Implementation a Data-to-Care Strategy to Improve HIV Continuum Outcomes for Out of Care People Living With HIV (PLWH) in Ukraine

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Appendix 3: Informed Consent Form for the main study

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH
UKRAINIAN INSTITUTE ON PUBLIC HEALTH POLICY

INFORMED CONSENT

Principal Investigators: Jill Owczarzak, Kostyantyn Dumchev

Study Title: Implementation, Evaluation, and Cost Effectiveness of a Data-to-Care Strategy to Improve HIV Continuum Outcomes for Out of Care PLWH in Ukraine

Funded By: The National Institute of Health, a United States government agency is funding this study.

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Key Information about the Study

- We are asking you to volunteer for a research study about how to help people living with HIV and histories of substance use stay engaged in HIV care. We want to learn if a program we developed to help people like you stay in care is effective.
- You do not have to join the study; it is your choice and there is no penalty for not joining. Ask as many questions as you need to help you make your decision. Please review the details outlined in the rest of this consent document before deciding.
- We received your contact information from your documentation in the HIV clinic.
- You may be eligible for this study because you are someone who has HIV, indicated that you have used drugs in the past year, and missed an HIV care appointment more than a week ago. This study will connect you with a case manager who will help you with your HIV and other medical needs, as well as help you access drug treatment and other supportive services.
- If you join the study, we will ask you to fill out three surveys: one at the start of the study, one six months after enrollment, and one 12 months after enrollment. We will ask you about HIV, drug use, and your personal relationships so it is also possible that you may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. Another risk may be loss of confidentiality. If this information were accidently seen, it could be used in a way that might embarrass you. We will also retrieve your clinical data from the electronic Medical Information System.
- Every effort will be made to keep your study records confidential, but we cannot guarantee it completely. A code number, not your name, will be included on the survey to protect the confidentiality of your data.
- If you join the study **in Odesa or Dnipro**:
    - We will also ask you to meet regularly with a case manager who will ask you about your health, personal life, and other needs. The case manager will help you make a plan to access services that will help you address these needs. Depending on your level of need, you will meet with the case manager more often.
- There are no costs to you for participating in the study. For each survey that you complete, you will receive a compensation of 400 UAH, up to three surveys total.

- We hope that the results of this study will help us improve services for people living with HIV in Ukraine.

Details about the Study

Why is this research being done?

As we mentioned earlier, this study is about helping people living with HIV (PLWH) and with histories of substance use access HIV and other care and stay engaged in care. Research shows that PLWH and use drugs are less likely to return to care after they are diagnosed with HIV and more likely to drop out of care and stop taking their HIV medication than other PLWH. We developed a program called "Data to Care" that uses different sources of data such as medical records and regular personal assessments with clients to identify people living with HIV who are not in care, link them to care, and support retention and engagement in care. Data to care programs have been successfully used in the United States and other countries and we want to learn if this approach will work in Ukraine. A "data to care" program is different from existing programs in Ukraine and other forms of case management because it provides tailored treatment and support plans for each individual and regularly monitors and evaluates participants' progress to make sure they can meet their treatment goals.

What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- You will complete a baseline survey that asks about your HIV and other health history, experiences receiving medical care, substance use history and treatment experiences, and paying for medical care.
- If you are in Odesa or Dnipro:
    - You will meet with a case manager who will ask you questions about your health, basic needs such as housing and finances, and relationships and support systems. Based on how you respond, you will receive a score that reflects how much support you need.
    - You will work with your case manager to develop a care plan to help you address areas of needs by connecting you to resources such as counseling sessions, legal aid, or medical care. You will check in regularly with your case manager to determine if your needs are being met and what you can do to get the care you need.
    - The number of visits and frequency of contact with your case manager will depend on your level of need. Participants with higher scores will receive more intensive contact with case managers, typically every month, until their level of need goes down. Participants with lower scores will meet with case managers less often, typically every three months. You case manager may also call or message you to check in.
    - All participants will have their level and types of needs reassessed to determine if you need additional support or are moving toward self-management.
    - You will work with the case manager for 6 months.
- At 6 and 12 months after you started the study, you will complete another survey that asks about your HIV and other health history, experiences receiving medical care, substance use history and treatment experiences, and paying for medical care.
- We will also extract data from the Medical Information System at your clinic to receive information about your treatment history, lab results, and visit frequency. The data we

extract will not contain your name, contact information, or anything that could identify you.

How long will you be in the study?

You will be in the study for about 12 months. Each survey (baseline, 6 months, and 12 months) is expected to take 1 hour to complete. Visits with your case manager will vary in frequency and length. A typical meeting with your case manager will last up to one hour and will occur at most once per month.

What happens to data that are collected in the study?

The data we collect from you will help advance science and public health. As a participant, you will not own your research data, and you will not benefit financially from any new product or idea that might arise from our work. Sharing of research data is often done to increase what scientists can learn. The data you provide us might be shared

- directly with other researchers, funders, government agencies, publishers of papers
- through government or other databases/repositories

We will do our best to protect the data you provide and sharing of data would normally only be done anonymously (that is, the data would not be linked to your name, address, or date of birth). If you are not comfortable with the use of your data in future research, you may not want to participate in this study.

What are the risks or discomforts of the study?

Risks associated with surveys

- You may get tired or bored while we ask you questions or you complete questionnaires. Some questions may make you feel embarrassed or uncomfortable. Let us know if you feel distressed. You do not have to answer any question you do not want to answer.

Risks associated with accessing and using health data

- There is a risk that information about you may become known to people outside this study. However, this risk is very minimal, because we will not use your name or other personal information in our study forms or data sets, and the only form that will contain your contact information will be the one kept by the case manager (if you are in Odesa or Dnipro). In any case, we will protect all information to reduce the chance of unauthorized access. The disclosure of HIV status, drug use history, and other health information to third parties can lead to conflicts with family members, loss of employment, stigmatization and discrimination, and personal distress.

How will the confidentiality of your data be protected?

Every effort will be made to keep your study records confidential, but we cannot guarantee it. A code number, not your name, will be included on surveys and medical records to protect the confidentiality of your data. Study data will be stored on password-protected computers that only authorized users can access.

What are the potential benefits to being in the study?

If there is a potential for direct benefits to individual participants, state:
You may or may not benefit directly from being in this study. You may access new services that might help you with your HIV care and medication adherence.

If you take part in this study, you may help others in the future.

What are your options if you do not want to be in the study?

You do not have to join this study. If you decide not to join this study, you can still receive HIV services and other programs offered by this and other organizations. If you do not join, your care at this organization will not be affected.

Will it cost you anything to be in this study?

There are no costs for you to be in this study.

Will you be paid if you join this study?

If you join this study, you will be able to receive 400 UAH after fully completing each questionnaire. If you complete all three planned questionnaires, you will receive 1200 UAH in total.

Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, the researchers may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, the researchers may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

What other things should you know about this research study?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB) at Ukrainian Institute on Public Health Policy, a group of people including scientists and community people, that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the Iryna Pykalo, the Head of the IRB by phone: +38 063-391-72-45.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

Call the principal investigator, Dr. Dumchev at +38067-5805605**.** If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at +38 063-391-72-45.

What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name)
Date/Time

_____

Signature of Person Obtaining Consent (Print Name)
Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

Appendix 4: Case management checklist

Recruiter:	
	Site ID
	AIDSID
	Syrex ID
/ /	Date ART started
/ /	Date of last visit missed
	Current ART Regimen
/ /	Last VL date
	Last VL result
/ /	Last CD4 date
	Last CD4 result
	Recruiter's Initials
Case manager:	
/ /	Date of consent
	Case managers' Initials

Appendix 5: Contact information form

Contact Information Form

Participant ID						Staff ID		Completion date			
Site no.			Participant no.			Initials		dd		mmm	yy

What is the best way to contact you in 6 months from now to invite you to participate in the next round of study?

Note! Not all fields should be filled in. Ask similar questions several times to find out as much information as possible.

When the form is updated during follow-up visits, changes must be initialed and dated!

Name

Nickname

Phone number

Social media

Address

Frequently visited locations

Contact person 1

Phone number of the Contact person 1

Contact person 2

Phone number of the Contact person 2

Social worker

Needle exchange site

Preferred methods of contact

Other

Original of this form is stored by the Interviewer

Appendix 6: Data Elements for MIS data extraction

Patient socio-demographic characteristics

- **Age at HIV identification/ date of birth (single observation)**
- **Sex (single observation)**
- Education (single observation, if available)
- Occupation (single observation, if available)
- Marital status at HIV identification (single observation)
- Location of residence relative to the health facility (interest in distance to health facility)

Pregnancy related data

- Last menstrual period date
- Expected delivery date
- Pregnancy end date
- Pregnancy outcome

HIV diagnosis and risk group

- **Date of HIV status identification as confirmed at the clinic site (single observation)**
- **Mode of transmission by category PWID, MSM, SW, partner of IDU, heterosexual (single observation)**
- On opioid substitution therapy (OST) at ART initiation (single observation)

ART treatment history

- **First ART date (single observation)**
- **Initial HIV regimen (single observation)**
- ART pick up date, regimen type, and expected next pick-up date for all ART drug pick-ups during evaluation period [Note: quantity of medication dispensed can be substituted for expected next pick-up date] (repeated observations)
- ART stop date(s) (repeated observations)
- Reason(s) for ART stop (repeated observations)

HIV viral suppression (primary outcome)

- **All HIV viral load test dates and results from HIV status identification to end of evaluation period (repeated observations for data quality assessment first and most recent viral load test dates and results will be compared)**

Other end points

- Date of death (single observation, if relevant)
- Date patient declared lost to follow up (most recent observation, if relevant)
- Date of transfer out (most recent observation, if relevant)

Disease severity and health conditions

- **CD4 test dates and results for all values from 12 months before ART start date through end of evaluation period (repeated observations; for data quality assessment first and most recent CD4 test dates and results will be compared))**
- Most advanced WHO stage ever documented prior to ART initiation (single observation)
- Presence of TB co-infection at ART initiation (single observation)
- Pregnancy at ART initiation, including estimated delivery date (single observation)