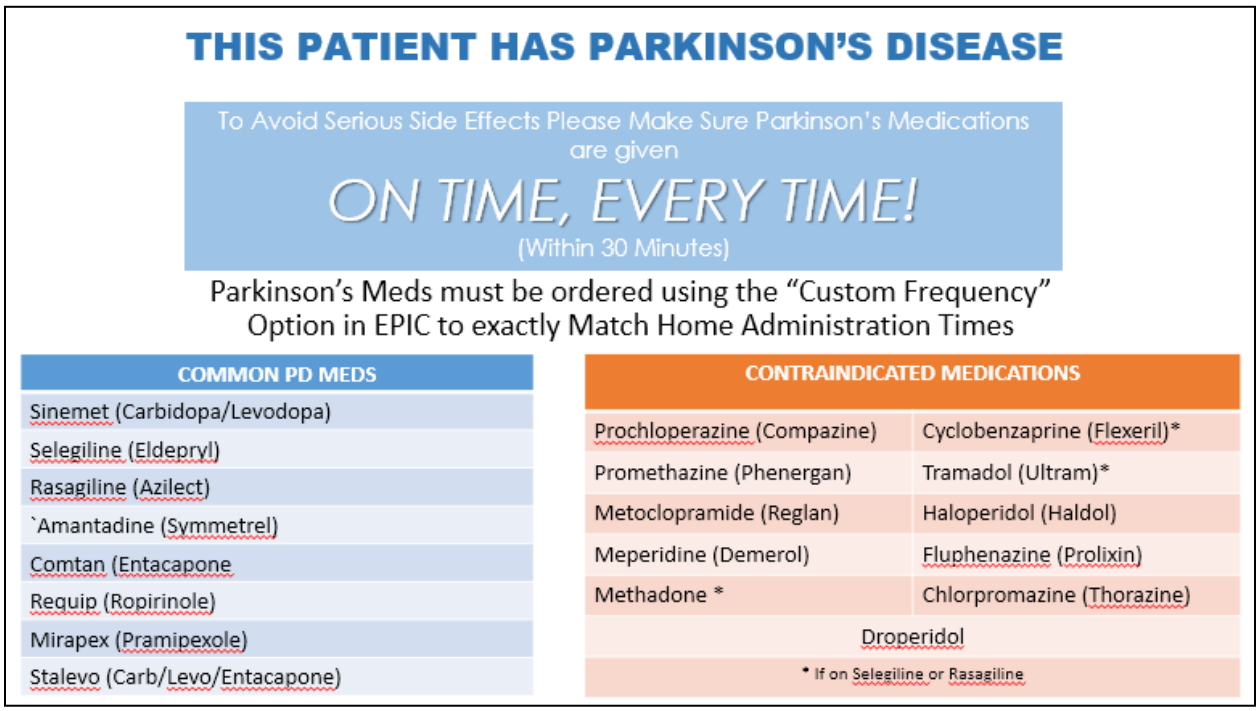
Medication Form

Includes information regarding prescriptions, existing medication regimen and scheduling, and other patient information.

PD Fact sheet

Information to be shared with hospital staff and included in patient chart.

Appendix E – Educational Information on PD Medication



THIS PATIENT HAS PARKINSON'S DISEASE

To Avoid Serious Side Effects Please Make Sure Parkinson's Medications are given

ON TIME, EVERY TIME!

(Within 30 Minutes)

Parkinson's Meds must be ordered using the "Custom Frequency" Option in EPIC to exactly Match Home Administration Times

COMMON PD MEDS
Sinemet (Carbidopa/Levodopa)
Selegiline (Eldepryl)
Rasagiline (Azilect)
`Amantadine (Symmetrel)
Comtan (Entacapone
Requip (Ropirinole)
Mirapex (Pramipexole)
Stalevo (Carb/Levo/Entacapone)

CONTRAINDICATED MEDICATIONS	
Prochloperazine (Compazine)	Cyclobenzaprine (Flexeril)*
Promethazine (Phenergan)	Tramadol (Ultram)*
Metoclopramide (Reglan)	Haloperidol (Haldol)
Meperidine (Demerol)	Fluphenazine (Prolixin)
Methadone *	Chlorpromazine (Thorazine)
Droperidol	
* If on Selegiline or Rasagiline	

Appendix F – PICK Data Collection Tool

DIET_ORDERED	COST_PER_CASE	DIET_ORDERED	PICK_WRIST_BAND_ADMIN_YES_NO	PICK_WRIST_BAND_ADMIN_TIME	PICK_AWARE_CARE_KIT_ADMIN_YES_NO	PICK_AWARE_CARE_KIT_ADMIN_TIME	PICK_REGISTRY_ENROLLED

Appendix F – PICK WatchRx Smartwatch Nurse Cleaning Log

Hackensack Meridian *Health*
Hackensack University Medical Center

Parkinson's Disease Inpatient Clinical Knowledge and Management
P.I.C.K. WatchRx Smartwatch Nurse Cleaning Log
Appendix F

Date (MM/DD/YYYY)	Watch cleaned with SuperSani Cloth	Unit	End of Shift/Handoff (Time)	Signature
	☐ Yes ☐ No		RN Day Shift ____________ PRINT NAME RN Night Shift ____________ PRINT NAME	
	☐ Yes ☐ No		RN Day Shift ____________ PRINT NAME RN Night Shift ____________ PRINT NAME	
	☐ Yes ☐ No		RN Day Shift ____________ PRINT NAME RN Night Shift ____________ PRINT NAME	
	☐ Yes ☐ No		RN Day Shift ____________ PRINT NAME RN Night Shift ____________ PRINT NAME	
	☐ Yes ☐ No		RN Day Shift ____________ PRINT NAME RN Night Shift ____________ PRINT NAME	
	☐ Yes ☐ No		RN Day Shift ____________ PRINT NAME RN Night Shift ____________ PRINT NAME	
	☐ Yes ☐ No		RN Day Shift ____________ PRINT NAME RN Night Shift ____________ PRINT NAME	
	☐ Yes ☐ No		RN Day Shift ____________ PRINT NAME RN Night Shift ____________ PRINT NAME	

Page 1__ of _1

Original 5/919