The effectiveness of alternative drug administration regimens for Kentucky inmates with type II diabetes

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Capstone Project

Rebecca Pettinato
PharmD/MPA candidate
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I. Executive Summary

Background: Adherence to antidiabetic medication therapy is essential for adequate glycemic control in patients with type 2 diabetes mellitus (T2DM). In a previous study, it was found that adherence to oral antidiabetic medication was lower among inmates than non-inmates. Additionally, nonadherence contributes to worsening of disease, death, and increased health care costs.

Purpose: To determine if medication administration method affects adherence among inmates with T2DM and if other factors (i.e. age or race) contributed to adherence.

Method: The study design was a retrospective descriptive study design with data collection from medication administration records of the total population of male Kentucky inmates administered the oral antidiabetic medication metformin through direct observation therapy (DOT) or self-administered medications (SAMs). Adherence rates for DOT and SAMs metformin administration were calculated using the medication possession ratio (MPR). Descriptive statistics included comparisons between DOT and SAMs. The Chi-squared test for categorical data was employed. Logistic regression analysis determined the association between adherence and the DOT and SAMs groups, controlling for age.

Results: Of the 276 male Kentucky inmates eligible for the study, 215 (77.9%) received medication by self-administration and 61 (22.1%) received medication by direct observation. Inmates were considered adherent to their medication if the medication possession ratio was >80%. The SAMs group contained 37.2% inmates who fell below an MPR of 80%, while the DOT group contained a much lower percentage of nonadherent inmates (13.1%). In the DOT group, 86.9% of inmates were adherent, while fewer inmates (62.8%) in the SAMs

group achieved an MPR greater than 80%. From univariate logistic regression analysis, the DOT group was nearly four times as likely to be adherent to their medication as shown by the odds ratio (OR) of 3.93 [1.78, 8.68]. If the inmate was in the 60-69 years age group they were 12 times as likely to adhere to medications (OR=12.57 [1.00, 157.73]). Age-adjusted OR from multivariate logistic regression analysis was 4.90 [2.10, 11.4] showing that there might be some confounding by age when compared with univariate OR.

Conclusions and recommendations: This research showed that inmates with T2DM who receive medications by DOT are more adherent than those who receive medications by SAMs. It also shows that the 60-69 years and 70+ years age group are more adherent than the 18-29 years group and the 30-59 years group. Health policy would recommend that a counseling program be implemented for all inmates with T2DM, a more intensive screening process be conducted for potential SAMs candidates, an age of ≥60 years be required for the SAMs program, and a strong social support group be maintained by the medical staff.

II. Introduction

According to the National Institutes of Health (NIH), in 2008 there were approximately 23.6 million people in the United States with type 2 diabetes mellitus (T2DM).[1] It was also estimated that total costs attributed to T2DM were $174 billion annually.[1] In 2009, diabetes was listed as the sixth most prevalent cause of death in the United States.[2] T2DM is the most common form of diabetes and results from either difficulty in the way the body uses or produces insulin.[3,4] Insulin is necessary for glucose (blood sugar) utilization which is used for energy in the body.[3,4] If not appropriately controlled, glucose will accumulate in the blood and result in microvascular and macrovascular complications, such as: coronary artery disease, peripheral artery disease, stroke, nephropathy, neuropathy, and retinopathy.[5] Glycemic (blood sugar) control is achieved through: diet, weight loss, exercise, and medication therapy.

Adherence to antidiabetic medication therapy is essential for adequate glycemic control. However, a discrepancy or "treatment gap" exists between recommended practice and the quality of care patients actually receive.[6] Adherence is major contributing factor to this discrepancy as half of patients with chronic conditions do not receive optimal benefits from their medication regimen due to non-adherence.[7,8] Adherence to prescribed medication regimens is essential for favorable treatment outcomes and there will be negative health and economic implications for those who are nonadherent.[9] Specifically, adherence to antidiabetic regimens is crucial for metabolic control as nonadherence is correlated with higher glycosylated hemoglobin (HbA_{1c}) levels, which is a marker of long-term glycemic control, and higher rates of hospitalization.[10, 11] It has been noted that the

primary factors affecting poor drug adherence include: regimen complexity, side effects, cost, and the attitudes and beliefs of the patient and their clinician.[12]

Medication adherence among inmates

Inmates in correctional facilities have high rates of chronic conditions, including T2DM. In 2004, 42.8% of inmates in state prisons had at least one chronic health condition.[13] It was shown that the prevalence of type 2 diabetes mellitus among inmates was comparable to that of the non-incarcerated population; however, after adjustments for age, the rates of T2DM appeared to be higher for inmates.[13] It has been found that inmates are less adherent to oral antidiabetic medication monotherapy than the general population.[14]

Kentucky Department of Corrections and medication administration

The Kentucky Department of Corrections (DOC) Division of Medical Services provides comprehensive medical care to inmates. They offer disease monitoring clinics for those with current conditions, such as diabetes, and meet the pharmaceutical needs of inmates.[15] To improve health care management services, the Kentucky Corrections Health Services Network (KCHSN) was created in 2003 through a partnership with the University of Kentucky and Correct Care - Integrated Health, Inc. This collaboration has been a cost effective means to provide improved health care to inmates. The quality of inmate care was furthered with the implementation of the electronic health and medication record by KCHSN in 2006.

Inmates receive medications through one of two administration methods known as direct observation therapy (DOT) or self administered medications (SAMs). Inmates receiving DOT, must attend a “Pill Call” where they obtain medication from a registered nurse, licensed practical nurse, or certified medical technician and are observed by a

corrections officer while taking their medication. Documentation completed on the medication administration record (MAR) indicates whether the inmate did not attend pill call, took the medication, or did not take the medication.

Inmates who receive SAMs have the opportunity to possess and self-administer their medications each day without returning to "Pill Call". To receive medications by SAMs, inmates must meet predetermined specifications and have some knowledge of medication administration, such as when to take the medication, any additional instructions (e.g., take with food), and importance of compliance. To be assigned to SAMs, inmates must comply with the rules and regulations of the SAMs program, have the ability to comprehend the rules of the SAMs program, and have a secure location with locking ability within living area to store medication. Certain medications, such as controlled medications, injectable medications, and psychoactive medications cannot be obtained by SAMs administration. Inmates qualified for SAMs are chosen by the medical staff with the consent of the warden. Those receiving SAMs obtain a 30-day supply of medication in a 30-day blister pack. A blister pack is a disposable form of packaging that allows for unit-dosing of medication (amount of medication a patient should receive in one dose) so ideally each dose will remain sealed within the package until the day it should be taken. Thus, a 30-day blister pack would contain the amount of medication each patient is to receive in a 30 day period. Refills are obtained by the inmate returning to Pill Call within seven days of when medication needs to be refilled to notify staff and retrieve refill when last dose of medication has been taken. However, if the inmate does not return within seven days, the prescription will remain active in the system until the inmate requests a refill or until the prescription expires. The date an inmate obtains a refill and the number of tablets received is documented in the inmates' MAR for that month.

Previously, KCHSN conducted a broad focus study with a small sample of inmates to assess the adherence of inmates receiving DOT therapy versus SAMs therapy. No statistically significant difference in adherence rates for DOT and SAMs were found; however, the sample size was small, decreasing the power to detect a difference between administration methods. The study also used all medications in the comparison, rather than a single medication, as in the present study. The aim of this research was to determine if medication administration method affects adherence among inmates with T2DM and if other factors (i.e. age or race) contributed to adherence, since nonadherence can result in worsening of disease, death, and increased health care costs.[16]

III. Methods

The study design was a retrospective descriptive study design with data collection from medication administration records of the total population of male Kentucky state inmates administered the oral antidiabetic medication metformin through DOT or SAMs.

Study Population

The study compared adherence rates of inmates with T2DM receiving medication through the DOT system or the SAMs system. The study population was Kentucky inmates with T2DM receiving treatment with the oral antidiabetic medication metformin, who were male and 18 years of age or older. The total state inmate population includes the full age range from 18 to 92 years. Subjects were included in the study if they had three consecutive months of medication administration records (each medication administration record covers a one month period of time) that have been scanned for electronic storage in a secure data repository with the Department of Corrections (DOC). Information for the study was extracted from the stored, electronically scanned MAR sheet. All patients were

eligible for inclusion without regard to ethnic background. The study period was from February 1, 2009 to January 31, 2010.

Subjects were excluded from the study if they were:

a) Female subjects to avoid risk identification of subjects in this small population as there is only one female prison in the state.

b) Subjects without three consecutive MARs.

c) Subjects switching from DOT to SAMs during study period.

d) Subjects with a change in frequency of medication administration during the study period.

Instead of taking a randomly selected sample of this population, the total population of inmates currently receiving the oral antidiabetic medication, metformin, was included to obtain a sufficiently large sample. After excluding female inmates, male inmates without three consecutive MARs, male inmates who were switched from DOT to SAMs during the study period, and male inmates with a change in frequency of medication administration during the study period, the population included 276 male inmates as shown in Figure 1.

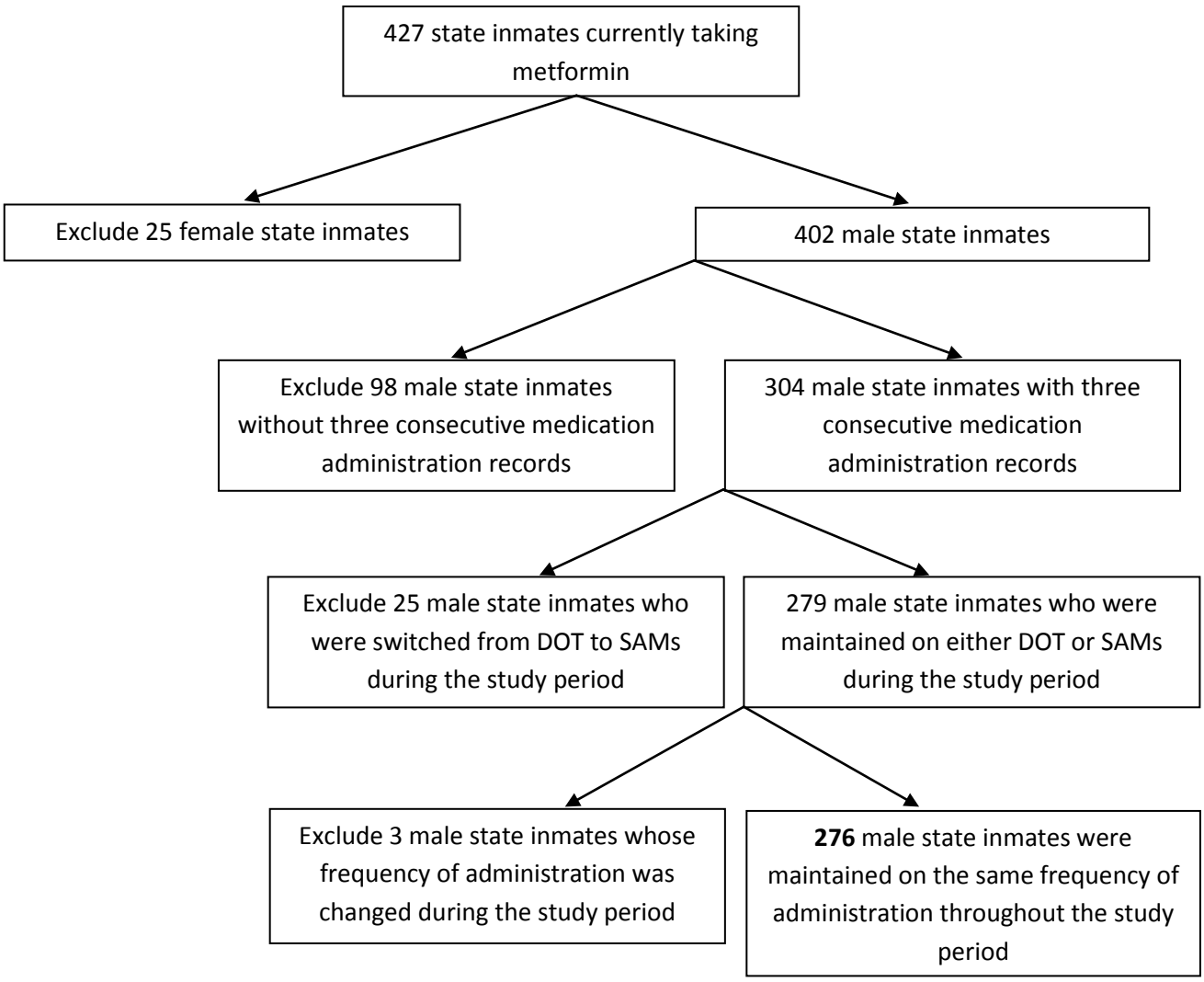

Figure 1. Study population of male state inmates taking metformin

The state inmate population was chosen because it is a unique confined population that must conform to strict rules. Also, as previously described, it was found that adherence to oral antidiabetic medication was lower among inmates than non-inmates.[14] Additionally, the Kentucky DOC utilizes a comprehensive electronic health record which allowed for ease of MAR review. Another factor of the inmate population that was critical to this study is the way in which their medications are administered (DOT versus SAMs) as mentioned earlier. This study extracted information for the study from the medication administration records through the Kentucky Corrections Health Services Network (KCHSN). Data manipulation and

statistical procedures to calculate the adherence rates of inmates receiving medications by DOT or SAMs used de-identified data with unique anonymous patient identifiers to allow for patient-specific data analysis. There was no patient contact or use of protected health information (PHI). Inmates receiving medications by DOT or SAMs had a thorough review of at least three consecutive medication administration records to identify the dates that metformin was given either as a single dose or a multi dose unit. The total time from first MAR to last MAR were recorded as the total time period which medication should have been administered and used in the calculation of the medication possession ratio (MPR) for each inmate (Figure 2).[17]

$$MPR = \frac{number\ of\ days\ supply\ of\ medication}{number\ of\ days\ in\ the\ three\ month\ period}\ x\ 100\%$$

Figure 2. Calculation of medication possession ratio.

Adherence was defined as a calculated MPR of 80% or more for metformin in this study. This value is generally accepted for chronic conditions.[16, 18] MPR is a widely used, accepted and validated measurement tool that assesses availability or possession of the medication over a specified refill interval.[19] In a previous study, MPR was compared with other measures of medication adherence and shown to make reliable determinations of adherence.[20]

Statistical Analysis

Adherence rates for DOT and SAMs metformin administration used the established method of MPR as described.[11] This calculation uses the number of days medication is dispensed during the study period divided by the number of days in the study period. A resulting MPR ratio of less than 1.0 would be indicative of lapses in medication refills or underuse. Conversely, a ratio of greater than 1.0 would be indicative of early refills or overuse; however, a ratio greater than 1.0 is often truncated at 1.0.[19] The specified interval

or denominator must be clearly defined and in this case was the total number of days in the study period for each subject.[21] Dates that metformin was refilled (SAMs) or administered (DOT) were obtained to determine adherence by the MPR method. Descriptive statistics included comparisons between DOT and SAMs. The Chi-squared test was used for categorical data. Logistic regression analysis was used to determine the association between adherence and the DOT and SAMs groups, controlling for age. The following formula demonstrates the components of the logistic regression (Figure 3).

$$logit\ (p) = \ln\left(\frac{p}{1-p}\right) = a + \beta_1 x_1$$

Figure 3. Logistic regression components.

where p = probability of greater than 80% adherence according to DOT and SAMs, and x_1 = age category. Age is a potential confounding factor as it could affect rates of adherence, so the odds ratio (OR) may need to be adjusted to take this into account. Age was stratified into the following groups: 18-29 years, 30-59 years, 60-69 years, and 70+ years as in a previous adherence study.[22] The age categories in the logistic regression were used as dummy variables so that the ordinal nature of the age data could be appropriately calculated.

All statistical analysis and data manipulation used STATA v.11 data management and statistical software (StataCorp, CollegeStation, TX, United States). This study will be presented to KCHSN for their internal policy and decision making regarding the difference in adherence rates for DOT and SAMs medication administration methods. Only aggregated data will be surrendered.

IV. Results

The demographic characteristics of the study population are given in Table 1. The total state inmate population contained 427 inmates currently receiving the oral antidiabetic medication, metformin. Of this number, there were 276 male State inmates that were eligible for this study (Figure 1). Of these, 215 (77.9%) received medication by the SAMs method, while 61 (22.1%) received medication by the DOT method. The mean age of all inmates studied was 52.3 years (S.D. 10.95) and the mean age for the SAMs group was 53.2 years (S.D. 10.51) and the DOT group was 49.3 years (S.D. 11.98). Among the four age strata allocated, the distribution ranged from 0.5% to 73.0% for those assigned to SAMs and 3.3% to 75.4% for those receiving medication by DOT as seen in Table 1. White/Caucasian race represented the largest percentage of the total population (56.5%), while Black/African American race was the second largest group identified representing 33.3% of the total study population. As expected from the race distribution given for the total population, the majority of those receiving SAMs were White/Caucasian (72.1%). However, the majority of those receiving DOT were Black/African American (64.0%). The large percentage of White/Caucasian inmates contained in the total population was expected as it closely mirrors the race distribution in the state of Kentucky with White/Caucasian and Black/African American races representing 89.9% and 7.7% of the total population, respectively.[23] Due to the large White/Caucasian population in the SAMs group, logistic regression was difficult when estimated due to the comparatively small numbers represented by other races. For this reason, race was excluded from the logistic regression model.

Table 1: Demographic Analysis

	Total Population N=276	
	SAM n=215	**DOT n=61**
Age (Years)		
18-29	1 (0.5%)	2 (3.3%)
30-59	157 (73.0%)	46 (75.4%)
60-69	41 (19.1%)	10 (16.4%)
70+	16 (7.4%)	3 (4.9%)
Race Distribution		
Black/African American	53 (24.6%)	39 (64.0%)
Hispanic/Latino	3 (1.4%)	21 (34.4%)
White/Caucasian	155 (72.1%)	1 (1.6%)
Unknown	4 (1.9%)	

In Table 2, the type of medication administration method (SAMs or DOT) and MPR are shown. The SAMs group contained 37.2% inmates who fell below an MPR of 80%, while the DOT group contained a much lower percentage of nonadherent inmates (13.1%). In the DOT group, 86.9% of inmates were adherent, while fewer inmates (62.8%) in the SAMs group achieved an MPR greater than 80%. The MPR of each age group, stratified by type is shown in Table 3. In the SAMs group, the age group with the largest percentage of inmates achieving an MPR <80% was 30-59 years, with the 18-29 years group representing the smallest percentage achieving an MPR <80%. Similarly, the 30-59 years age group also represented the largest percentage achieving an MPR >80% and the 18-59 years group represented the smallest percentage achieving an MPR >80%, in the SAMs group. Similar results were observed for DOT group as the largest group achieving an MPR >80% and MPR <80% was the 30-59 years age group, while the 18-29 years age group represented the smallest percentage of inmates achieving an MPR >80% and an MPR <80%.

Table 2: Medication administration type versus MPR

	Type	
Adherence	**SAMs**	**DOT**
MPR <80%	80 (37.2%)	8 (13.1%)
MPR >80%	135 (62.8%)	53 (86.9%)

Table 3: Age Group versus MPR stratified by type

	Adherence		
Type		**MPR <80%**	**MPR >80%**
SAMs	**Age Group**		
	18-29	1 (1.25%)	0.00
	30-59	69 (86.25%)	88 (65.19%)
	60-69	7 (8.75%)	34 (25.19%)
	70+	3 (3.75%)	13 (9.63%)
DOT	**Age Group**		
	18-29	1 (12.50%)	1 (1.89%)
	30-59	6 (75.00%)	40 (75.47%)
	60-69	0.00	10 (18.87%)
	70+	1 (12.5%)	2 (3.77%)

The univariate logistic regression analysis results are given in Table 4. The association of adherence at each age strata shows that there is evidence of confounding by this variable on both the exposure (medication administration type) and outcome (adherence). The final odds ratio relating to adherence to medication administration type was controlled by the difference of each age strata with 95% confidence intervals (Table 4). There was a significant difference observed in the DOT group as the p-value was <0.05 and the 95% confidence interval did not cross 1. The OR for the DOT group was 3.93 which would indicate that an inmate in the DOT group would be almost 4 times as likely to achieve an MPR >80% than an inmate in the SAMs group. The age group 60-69 years also demonstrated a significant difference and the OR of 12.57 indicates that an inmate in this age group is 12 times as likely to achieve an MPR >80% than an inmate in the 18-29 age group. Since there was a significant difference in age, the results needed to be stratified as

the OR of 3.93 for the DOT group could potentially be confounded solely by the difference observed among the age groups. To address age as a confounder, a multivariate logistic regression analysis was conducted as shown in Table 5. Odds ratios are shown for age group and medication administration type with 95% confidence intervals of those achieving adherence (MPR >80%). There was a significant difference observed in the 60-69 years age group as in the univariate logistic regression analysis with an OR of 33.3 which indicates that an inmate in this group would be 33 times as likely to be adherent to metformin than inmates in the other age groups. A significant difference was also observed in the 70+ years age group with an OR of 20.5 which indicates that inmates in this group are 20 times as likely to be adherent than inmates in other age groups. There was also a significant difference observed in the DOT group with an age-adjusted OR of 4.90 which would indicate that inmates receiving metformin by the DOT method are almost 5 times as likely to be adherent than inmates receiving metformin by the SAMs method.

Table 4: Univariate Logistic Regression Analysis

Adherence	
Age Group	**OR [95%CI]**
18-29	Reference
30-59	3.41 [0.304, 38.28]
60-69	12.57 [1.00, 157.73]*
70+	7.5 [0.534, 105.3]
Type	
SAMs	Reference
DOT	3.93 [1.78, 8.68]*
*Denotes statistical significance of p<0.05	
N=276	

Table 5: Multivariate Logistic Regression Analysis

Adherence	
Age Group	**OR [95%CI]**
18-29	Reference
30-59	8.25 [0.615, 110.8]
60-69	33.3 [2.21, 503.6]*
70+	20.5 [1.22, 345.1]*
Type	
SAMs	Reference
DOT	4.90 [2.10, 11.4]*
*Denotes statistical significance of p<0.05	
N=276	

V. Discussion

The purpose of this research was to determine if the medication administration method affected adherence among inmates with T2DM and if age contributed to adherence. This was necessary as adherence is essential for glycemic control, prevention of diabetes-related complications, and will have negative economic and health implications if not achieved.[5,9] It was determined that the relationship between medication administration method and age were significant when assessing inmate adherence to metformin. The results of this study conflict with previous research assessing inmate adherence, conducted by KCHSN. The previous research conducted by KCHSN found no statistically significant difference between medication administration type and adherence. However, the previous study was focused on all medications and disease states and contained a smaller sample than the present study. These differences likely contributed to the conflicting results between the two studies. This is novel research in that it was specifically focused on male inmates in the state of Kentucky with T2DM who were receiving the oral antidiabetic medication, metformin for treatment.

The medication possession ratio did differ based on medication administration method (SAMs or DOT). The SAMs group contained more nonadherent inmates than the DOT group (37.2% versus 13.1%). Thus, the DOT group contained more adherent inmates that the SAMs group (86.9% versus 62.8%). These results were expected as the SAMs administration method relies on the responsibility of the inmate alone to be adherent to their medication. Conversely, when inmates receive medication by the DOT method, they are accountable for taking medications as they are observed by a corrections officer and the person who administers the medication to them.

When the MPR of each age group was stratified by type, in both SAMs and DOT groups the largest group achieving an MPR >80% and MPR <80% was the 30-59 years age group, while the 18-29 years age group represented the smallest percentage achieving an MPR >80% and an MPR <80%. These results were expected as the 30-59 years group represented the largest population of inmates and the 18-29 years group represented the smallest population of inmates for both administration methods, as shown in Table 1.

When analysis was conducted to determine if medication administration method significantly affected adherence it was found that inmates in the DOT group demonstrated increased adherence compared with the SAMs group. From the univariate analysis of adherence by age group, the 60-69 years group was the only group that had a statistically significant increase in the OR when compared with younger and older age groups with the reference population of 18-29 years. From this, it may be concluded that age is correlated with adherence. An age-adjusted OR was calculated due to the confounding effects of age and the DOT group OR increased from 3.93 to 4.90, indicating inmates in DOT group were almost 5 times as likely to achieve adherence than those in the SAMs group. Additionally, another age group was found to be statistically significant, the 70+ years age group. This

multivariate analysis further solidified the association between medication administration method and adherence, and confirmed the positive correlation of age and adherence that has been previously documented in patients with T2DM.[24] These results are consistent with previous research that has documented the effect of age on metabolic control in the general population. It was shown that HbA_{1c} was 0.26% lower per decade increase in age.[10]

VI. Limitations and Future Research

Within the scope of this project it was not possible to include all factors that could potentially affect adherence which contributed to a number of limitations in this study. A possible confounding variable in this study was the length of time the subject had been taking the medication. Adherence generally decreases over time while the patient is taking the medication.[25] It would be useful in future studies to identify inmates that have been prescribed metformin for less than one year or more than one year as it has been shown in one study that only 37% of patients remained adherent after one year.[26] Any medications taken concurrently with the antidiabetic therapy would also be useful to collect to determine the relationship between the adherence to antidiabetic therapy and other medications. Similarly, the number of concurrent medications may also affect adherence rates. Although changes in frequency of medication administration were addressed and excluded in the present study, dose changes were not addressed in this research. Dose changes that occurred during the period of medication administration record review may be a variable as an increase in dosage could result in decreased tolerability which may decrease adherence. The time of day the medication is administered (in the morning, afternoon, or evening) could be collected for the DOT group in future research as adherence may be impacted. Another limitation would be that the frequency of administration was not

analyzed in this research. The method of data collection was through review of medication administration records. The medication administration records for the SAMs group show dates an inmate obtained a refill, but it is unknown whether an inmate actually took the medication. With regard to external validity, the results of this study are generalizable to male inmates with T2DM; however, due to the large proportion of White inmates in this study, the results may not be as generalizable to inmates in other states with differing race distribution from Kentucky. Also, this study is not generalizable to women as they were excluded from this study.

Future research could also include evaluating the association between adherence to antidiabetic medication and adverse health outcomes, such as myocardial infarction ("heart attack") or other vascular diseases (e.g., stroke). However, this study was not designed to look at future outcomes and could only be conducted with long term inmates.

VII. Conclusions and recommendations

It can be concluded from this research that inmates with T2DM who attend "Pill Call" daily to receive their medications are more adherent than those who are in possession of their medication and are responsible for their own administration. The implementation of a counseling program is recommended for inmates with T2DM so that they may gain a better perception of consequences of nonadherence as a previous study found that nonadherence was >1.5 times higher among those who did not understand the severity of their disease.[27] While benefits should be gained by all inmates, a counseling program may be most beneficial for inmates in the SAMs program as they are responsible for taking their medication at the specified time each day. Since inmates assigned to the DOT method of administration were found to be more adherent than those assigned to SAMs, it is

recommended that a more intensive screening process be undertaken with inmates who are potential candidates for the SAMs program.

This research uncovered that age was positively correlated with adherence. Based on this finding, it is recommended that age restrictions be placed on inmates who are candidates for the SAMs program. Since adherence was higher for those over the age of 60 years (the 60-69 years age group and the 70+ years age group), there could be an age requirement of ≥60 years for inmates to be eligible for the SAMs program. This would result in higher costs due to an increase in resources necessary for DOT administration such as: medical staff to administer and prepare medications and complete documentation, and corrections officers to observe medication administration. However, it would likely result in lower overall costs due to a decrease in costly diabetes-related complications and resulting morbidity and mortality. Also, as suggested in a previous study, a strong social support group which could be achieved by the continued encouragement of medical staff is recommended to potentially increase adherence rates among male inmates in Kentucky with T2DM.[28] These findings should be confirmed by further research in this area to address limitations that were not within the scope of this project to better patient care for inmates with T2DM.

VIII. Acknowledgements

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X. Appendices

KENTUCKY CORRECTIONAL HEALTH SERVICES NETWORK

2355 Huguenard Dr.
Lexington, KY 40503

January 25, 2010

Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)
Office of Research Integrity
315 Kinkead Hall, 0057

Dear Members of the IRB:

Protocol Number: 09-0973-P2H

I am writing on behalf of the Kentucky Corrections Health Services Network (KCHSN) to give permission for Rebecca (Hampton) Pettinato to use the prison health data for her current study. She will be working with us and following rules and regulations of the Kentucky Department of Corrections in her use of the data.

The Kentucky Department of Corrections complies with HIPPA rules and regulations. We support Ms. Hampton's work on this project. Please feel free to contact me at above address or at phone number 859-257-8470/859-338-9928

Cordially,

_____

Dr Peace Jessa DO, M.P.H., Pharm.D.
Assistance Professor

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report

Learner: Rebecca Hampton (username: rlhamp2)
Institution: University of Kentucky
Contact Information Department: Pharmacy Practice and Science
Phone: (859) 608-0115
Email: rlhamp2@uky.edu

Group 1 Biomedical Investigators and Key Personnel:

Stage 1. Basic Course Passed on 04/06/09 (Ref # 2689736)

Required Modules	Date Completed	Score
Introduction	04/04/09	no quiz
History and Ethical Principles	04/04/09	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	04/04/09	5/5 (100%)
Informed Consent	04/05/09	4/4 (100%)
Records-Based Research	04/05/09	2/2 (100%)
Genetic Research in Human Populations	04/05/09	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	04/05/09	4/4 (100%)
Vulnerable Subjects - Research with Prisoners	04/05/09	4/4 (100%)
Vulnerable Subjects - Research Involving Minors	04/05/09	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	04/05/09	3/3 (100%)
FDA-Regulated Research	04/05/09	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects	04/06/09	2/2 (100%)
University of Kentucky	04/06/09	no quiz