

ADHERENCE OF PATIENTS TO ORAL ONCOLYTIC AND NEUROLOGIC SPECIALTY MEDICATIONS PROVIDED BY A SPECIALTY PHARMACY

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BACKGROUND

Specialty medications (SP-D) are high cost prescription drugs designed for the treatment of complex chronic conditions, e.g., oncologic and neurological diseases. Such medications require special handling, shipping, administration, and patient support services. To achieve desired treatment outcomes and minimize adverse events, medication adherence is key. Barriers to medication adherence include high out of pocket costs, poor understanding of disease and associated therapy, psychological and psychosocial issues, forgetfulness, complex dosing regimens and side effects.¹ Consequences of nonadherence include increased healthcare resource consumption and poor treatment outcomes, e.g., increased relapse, decreased survival time and/or lack of patient satisfaction.¹ Specialty pharmacy medication therapy management programs

(SPMTM) are designed to track patient progress, reduce barriers to adherence, and improve treatment outcomes.^{2,3,4}

The specialty pharmacy in this study is a community pharmacy focused on dispensing and clinical support services related to SP-D. The pharmacy has permits in fifty states as well as in Washington D.C., Puerto Rico and the U.S. Virgin Islands. The organization maintains dual specialty pharmacy accreditation by leading healthcare accrediting bodies URAC and ACHC. Therapeutic expertise at this pharmacy includes: oncology, neurology, and autoimmune disorders, analgesia (noncontrolled drugs), investigational drugs, and other SP-D used to treat rare/ultra-rare conditions.

OBJECTIVES

The primary objective of the study was to measure the adherence rate to the oncology and neurology SP-D dispensed by the specialty pharmacy. The secondary objective of this study was to compare the quality of life (QOL) of patients who voluntarily participated in the SPMTM program at the program's Start of Care (SOC) Assessment (before the SP-D had been started) and at the Follow-up (F-U) Assessment (after SP-D had been started).

RESULTS

The total number of unique patients was 39,567 and average number of dispenses per unique patient was 2. The number of unique patients who voluntarily participated in the SPMTM program who received clinical assessments was 33,243 (84%). 6,331 (16%) patients declined to participate in the SPMTM program. The number of patients who completed only the SOC assessment were 19,946 (60%); the number of patients who participated in only F-U assessment were 3,324 (10%); and the number of patients who participated in both assessments were 4,322 (13%).

The overall mean annual Proportion of Days Covered (PDC) was 0.962 or 96.2%. Medication adherence rate is 20.25% higher as compared to the industry standard adherence rate of approximately 0.8 (80%).

The mean Days of Work/School Missed QOL metric at SOC was 0.16 days and was 0.02 days after F-U assessment. The annualized mean difference in work/school days missed demonstrated an improvement between before and after receiving SP-D and SPMTM was 0.14 days. The calculated Mann-Whitney U-value (M-WU) was determined to be 4 which had a calculated p = 0.0001 and the M-WU value at the p<0.05 level was 37.

The How Have You Been Feeling QOL metric annualized mean at SOC assessment was 7 and the annualized mean at refill assessment was 7.46. The total improvement in feeling is 0.46 higher on the 10-point scale. Therefore, patients reported improvement in how they felt after taking SP-D and participating in the SPMTM program. The calculated M-WU value is 4 and calculated p = 0.0001. The critical value of M-WU at p<0.05 is 37.

CONCLUSION

From this one-year study it was determined that: (1) the annualized PDC adherence rate of 0.96 was 20.25% higher than the industry standard of 0.8 (2) on average the Number of Days Work Missed QOL was less after starting on a SP-D with SPMTM and (3) How Patients Feel QOL metric demonstrated that on average patients felt better after starting SP-D with SPMTM.

The improved adherence rate was associated with taking the SP-D while participating in the SPMTM. The encouraging findings of this study suggest that additional larger studies should be conducted.

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METHODOLOGY

A retrospective, observational study of patient reported outcomes (PRO) conducted at specialty pharmacy among patients diagnosed with various forms of cancers and neurological issues who had prescriptions filled for SP-D from 01/01/2018 to 12/31/2018. Patient education by the pharmacist was offered as part of the SPMTM program throughout patient participation in the program. Each patient was offered medication therapy assessment at SOC and seven days prior to each refill dispense, using a proprietary clinical assessment instrument designed to capture patient reported data via telephonic interview with patients or their caregivers. Embedded in the assessment instruments were two QOL PRO metrics: (1) Number of Days Work/School Missed and (2) How Have You Been Feeling (1 to 10 scale where 1 was feeling terrible and 10 was feeling wonderful). The means of the SOC (BEFORE SP drug start) and the F-U (AFTER SP drug start) data were captured monthly and annualized. The annualized means were compared, using the Mann-Whitney U-value (M-WU) two-tailed statistic to test for a statistically significance difference in between the annualized means of the respective QOL measures at the p<0.05 level of significance. In addition, the means of the Proportion of Days Covered (PDC) were calculated by month and for the year².

AUTHORS' STATEMENTS

Statement of Inclusion:

All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the manuscript. Furthermore, each author certifies that this material or similar material has not been and will not be submitted to or published in any other publication.

No Conflict of Interest:

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Differences Between Means of Monthly Data for Quality of Life Metric (Mean Number of Days Work/School Missed)

Months	Average days missed at SOC assessment	Average days missed at refill assessment	Average days missed improvement
Jan	0.07	0.031	0.04
Feb	0.15	0.034	0.12
March	0.13	0.032	0.1
Apr	0.1	0.006	0.09
May	0.27	0.027	0.25
Jun	0.2	0.016	0.19
Jul	0.15	0.03	0.12
Aug	0.12	0.044	0.08
Sep	0.34	0.033	0.31
Oct	0.31	0.026	0.29
Nov	0.13	0.006	0.13
Dec	0.25	0.188	0.06
Annualized Mean	0.16	0.02	0.14

Mann-Whitney U Value (Level of Significance) / Difference Between Annualized Means Calc. M-WU = 4 (P=0.0001)

Differences Between Means of Monthly and Annualized Data 2018 for QOL Metric "How Are You Feeling?" on 1-10 Scale

Months	Average days of currently feeling at SOC assessment	Average days of currently feeling at refill assessment	Average feeling improvement
Jan	7.33	7.383	0.05
Feb	7.09	7.83	0.74
March	6.94	7.851	0.91
Apr	6.96	7.104	0.15
May	7.06	7.756	0.7
Jun	6.71	7.777	1.07
Jul	6.75	7.868	1.12
Aug	7.18	7.754	0.57
Sep	6.58	7.795	1.21
Oct	6.86	7.831	0.97
Nov	6.72	7.745	1.03
Dec	7.26	7.325	0.06
Grand Total	7	7.468	0.46

Mann-Whitney U Value (Level of Significance) / Difference Between Annualized Means Calc. M-WU = 4 (P=0.0001)

PDC (Proportion of Days Covered) for Medication Adherence

Month	Average PDC
Jan	1.000
Feb	0.998
Mar	0.973
Apr	0.951
May	0.957
June	0.951
July	0.95
Aug	0.962
Sep	0.945
Oct	0.955
Nov	0.945
Dec	0.942
Annualized Mean	0.962 (20.25% higher than industry mean of 0.8)