Informed Consent

Study Title:	Impact of Providing Medical Records in a Patient-Centered, Community Pharmacy Based, HIV Care Model (HIV-MOI) of the Community Pharmacy-Based HIV Care Model study
ClinicalTrials.gov Identifier:	NCT03437694
Sponsor:	National Institute on Minority Health and Health Disparities
Sponsor Project Title:	Texas Center for Minority Health, Education, Research and Outreach
FAIN Number:	U54MD006882
IRB Number	1436643/2018-094
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University of North Texas Health Sciences Center at Fort Worth

Research Participant Information and Consent Form

Title: Medical record based versus non-medical record based community pharmacy provided medication therapy management

Protocol Number: 2018-094. *ClinicalTrials.gov Identifier: NCT03437694*

Sponsor: National Institute on Minority Health and Health Disparities

Principal Investigator: Crystal Hodge, PharmD, BCIDP, BCPS

E: Crystal.Hodge@unthsc.edu; Office: (817) 735-0131
UNTHSC, 3500 Camp Bowie Blvd, Fort Worth, Texas 76107

Study Related:

This is a research study consent form which may contain words that you do not understand. Please ask the study team members to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision. The study team can also mail this to anyone you would like at no cost to you.

SUMMARY

You are being asked to be in a research study. Your decision to be in the study is voluntary. If you decide to be in this study and then change your mind, you can leave the study at any time. The study lasts for 2 years. You will be asked to complete 9 visits. This includes today's visit. If you agree to be in this research study, your medical records will become part of the research. The information from your medical records will be seen by the study pharmacist, members of the study team, or by government, agencies or other groups responsible for the study, including review boards, or as federal law or regulations require. More detailed information about this study is in this consent form. Please read it carefully.

PURPOSE OF THE STUDY:

Your pharmacist counsels you about your medicines. This typically happens when you pick up your medicines from the pharmacy. Pharmacists also provide a more in-depth

service called medication therapy management or MTM. MTM is when you and a pharmacist schedule an appointment to talk about all of your medicines, medical conditions, lifestyle and habits. Usually for MTM, the pharmacist only knows what medicines are being filled at the pharmacy and what you remember about your health. MTM takes place in a quiet, private place inside the pharmacy or over the phone. The goal of MTM is to help you get the most benefit possible from your medicines.

This is a study about a new way for pharmacists to conduct MTMs. Remember how the pharmacist usually only knows what your prescriptions are or what you tell them about your medical conditions. This study is testing to see if providing the pharmacist with your medical information from your doctor's office before your MTM visit, improves the care provided by the pharmacist.

How will this be tested?

Everyone who participates in this study will be assigned to be in one of two groups. Group 1 will be those whose medical information is given to the pharmacist. Group 2 will be those whose medical information is not given to the pharmacist. Remember, Group 2 is what regularly occurs today and is called standard of care. Both groups are considered part of the study.

The purpose of this study is to find out if there is a difference in health changes between Groups 1 (pharmacist sees medical information) and 2 (pharmacist does not see medical information). The two main health conditions that will be compared are diabetes and high blood pressure. You may have one or both of these conditions.

You will be assigned to a group randomly by a computer. The random process is like flipping a coin. You will have an equal chance of being assigned to Group 1 or Group 2. You will not know which group you have been assigned. The pharmacist and the research team will know which group you have been assigned. You cannot change groups at any time during the study. If you don't want to be in the group to which you have been assigned, you can elect not to participate in the study. You can also elect not to be in the study at any time for any reason. Once you are assigned, you would be in that group for 2 years

Can the study pharmacist contact your doctors even if you are in Group 2?

Yes, the study pharmacist can contact your doctor if they feel it is important to your health. If the pharmacist does this, you are still able to participate, even if you are in Group 2.

PROCEDURES

Visit 1 (today's visit): If you decide to be in the study, the following events will happen today:

1. This is a screening visit to assess your eligibility to participate in the study. No physical assessments or surveys will be conducted on this visit. You will not be paid for this visit because you are still not enrolled in the study. You will be asked to sign this document.

2. You will be offered a copy of the signed consent form. It contains all the information about this study. It has information about who to contact if you have questions. It has information about your rights as a study participant. It has information about who to call about those rights. Please keep your copy in a safe place.

3. Clinical research centers are encouraged to notify research participants' medical providers of research activity. Your response does not affect your ability to participate in this study. Please select ***ONE*** option below. You may either check it or write your initials:

_____ Yes, I give you permission to inform my HIV / primary care physician / specialist of my participation in this study.

_____ No, I do not give you permission to inform my HIV / primary care physician / specialist of my participation in this study.

_____ I do not have a HIV / primary care physician / specialist to be notified.

4. You will be required to provide information that will allow the research team to contact you and your healthcare providers. This will include a telephone number and a mailing address. The research team must have at least 1 way to contact you during the study. It is your responsibility to update the research team if the phone number that we use to contact you changes or if you have a new mailing address. This responsibility carries forward the entire time you are on the study.

5. To participate, you must be willing to notify the research team if you become pregnant, are moving, have to receive chemotherapy for cancer, go into hospice services, or are no longer able to give yourself your medicines or participate in study activities.

6. You are not required to be a Walgreens customer or have ever received medicines from a Walgreens pharmacy. You are not required to change any of your medicines or doctors to participate.

Between Visit 1 and 2:

Following today's visit, the research team will begin the process of obtaining your medical records. Your medical records will be obtained from the offices of your primary care provider or PCP, your HIV provider's office (if this is not your PCP) and any other doctor you have seen the last 12-24 months. The request of records will be made using the release of medical information form you signed. You may be asked to sign additional forms because those hospitals or offices require you to sign their form. If this happens, we will contact you and ask you to sign the additional form. Once these records are received, the records will be placed in a secure place at UNTHSC. Only UNTHSC study team members will be able to see the records. The records will always stay at UNTHSC.

It is only after the medical records are received at UNTHSC that you will be assigned to a group.

The UNTHSC research team (Dr. Hodge and other team members who are trained healthcare professionals with expertise in medical record review) will review your medical records. They will identify the important information from your records and only those important information will be given to the pharmacist.

What information is being used from your medical records?

The information used will be information about your current or past medical conditions. For instance, if you have high blood pressure or diabetes, that will be used. To help the research team better know if the study makes a difference, other information about your diabetes such as blood glucose or A1c would also be used. Further, what medicines you take for diabetes, when you started the medicine and how much do you take would be used. Information about your blood pressure, height, weight, tobacco, alcohol and drug use or other laboratory values that are important to know in people with diabetes. This may include information about any psychiatric conditions you have, like depression or anxiety. It may also include information about Hepatitis C (if it is in your medical records).

Once the form is completed, it will be securely transported to the study pharmacist by the research team. The research team will work with the study pharmacist and you to determine when your next visit will take place.

If no records are received after 8 weeks, we will contact you to arrange a meeting to complete new medical records release forms, at a place convenient to you. If you are not able to arrange for this meeting, you will not be eligible to be a participant in the study.

Visit 2: This visit could last up to 1 hour.

Before scheduling Visit 2, you will be required to provide your social security number. The research team's employer, University of North Texas Health Science Center, requires that study participants provide this information in order to be paid. If you choose not to provide or sign, you will not be able to participate in the study.

1. Study visits will take place over the phone. A research team member will be present with the study pharmacist to take notes. The information is written on a document that only the research team or the study pharmacist will see. This information may be used by the study pharmacist to communicate with your medical doctor at your upcoming visits.

2. You are asked to have all of your medication or a list of your medication with you.

3. You are welcome to share any other information you choose to your visit, including any medical information you have.

4. At the end of your visit, you, the study pharmacist and the UNTHSC research team member will discuss when your next visit will take place. The goal is to have visits take place about every 3 months; we will work with your schedule.

Visit 3-8: Each of these visits could last up to 1 hour. At each of the next visits, steps 1-4 will be repeated. If at any of these visits it is determined you need to provide access to additional medical records, research team members will arrange to have you sign additional medical record release forms. If you do not sign the additional medical record release forms, you may not be able to continue participating. If your doctor does not send the researchers these new medical records, you will still be allowed to participate.

Visit 9: This visit may take up to 1 hour. At visit 9, steps 1- 3 will be repeated. Instead of making a future appointment, the study pharmacist will work with you to help you understand how you can continue receiving MTM after this visit. The costs to receive MTM after the study ends at a Walgreens pharmacy will be provided by the study pharmacist. The study pharmacist will not know what other pharmacies can provide MTM or if they do, what will be the cost to you.

SURVEY INFORMATION

At Visits 2-8, you will be asked to complete a survey. All the questions are multiple choice. A research team member can be asked to read it to you and write down your responses if you prefer. You may complete the survey yourself. It will take about 10

minutes to complete the survey each time. The purpose of the survey is to help the research team know what influences your health. You may choose not to complete the surveys. You may choose not to answer some of the questions on any of the surveys. If you choose either, you will not be able to continue in the study.

RISKS AND DISCOMFORTS

Accidental disclosure of your survey responses and medical conditions including HIV status is a risk in this study. All unattended records and information will be securely locked at all times.

Discussing your health with a study pharmacist or answering survey questions may make you uncomfortable. Having a research team member present when talking with the study pharmacist may make you uncomfortable. If you are uncomfortable answering any question, you may choose not to answer the questions the study pharmacist asks.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the U S. Department of Health and Human Services. With this certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of federal agencies. A Certificate of Confidentiality does not protect you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The protection offered by the Certificate does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threat of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities and will do so without disclosing your participation in this study.

BENEFITS

It is possible you will not benefit in any way from participating in this study. Your participation in this study may help healthcare providers learn more about how to give

better care. It is possible you will have improvements in the control of your HIV, diabetes or high blood pressure. It is also possible your medical conditions could get worse.

COSTS

You will not be charged to take part in this study. The doctor's office might mistakenly send you a bill for the request of your medical record by the study team. If this happens, do not pay the bill. Please contact the Principal Investigator at (817) 735-0339. He will resolve the issue. A research team member will follow up with you weekly until the issue has been resolved. If you discover you have paid for medical records for this study, please bring the receipt to your next visit or contact the PI at the number above. We will make arrangements to meet with you, get a copy of the receipt and reimburse you.

Even if you are no longer in the study and you receive a bill or pay for medical records because of this study, we will still take care of this. If this occurs, please contact the Principal Investigator at (817) 735-0131 or the research coordinator at (817) 735 - 2252. To get reimbursed, you must have a copy of the receipt showing you paid for the copies of medical records.

PAYMENTS

You must remain in the study to continue receiving payment. At the conclusion of each visit, you will be paid $50.

This payment will be in the form of a pre-loaded debit card. You will be provided this card at Visit 2. This card will be provided at no cost to you. This card will not contain your name. This card can be used just like any credit card. You will not need a PIN number to use this card. It is very important you hold onto this card. It will be automatically reloaded after every visit is completed. If you lose the card, another one will be provided, and you will have to pay $3 to replace it. The amount to have it replaced will be deducted from the $50 payment you receive after the next visit you complete. You will be paid up to $400 if you attend all the study visits and assessments and never lose your prepaid debit card.

If for any reason there is a problem with the debit card system, you will be paid using a gift card. Please select ***ONE*** option below. Your response does not affect your ability to participate in this study.

_____Yes, I agree to receive a gift card instead of having money put on the debit card when the debit card is not available.

_____No, I do not agree to receive a gift card instead of having money put on the debit card when the debit card is not available. I will defer accepting payment until the debit card is available.

ALTERNATIVE TREATMENT

Your regular pharmacist can request your medical records. Your regular pharmacist may be able to provide MTM using those records. There may be a charge to you to get the medical records and to receive MTM from your regular pharmacist. The cost for this would fall to you or your regular pharmacist. The costs to do this would be something only you and your regular pharmacist can discuss.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get information and why they are able to get it. The study team must get your permission to use or give your identifiable health information.

What information may be used and given to others?

If you choose to be in this study, the study team will get your personal and health information about you. No medical records will be collected that you have not given us permission to collect. The principal investigator named above and their assistants, as well as Walgreens study pharmacists involved in your care will be allowed to see and to use your health information for this research study. We may share your health information with people at the University of North Texas Health Science Center who help with the research. To do the research, we need to collect health information that identifies you. For you to be in this research, we need your permission to collect and share this information.

Information about you and your health would only be given to the below listed agencies as the law requires.

1. National Institute on Minority Health and Health Disparities (NIMHD)
2. Department of Health and Human Services (DHHS)
3. North Texas Regional Institutional Review Board (NTRIRB). NTRIRB is a group of people who perform individual review of research as required by regulations.

Results of this research may be published in scientific journals or presented to medical meetings, but your identity will not be disclosed.

One year after the last participant on the study has completed their last visit, all medical records that were received for all participants (both groups) will be destroyed. This does not destroy the case report forms that contain the information that was taken from your medical records.

The UNTHSC research team will keep the information taken from your medical records for up to 6 years after your study participation has ended, in case we need to look at it again. Throughout this entire time, we will protect your information and keep it confidential and secure. It will only be accessible to the research team.

Walgreens will retain the information from this study in securely locked cabinet until 2031. After this time, Walgreens will destroy the records for this study. This will not destroy any medication information or other information in Walgreens computers. This only applies to the documents used for this study.

What if I decide not to give permission to use and give out my health information?

If you decide *not* to sign this form, you cannot be in the research study. We cannot do the research if we cannot collect, use and share your health information.

If you change your mind later and do not want us to collect or share your health information you need to send a letter to Dr. Crystal Hodge at 3500 Camp Bowie Blvd., Fort Worth, Texas 76107.

Questions regarding your privacy rights:

A description of this clinical trial will be available on www.clinicaltrials.gov as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Any questions? Please ask the researcher (their phone numbers are listed on the first page of this form). You can also call the North Texas Regional Institutional Review Board (an ethics committee) at 817-735-0409 with questions about the research use of your health information. The researcher will give you a signed copy of this form.

COMPENSATION FOR INJURY

In this study the risk of injury is very low. However, we, at the University of North Texas Health Science Center at Fort Worth, have not set aside any funds for financial compensation, including costs of medical treatment, should you be harmed or injured as a result of your participation in this research. You should know that by signing this form you are neither waiving any of your legal rights against nor releasing the sponsor, the principal investigator, the University of North Texas Health Science Center at Fort Worth or any of their respective agents from liability for negligence with respect to the conduct of this study. If you are harmed and you feel that this harm justifies pursuing a legal remedy, you have the right to do so."

All this means is that there is no specific compensation available. By signing this consent form, you do not give up any legal rights.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Taking part in this study is your choice. You may decide not to participate, or you may leave the study at any time. If you decide not to take part in this study, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from your pharmacy the way you usually do. If the study pharmacy is your regular pharmacy, you will still receive all the care and benefits from that pharmacy that you had before you decided not to participate in this study.

If you chose to participate, you will be asked to complete all the MTM sessions, study surveys and assessments. You will need to provide initial, annual and as needed authorization for the medical release of your health information from where you receive medical care.

You are again encouraged to notify the study pharmacist if you become pregnant during the study. This will enable the pharmacist to accommodate and better attend to your pregnancy.

INVOLUNTARY WITHDRAWAL

Your participation in this study may be stopped at any time by the research team without your consent due to:

- You demand to be switched to the other group after becoming aware of assignment
- We cannot reach you (lost-to-follow-up)
- The study researchers think it is necessary for your health or safety;
- You have not followed study instructions;
- You no longer meet study entry criteria (i.e., enter hospice)
- The sponsor has stopped the study;
- Incarceration during the study.

SOURCE OF FUNDING FOR THE STUDY

The study team's expenses are being paid by a National Institute on Minority Health and Health Disparities grant, including the salaries of the researchers.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

You can talk to the study team members about any questions, concerns, or complaints you have about the study. The contact person is Dr. Crystal Hodge. The study phone number is (817) 735-2252.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns, you may have about the study, you may contact:

North Texas Regional Institutional Review Board

3500 Camp Bowie Blvd, Fort Worth, TX, 76107

Telephone: (817) 735-0409

Do not sign this consent form unless you have a chance to ask questions or you have read and received satisfactory answers to all of your questions.

CONSENT

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to be a part of this research study. I have been given a copy of this consent form to keep.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

PARTICIPATION IN RESEARCH IS VOLUNTARY. I have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which I am otherwise entitled. By signing this consent form, I have not given up any of my legal rights.

CONSENT SIGNATURE: If you wish to participate in this study, you should sign below.

Participant name (print) _____

_____ _____

Date Participant's Signature of Consent

_____ _____

Date Signature (& Initials) of Person Obtaining Consent