Integrating Community Pharmacists and Clinical Sites for Patient-Centered HIV Care

Formerly: Improving HIV Prevention and Treatment Outcomes Among HIV-Infected Persons by Integrating Community Pharmacists and Clinical Sites into a Model of Patient-Centered HIV Care
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Supporting Statement B

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Project overview

To address these problems, CDC has entered into a partnership with Walgreen Company (a.k.a Walgreens pharmacies, a national retail pharmacy chain)and the University of North Texas Health Science Center (UNTHSC) to develop and implement a model of HIV care that integrates community pharmacists with primary medical providers for patient-centered HIV care. The model program will include the core elements of MTM which include: Medication Therapy Review, Personal Medication Record, Medication-related action plan, Intervention and/or referral and Documentation and follow-up.(8) In addition, project pharmacists will perform additional services such as individualized medication adherence counseling, active monitoring of prescription refills and active collaboration with medical clinic providers to identify and resolve medication related treatment problems such as treatment effectiveness, adverse events and poor adherence.

The service model will be developed by CDC in collaboration with Walgreens pharmacies and UNTHSC. The University of North Texas Health Science Center is a CDC grantee funded through a co-operative agreement who will manage and coordinate project sites, collect data from the project sites and transmit the data to CDC.

The pilot program will be conducted in ten project sites. Each project site will be made up of at least one Walgreens pharmacy and one medical clinic with which the pharmacy will partner. Each project pharmacy will be a Walgreens HIV Center of Excellence (COE). Walgreens COEs are pharmacies that are staffed with specially-trained pharmacists who work closely with HIV patients to offer guidance and support with their medication therapy. A total of 1000 HIV-infected persons (~100 patients per site) will be enrolled in the patient-

centered HIV care pilot project. The project sites will enroll minority populations disproportionately affected by HIV. Walgreens will provide expanded MTM services to participants of the pilot program and will work with medical clinic providers to implement the service model.

The project clinics will be funded to participate in the project through a sub-contract of the co-operative agreement. Walgreens is donating its time and resources in-kind. Project staff at project clinics and pharmacies will collect data from their respective clinics and pharmacies. Most data collected from the project clinics and pharmacies are routinely collected as part of normal patient care. Program data will then be sent to the grantee (UNTHSC) who will clean the data and resolve any data discrepancies before sending the data to CDC.

The patient-centered HIV care model program is a 3 year pilot project. No statistical sampling will be used to identify or enroll project participants. Project outcomes will be compared within the project cohort (i.e. outcomes pre- and post-intervention) and are not meant to be generalizable to the general public. Rather, the purpose of the project is to develop a patient-centered HIV care model to increase clinic and pharmacy collaboration and to determine the service model’s performance within the project cohort. The expected outcomes, of the model program, are improved retention in care, adherence to medication therapy and viral load suppression, among the project cohort. The project has been determined to not be human subjects research.

B. Collections of Information employing statistical methods

1. Respondent Universe and Sampling Methods

Our sample will be a non-probability based convenience sample. The respondent universe is HIV-infected persons, from targeted minority populations, receiving HIV medical care at one of the 10 project sites. Targeted minority populations include Black, Latino and American Indian/Alaska Native populations. A project site will contain one or more Walgreens pharmacy and one or more medical clinic. Each project site will enroll 100 patients for a total of 1000 patients.

The sample size is based on the maximum number of patients to which Walgreens Company is willing to provide in-kind services. Because project clinics must be chosen in concert with Walgreens project pharmacies (who will ultimately decide which pharmacies will participate), no sampling methods will be employed to choose project sites. Both the project sites and project participants will represent convenience samples.

Participant eligibility includes HIV patients 18 years of age and older who receive medical care at one of the project clinics. CDC will work with Walgreens and the University of North Texas Health Science Center to define additional eligibility criteria. Participants will be enrolled into the project on a rolling basis until each project site has enrolled the targeted number of participants.

2. Procedures for the Collection of Information

<u>Data collection methods</u>

Project clinics and pharmacies are the sites for the data collection. Most data will be abstracted from the clinics' and pharmacies' archived patient medical and pharmacy records by project clinic and pharmacy staff. Data collected from participants' medical and pharmacy records are routinely collected and stored information used

by participants' providers for routine medical care. Medical record data will be abstracted at the baseline of the study and quarterly thereafter. Pharmacy record data will be abstracted quarterly. In addition, baseline descriptive data on the characteristics of the project sites will be collected at the beginning of the project by project staff and annually thereafter.

Data Transmittal

The project clinics and pharmacies will send data to the grantee who will clean the data, resolve data discrepancies and then transmit the data to CDC. Data will be electronically transmitted to CDC through the CDC Secure Data Network (SDN). All data transmissions are automatically encrypted by the software that generates the transfer files. Security certificates are used to control access to the SDN.

Sample Size Justification

This project has a fixed maximum sample size of m = 10 sites and 100 participants per site, giving a total of n_{max} = 1000 participants. We account for the group structure of this non-randomized trial by assuming a standard intraclass correlation of ρ_{ICC} = 5%. We also account for the potential loss of retention by assuming that λ = 20% of participants will be lost to follow-up over the course of the project. We thus obtain an effective sample size of n_{ess} = 441. See Table 1 for the effective sample sizes (ESSs) for various intraclass correlations (ρ_{ICC}¿ and proportions of loss-to-follow-up (λ).

The primary outcomes are the binomial proportions of participants with a HIV diagnosis who (a) are retained in care (b) are virally suppressed (c) are adherent to HIV medication therapy. Retention in care will be defined as the percentage of patients who had at least one medical visit in each 6-month period of the measurement period with a minimum of 60 days between medical visits. A medical visit is any visit at the project clinic with a physician, nurse practitioner and/or a physician assistant. HIV viral load suppression will be defined as the proportion of participants with HIV viral loads < 200 copies/ml at the end of the project period. The *Proportion of Days Covered* (PDC) will be used to calculate adherence to HIV medication therapy. The PDC is defined as the total number of days a patient was in possession of a medication divided by the number of days between the patient's last fill date and last fill date plus the days' supply of the last fill. These outcomes will be measured for all

participants both at baseline (BL) and 24 months follow-up (FU). Thus, the data will be paired on each participant. Improvements (changes) in these outcomes will be tested using McNemar's test with a two-sided significance level of α = 5%.

We assume that the BL proportions for each of these three outcomes are (a) π = 45%, [1] (b) π = 75% [2] and (c) π = 69% [3] respectively. For the above effective sample size of n_{ess} = 441, we have 80% power to reject the null hypothesis of no change when the absolute increases in these proportions at FU for each of these three outcomes are at least (a) δ = 10%, (b) δ = 8%, and (c) δ = 9%, respectively. For the above effective sample size of n_{ess} = 441, we have 90% power to reject the null hypothesis of no change when the absolute increases in these proportions at FU for each of these three outcomes are at least (a) δ = 11%, (b) δ = 9%, and (c) δ = 10%, respectively. Tables 2 and 3

Table 1: Effective sample sizes for various intraclass correlations **(** ρ_{ICC}**)** and proportions of loss to follow-up (LTFU, λ)

	intraclass correlation (ρ_{ICC})										
LTFU (λ)	**0.00**	**0.01**	**0.02**	**0.03**	**0.04**	**0.05**	**0.06**	**0.07**	**0.08**	**0.09**	**0.10**
0.00	1000	917	847	787	735	689	649	613	581	552	526
0.05	902	827	764	710	663	622	586	553	524	498	475
0.10	810	743	686	637	595	558	525	496	470	447	426
0.15	722	662	612	568	531	498	469	443	420	399	380
0.20	640	587	542	503	470	441	415	392	372	353	336
0.25	562	516	476	442	413	387	365	345	327	310	296
0.30	490	449	415	385	360	337	318	300	284	270	257
0.35	422	387	358	332	310	291	274	259	245	233	222
0.40	360	330	305	283	264	248	233	220	209	198	189

Table 2: Sample sizes required to have 80% power to reject the null hypothesis of no change from baseline to follow-up using McNemar's test with two-sided significance level of α = 0.05.*

	absolute increase from BL to FU (δ)								
BL % (π)	**0.05**	**0.06**	**0.07**	**0.08**	**0.09**	**0.10**	**0.11**	**0.15**	**0.20**
0.35	1474	1029	761	586	465	379	315	173	99
0.40	1537	1071	789	606	481	391	324	176	100
0.45	1568	1090	802	615	487	395	326	176	99
0.50	1568	1088	799	611	483	391	322	173	96
0.55	1537	1064	780	595	469	379	312	166	91

0.60	1474	1018	745	567	446	359	295	155	84
0.65	1380	951	693	527	413	332	272	141	76
0.70	1254	862	626	474	370	296	242	124	65
0.75	1097	750	543	409	318	253	206	103	52
0.80	909	617	443	332	256	202	163	78	--
0.85	689	463	328	242	184	143	114	--	--

*Assuming a minimal within-participant correlation of ϕ = 0.

Table 3: Sample sizes required to have 90% power to reject the null hypothesis of no change from baseline to follow-up using McNemar's test with two-sided significance level of α = 0.05.*

	absolute increase from BL to FU (δ)								
BL % (π)	**0.05**	**0.06**	**0.07**	**0.08**	**0.09**	**0.10**	**0.11**	**0.15**	**0.20**
0.35	1972	1377	1017	783	622	506	420	230	132
0.40	2056	1432	1056	811	642	522	432	234	133
0.45	2098	1459	1073	822	650	527	436	234	132
0.50	2098	1456	1069	817	645	522	431	230	128
0.55	2056	1424	1043	796	627	506	417	220	121
0.60	1972	1362	996	758	596	480	394	206	112
0.65	1846	1272	927	704	552	443	363	188	100
0.70	1678	1152	837	633	494	396	323	164	86
0.75	1467	1003	725	546	424	338	274	136	68
0.80	1215	825	592	443	341	270	217	104	--
0.85	921	618	438	323	245	191	151	--	--

*Assuming a minimal within-participant correlation of ϕ = 0.

3. Methods to Maximize Response Rate and Deal with Nonresponse

Most of the data collected for this project is routinely collected and archived by the project clinics and pharmacies and does not involve participant response to any surveys. A data manager at each clinic will collect the data and send the data to the grantee. The clinics will be funded to participate in the project and will be required to submit data as a condition of funding. Submission of data by the clinics is, therefore, expected to be high. The grantee will work with the project sites to address any problems with data collection and to resolve data discrepancies. The grantee will electronically transmit the data to CDC.

4. Tests of Procedures or Methods to be Undertaken

Data collection for this project does not involve participant response to any surveys. Most data will be abstracted from the clinics' and

pharmacies' archived patient medical and pharmacy records by project clinic and pharmacy staff. The data collection forms have been reviewed by project team members from CDC, Walgreens and the University of North Texas Health Science Center. In addition, input was received from clinicians at one large HIV-care clinic and from staff from the Health Resources and Services Administration and the National Minority AIDS Council.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals were consulted on the statistical aspects of the project:

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Data will be collected form the project sites by the University of North Texas Health Science Center through a co-operative agreement.

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