The Use of Electronic Medical Records and Clinical Decision Support Tools to Evaluate and Strengthen HIV Care in Haiti and Ukraine

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A dissertation

Submitted in partial fulfillment of the

Requirements for the degree of

Doctor of Philosophy

University of Washington

2023

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Global Health

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Abstract

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Use of electronic medical records (EMRs) and clinical decision support (CDS) tools to support HIV care has been growing in low- and middle-income countries. Data from these systems can inform incidence surveillance, index partner tracing, HIV program evaluation, and individual patient care. However, there are several barriers to the use of this data for decision making, including negative perceptions of the usefulness and trustworthiness of routine data, data quality issues, and limitations of observational data for causal inference in program and policy evaluation. Our objective was to better understand how EMRs and CDS tools could be leveraged to strengthen and support HIV care in Haiti and Ukraine, including understanding barriers and facilitators to tool use, associations between EMR data quality and patient outcomes, and use of quasi-experimental methodology to evaluate public health interventions (here, index testing and

partner services). Related to each of these questions, we found that: 1) providers had generally positive views of EMR-informed CDS tools, particularly their potential to improve decision-making and patient outcomes; 2) that EMR data missingness is associated with poorer retention in care, particularly among children living with HIV, suggesting that data quality is a crucial element of clinical case management and quality of care; 3) and that EMR data can enable large-scale analyses of effectiveness of public health interventions, and specifically in this case example, showing evidence of index testing program effectiveness at brining named partners into HIV care and treatment at earlier stages of HIV disease progression.

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Acknowledgements

This dissertation would not have been possible without the support, dedication, and positivity of my committee, whose thoughtful and detailed feedback pushed me to further my skills and helped shape me into the researcher that I am today. I want to particularly thank my chair, Nancy Puttkammer; this dissertation would not have been possible without her unflagging mentorship and support. I want to note the exceptional work done by the staff of I-TECH US, I-TECH Ukraine, and CHARESS (Haiti), without whom none of this research would have been possible. In particular, I would like to thank John Justafort, Chenet Torrilus, Kemar Célestin, Margareth Jasmin, Jean Honoré, Alyona Ihnatiuk, Anna Shapoval, and Misti McDowell. I would like to thank my PhD cohort, whose camaraderie made the long days and exam seasons survivable, and from whom I’ve learned just as much as from my coursework. And finally, I'd like to thank my wonderful wife Jess, who has shown infinite patience, understanding, and support through this long process.

Chapter 1. Introduction, theoretical framework, and specific aims

1.1. Introduction

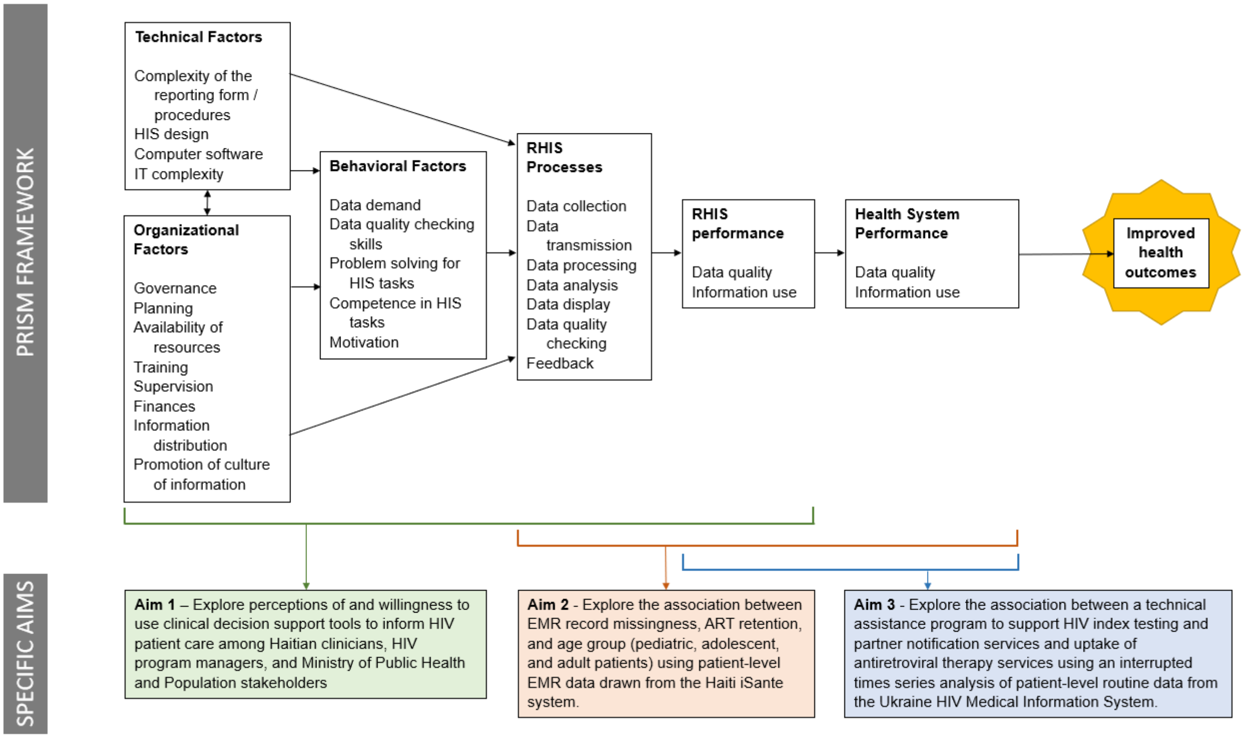
Advancing technology and broadened telecom access has enabled and expanded the use of technological solutions to public health issues around the globe.[1] As part of this, considerable time and resources have been put into the digitization of health data, including development and implementation of electronic medical record systems (EMRs), including in low- and middle-income countries (LMICs).[2,3] These systems can allow facility, regional, national, and global decision-makers to identify spatiotemporal disease and service provision trends, optimize resource allocation, conduct program evaluation, better target quality improvement measures, and tailor individual patient care through various mechanisms such as clinical decision support tools.[3–6] In the context of HIV care, such data systems can be used for incidence surveillance, index partner tracing, HIV program evaluation, and informing individual patient care, such as notifying providers when patients are due for viral load testing or may be at risk of treatment default.[7–11] CDS tools for HIV care have been shown to result in higher quality of care and better patient outcomes, including improved data quality, better adherence to testing and treatment guidelines, reductions in missed laboratory results, and reduced patient loss to follow up.[7,11,12]

However, there are several barriers to the use of this data for decision making, including negative perceptions of the usefulness and trustworthiness of routine HMIS and EMR data among providers, ministry staff, and other stakeholders; data quality issues; and limitations of non-randomized data for causal inference.[5,13–15] This dissertation explored the use of routinely collected patient-level electronic data for program evaluation and improvement in HIV patient care from three perspectives: 1) technical, organizational, and behavioral factors that impact perceptions of routine data systems and willingness to use clinical decision support tools informed by routine data to improve patient care; 2) the intersection of routine data quality and quality of care; and 3) how routine data can be leveraged for evaluation of public health programs and health system performance using quasi-experimental designs.

1.2. Theoretical Framework

This dissertation was primarily guided by the Performance of Routine Information System Management (PRISM) framework. The PRISM framework was designed to support the design, strengthening, and evaluation of routine health information systems (RHIS).[16] For this dissertation, the PRISM framework contextualized each aim as part of a broader exploration of routine EMR data to inform and improve HIV care and outcomes (Figure 1) as well as informed the coding schema for Aim 1.

Figure 1.1. Framework and Specific Aims



1.3. Specific Aims

In Aim 1, we explore perceptions of and willingness to use clinical decision support tools to inform HIV patient care among Haitian clinicians, HIV program managers, and Ministry of Public Health and Population stakeholders using mixed methods analysis of structured questionnaire and semi-structured interview data. This aim used a convergent, parallel mixed methods design, wherein the qualitative and quantitative data were collected and analyzed contemporaneously. Deductive thematic analysis framed by the Performance of Routine Information System Management (PRISM) was used to identify common elements around provider perceptions of clinical decision support tools as well as barriers and facilitators to tool use. Additional inductive coding was used to identify themes not captured by the frameworks.

Narrative weaving and joint display of data were used to integrate the qualitative and quantitative findings.

In Aim 2, we explore the association between EMR record missingness, interruption in ART treatment, and age group (pediatric vs. adult patients) using patient-level EMR data drawn from the Haiti iSante system and generalized linear regression models. Mixed effects regression models were used to explore the association between data missingness and interruption in ART treatment (at 6- and 12-months post ART initiation) by age group (pediatric: 0-14 years, adult: $\geq$15 years). Data missingness on a patient's intake form was assessed both as individual indicators (binary: missing or non-missing) and as a composite indicator (continuous and categorical: number of indicators of interest missing) for weight, current WHO stage, and current TB diagnosis. Our hypothesis was that higher data missingness would be associated with greater interruption in treatment and that this effect may be more pronounced among the younger age group. These associations were assessed using mixed effects modified Poisson regression models.

Finally, in Aim 3, we explore the impact of a technical assistance program to support HIV index testing and partner notification services (IT/PS) on uptake of antiretroviral therapy (ART) services using an interrupted times series analysis of patient-level routine data from the Ukraine HIV Medical Information System (HIV MIS). Mixed effects modified Poisson regression was used to assess differences in clinical factors and ART initiation timeliness between named partners and other ART initiators. Outcomes of interest for the secondary analyses were confirmed TB diagnosis, WHO HIV stage, and CD4 count at the time of ART initiation as well as timeliness of ART initiation. Our hypothesis was that named partners would initiate ART at earlier stages of HIV disease and would have decreased time between HIV testing and ART initiation. An uncontrolled time series analysis was used to evaluate the program impact on ART uptake using EMR data from 35 intervention facilities in 11 oblasts (regions) from October 2018 to May 2021. Our hypothesis was that the program would lead to both an immediate and slope level change in new ART initiations. The primary outcome was the number of new ART initiations per facility per month.

Chapter 2. "Following the data": perceptions of and willingness to use clinical decision support tools to inform HIV care among Haitian clinicians

2.1. Abstract

Introduction: Clinical decision support (CDS) tools informed by electronic medical records (EMRs) can support HIV care, including through case tracking, treatment and medication monitoring, and promoting provider compliance with care guidelines. However, these benefits are predicated on the willingness and ability of providers to effectively engage with and use these tools to inform patient care. There has been limited research into the technical, organizational, and behavioral factors that impact perceptions of routine data systems and willingness to use these EMR-informed CDS tools at scale in resource limited settings.

Methods: Our sample included fifteen purposively chosen HIV program experts, including active clinicians, HIV program managers, and national health policy leaders employed by the Ministry of Health in Haiti. Participants completed structured quantitative surveys and one-on-one qualitative semi-structured interviews about their perceptions of and experiences with iSante, the most widely used EMR in Haiti, and CDS tools.

Results: Study participants had high levels of familiarity and experience with iSante and CDS tool use. The majority of patient-facing respondents said that EMR and CDS tool use would improve their skills and patient engagement, and all said that additional CDS tools would be beneficial to their work. The primary motivator for CDS tool use was a perceived benefit to quality of care, including improved provider time use, efficiency, and decision-making ability, and, ultimately, patient outcomes (e.g., reduced viral load and better ART retention). Decision-making autonomy was a common theme in the interviews, particularly around how CDS tools could support but should not supplant provider knowledge and experience. Participants highlighted the need for sufficient provider training/sensitization, inclusion of providers in the system design process, and prioritization of tool user-friendliness as key mechanisms to drive tool use and impact. Some participants noted that systemic issues, such as limited laboratory capacity, may reduce the usefulness of CDS alerts, particularly concerning differentiated care and priority viral load testing.

Conclusion: Respondents had largely positive perceptions of EMRs and CDS tools, particularly due to perceived improvements in quality of care. To improve tool use, stakeholders should prioritize tool user-friendliness and provider training and address systemic health system issues.

2.2. Introduction

Advancing technology and broadened telecom access has expanded the promotion and adoption of technological solutions to public health issues around the globe.[17] As part of this, there has been a push for the development of robust, interoperable digital health management information systems (HMIS), including electronic medical record systems (EMRs), in many countries over the past decades, including in low- and middle-income countries (LMICs).[18,19] These systems allow for rapid collection and analysis of a wide variety of aggregate and patient-level indicators. These data can allow facility, regional, national, and global decision-makers to identify spatiotemporal disease and service provision trends, optimize resource allocation, conduct program evaluation, better target quality improvement measures, and tailor individual patient care through various mechanisms such as clinical decision support (CDS) tools.[19–22] CDS tools generally join patient information with “a computerized clinical knowledge base” to generate “patient-specific assessments or recommendations” through alerts or reminders.[23]

Chronic conditions such as HIV/AIDS require regular patient interactions, laboratory tests, and detailed treatment maintenance.[24] EMRs and EMR-informed CDS tools can support HIV care through case tracking, treatment and medication monitoring, and promoting provider compliance with testing and treatment guidelines. In both high-income countries and LMICs, such systems and tools have been shown to result in higher quality of care and better patient outcomes, including improved data quality, better adherence to testing and treatment guidelines, reductions in missing laboratory results, and reduced patient loss to follow up.[7–11,23,25–27] However, these benefits are predicated on the willingness and ability of providers to effectively engage with and use EMRs and CDS tools to inform patient care. There are a number of barriers to the implementation and use of EMRs and CDS tools, particularly in LMICs, including logistics (e.g., unstable electricity, outdated or poorly functioning technology), human resources (e.g., low computer literacy, insufficient training or supportive supervision), and personal/professional (e.g., not seeing CDS tools as beneficial to care, perceived threats to professional autonomy, and poor perceptions of data quality).[7,28–33] Rapidly evolving care and treatment guidelines, and issues translating these guidelines into machine-readable algorithms, also pose technical challenges in developing and maintaining CDS tools.

In Haiti, there are multiple EMRs used by different facilities. The largest, iSante, was originally developed in 2005 in partnership between the Haiti Ministry of Health (MSPP), US Centers for Disease Control, and the International Training and Education Center for Health (I-TECH, a center in the University of Washington’s Department of Global Health) to assess quality of care across HIV, TB, maternal and child health, nutrition, and immunization indicators.[34–36] Use of iSante has since spread to cover over 1.8 million primary care patients and more than 200,000 PLHIV across 162 facilities, representing roughly 75% of all facilities offering HIV services in the country. While prior research has shown the acceptability and feasibility of iSante-informed CDS tools to inform and improve HIV care in Haiti through a pilot study, there has been limited research into the technical, organizational, and behavioral factors that impact perceptions of routine data systems and willingness to use these EMR-informed CDS tools at scale.[37] This study sought to better understand such perspectives among Haitian providers and national health policy leaders.

2.3. Methods

Design

Data for this analysis were collected as part of a larger mixed methods study that sought to develop CDS tools to support antiretroviral therapy (ART) adherence and maintain HIV viral suppression, including a machine-learning model for predicting high viral load risk using iSante EMR data to support targeted prevention and early intervention services as part of differentiated service delivery (see Supplemental Figure 2.1). Additional information on development of the iSante system and CDS tools as part of differentiated care in Haiti can be found in prior publications.[35,37] This study employed a mixed methods convergent, parallel design, wherein qualitative and quantitative data were collected and then analyzed concurrently.[38]

Sample

Participants were purposively chosen based on their knowledge of and experience with HIV care in Haiti and the iSante system as well as their interest and experience in advising the Ministère de Santé Publique et de la Population (MSPP) on HIV care norms and guidelines, with selection informed by staff of CHARESS, a Haitian non-governmental organization that supports the quality and accessibility of the public-sector health care system in Haiti in partnership with the MSPP. Our participants included active clinicians, HIV program managers, and national health policy leaders employed by the MSPP. Two participants completed the quantitative survey but not the qualitative interviews due to personal reasons and were excluded from the analysis, for a final sample size of 15.

Data Collection

Participants were contacted by phone, informed about the study and objectives, read an informed consent form, and provided verbal consent to participate. Participants completed structured quantitative surveys online, followed by individual semi-structured interviews. Survey and interview questions explored prior and present iSante use, general perceptions of iSante and iSante-informed CDS tools, and factors affecting CDS tool adoption. As part of the larger study, participants were asked to provide input on potential formats for the proposed viral load risk estimation tool, an example of which can be found in the appendix, as well as the appropriateness of CDS tools to cue providers around HIV viral load testing at different frequency intervals depending on the risk level of patients for HIV viraemia (cuing providers for more frequent testing for those at high risk and less frequent testing for those at low risk). Interviews were conducted in person or via Zoom between July and September 2021 by JJ and CT, who also transcribed and translated the data.

Analysis

Quantitative data were analyzed through descriptive statistics and frequency tables. Qualitative data were analyzed using a directed content approach using a codebook guided by the Performance of Routine Information System Management (PRISM) framework.[16,39] PRISM was designed to support the design, strengthening, and evaluation of routine health information systems (RHIS) in resource-limited settings. Inductive coding was used to identify additional concepts not covered by the framework-informed codebook and to ensure that participants' language and voices were represented in the analysis. Our coding schema can be found under Supplemental Table 2.1. Transcripts were segmented by one member of the study team (AS) and then independently dual coded by AS and SK. Coding discrepancies were resolved through discussion. Queries of coded data were used to synthesize participant experiences into three primary thematic areas roughly corresponding with the behavioral determinants (theme 1) and organizational and technical determinants (theme 2) of the PRISM framework as well as a third theme pertaining to a broader health system context not covered by the framework. Qualitative data were analyzed using ATLAS.ti Web (v.4.5.0),[40] and quantitative data were analyzed using R (v 4.1.1).[41]

Ethics approval

This study protocol was approved by the University of Washington Human Subjects Division (#STUDY00011157) and the MSPP's National Bioethics Committee (#2021-13). All participation in the qualitative study was voluntary, and invitations to participate included a written participant information sheet about the study.

2.4. Results

In total, fifteen healthcare providers participated in the study. Participant demographics are detailed in Table 2.1. Overall, three-fifths of respondents were female (n=9, 60%) and the majority were medical doctors (n=13, 87%). Most participants worked in health facilities (n=11, 73%), with three working as HIV program managers for PEPFAR implementing partners and one for the MSPP. Of those who had experience working directly in patient-facing clinical settings (n=13), all but one had worked as a health professional for more than 10 years (n=12, 92%).

Table 2.1. Participant characteristics

Characteristic	**n**	**(%)**
Sex		
Female	9	(60%)
Male	6	(40%)
Cadre		
Nurse	1	(7%)
Psychologist	1	(7%)
Doctor	13	(87%)
Professional role		
Clinical service provider	5	(33%)
Site coordinator	7	(47%)
HIV program manager	2	(13%)
MSPP program manager	1	(7%)
How long have you worked as a health professional?		
3-5 years	1	(7%)
6-10 years	2	(13%)
11-20 years	9	(60%)
>20 years	3	(20%)

In how many different health care facilities have you provided care (sites in Haiti)?	
1	3 (20%)
2-4	7 (47%)
5-10	4 (27%)
>10	1 (7%)

Study participants had high levels of familiarity and experience with iSante use. Participants who used iSante in their routine work (n=12) reported using it every day (n=8, 67%) or a few days per week (n=4, 33%) when not with patients to review summary reports or patient data. Of the 11 participants who routinely engage directly with patients, nearly all (n=10, 91%) reported using iSante for every or almost every patient visit. We identified three primary themes characterizing provider perspectives on how CDS tools support patient care and can be improved moving forward: (1) CDS tools improve quality of care by facilitating informed decision-making; (2) CDS tool use can be improved by providing quality training, user-friendly interfaces, and seeking early provider input; and (3) CDS tools should consider systems-level issues and limitations during design and implementation.

CDS tools improve quality of care by facilitating informed decision-making

Provider motivation was the primary behavioral determinant of EMR and CDS tool use discussed by participants. Most respondents felt iSante and CDS tools had a positive impact on quality of care, which served as a motivator for system and tool use. Of the 11 participants that routinely engage with patients, none reported that iSante use negatively impacted their focus on the patient, and five (45%) reported improved patient focus. Respondents also felt that the current alerts and reminders were useful, with all but one who used iSante in their routine work reporting them as generally (n=2, 17%) or very useful (n=9, 75%). Similarly, most respondents said that additional reminders, alerts, or other decision-making tools would be quite (n=4, 31%) or very (n=8, 62%) beneficial.

In the qualitative interviews, providers appreciated how the system facilitated improved access to data, therefore simultaneously improving provider decision-making. CDS tools helped providers be more proactive by alerting them to potential issues, which was felt to be particularly important when providers had high patient volumes:

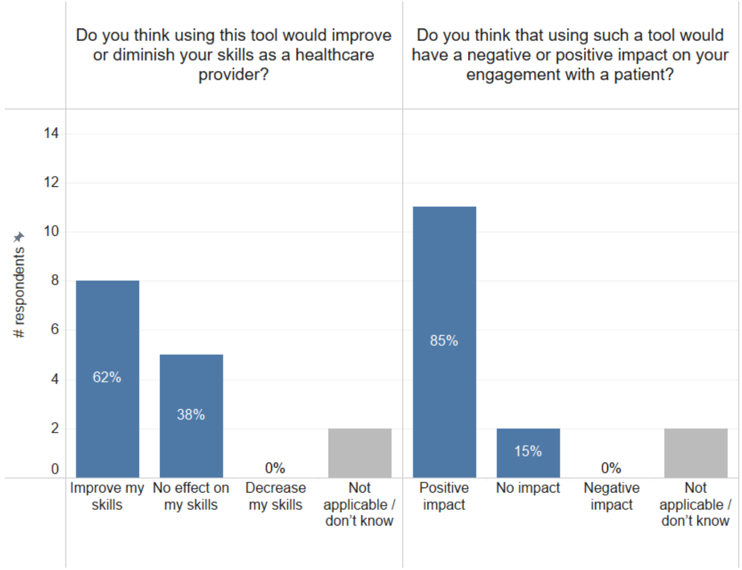
> *"…[T]he fact that we are following the data, the information, I think that will allow us to make better decisions. Because we are seeing everything on iSante." (Doctor, facility coordinator)*
>
> *"I think the introduction of this type of electronic tool is a very good thing for us as well as for iSante. For example, when we have people who have high viral loads…Before, we had no alert, but now we have it on the cover page of the patient's file. As soon as something is not right, we notice it…" (Doctor, clinical service provider)*

Participants also appreciated how the system improved efficiency because it "brings together several pieces of information" and helps to "reduce the time needed to analyze certain information" by automating calculations originally done by providers:

> *"[T]his tool does the risk estimation…Based on how the tool is designed or developed it allows you to spend less time on things you would have otherwise spent more time on." (Psychologist, clinical service provider)*

Some providers also suggested that CDS tools would help providers break out of ineffective routines by highlighting different aspects of the patient file and flagging potential issues that may not have been as evident without CDS.

Figure 2.1. Participant perceptions on a proposed new iSante viral load patient alert tool



Note: Not applicable / don't know responses are excluded from percentage calculations

"I think it would be a very important thing if we introduce [the proposed CDS tool] to iSanté, because it would attract the attention of the providers and that would improve the care of the patients, and it would be done faster too." (Doctor, site coordinator)

"No, [CDS tools] won't hinder the work - on the contrary, they would make the work easier." (Nurse, clinical service provider)

"I think this [CDS tool] will help the provider follow the patient better so that he doesn't miss important things, because if there are tools that will help them manage this, they will be more proactive. This will allow them to make decisions, it will allow the provider to act faster to help the patient. This would help patients avoid reaching a stage they should not have been reached." (Doctor, site coordinator)

"[The CDS tool]...will help the caregiver to make appropriate decisions, to make timely decisions to enable patients to benefit from better care..." (Doctor, clinical service provider)

"We are looking for the well-being of the patient...if there is a tool that is going to help us, we welcome this tool." (Doctor, clinical service provider)

Despite beliefs that data and recommendations from CDS tools could support provider decision-making, providers felt that these data systems should not supplant provider knowledge and experience:

> *"These tools will not replace a health professional, a provider. These tools are there to help the provider…[T]ools are there as an accompanist and can never replace a medical decision taken by a health professional." (Doctor, clinical service provider)*

When asked how they would respond to a risk estimate from a CDS tool that differed from their professional opinion, no respondents said that they would ignore the estimate. Instead, the majority (n=13, 87%) said they would want to better understand how the risk estimate was determined. Rather than acting as a stand-alone decision-making mechanism, CDS tools were generally viewed as a useful supplemental source of information and prompting for providers, who could then integrate it into their existing professional clinical decision-making process.

A few providers raised concerns about over-reliance on CDS tools, which could limit critical thinking skills development and lead providers to miss inclusion or consideration of data not highlighted by the tools, such as drug stockouts or patient financial constraints. Providers felt this overreliance could ultimately lead to decreased quality of care:

> *"Now you have to remember that each patient is unique, and these tools will never take into consideration all the individual parameters. There are aspects that we risk missing, so we will always have to refer to the clinician for his experience and expertise, and to the professional rigor to make appropriate decisions…we're going to have to adapt this treatment to the reality of the patient to try to get the best out of the situation." (Doctor, HIV program manager)*

Similarly, some providers expressed concerns about the accuracy of the CDS prediction models if informed by incomplete or inaccurate data, and the potential negative impacts of incorrect information on decision making, trust in providers, and patient care. The majority (80%) of respondents believed that iSante data quality was very important for the quality of patient care, and over half (54%) of respondents felt that inaccurate data could lead to patient harm. Providers were particularly concerned that poorly completed data might lead to false alerts or missing key information.

> *"My biggest concern is if the things that we say will be respected if we have this tool. Are they going to fill the files correctly, so it doesn't give me a false alert?" (Doctor, facility coordinator)*

CDS tool use can be improved by providing quality training, user-friendly interfaces, and seeking early provider input

Organizational factors impacting iSante and CDS tools were discussed in the interviews, with many participants highlighting the need for training and sensitization to the iSante system and new CDS tools, particularly focused on explaining the purpose and potential benefits of the tools. A better understanding of these benefits could help overcome the perceived burden from learning and using new systems and tools, a commonly cited barrier to tool uptake among participants.

> *"You can't just come with it and tell the provider 'here use it.' If they sensitize the provider on the importance of the tool, I think the message would get to the provider better and they are more likely to accept it. But if you put it on a version and you tell the person 'here is what you need to do'…if the person is not sensitized to see the importance of the tool and see how it can ameliorate the quality of care provided to the patient, I think it would be forgotten." (Doctor, facility coordinator)*

Technical factors, particularly CDS tool complexity, were also discussed as potential barriers to widespread adoption and use. Participants advised prioritizing adaptations focused on improved usability of iSante and CDS tools to improve uptake. Strategies suggested by providers to improve uptake and usability included using iterative feedback processes and early involvement of providers to ensure that the tools accurately reflect the on-the-ground reality experienced by providers.

> *"Don't forget sometimes when you are doing the programming, you don't know exactly the reality of the people. It is true sometimes you do certain planning but when you get to the reality you can't adapt it because it doesn't suit." (Doctor, facility coordinator)*

Providers also highlighted the importance of ensuring the tools reflect current care practices and guidelines. Outdated CDS recommendations, such as suggesting switching patients to outdated ART regimens, could lead to decreased trust in system outputs.

> *"I told you my concern was the fact that [the CDS tool] was not updated. When the person looks and sees that they are giving [recommendations for an outdated ART regimen], the person would question the use of this tool." (Doctor, clinical service provider)*

CDS tools should consider systems-level issues during design and implementation

EMRs and CDS tools operate within a broader healthcare and health system context, and systems-level issues can constrain the ability of providers to use and follow guidance provided by EMRs and CDS tools. Limited access to electricity and network connectivity was a commonly cited barrier to iSante and CDS tool implementation and use.

> *"The challenge that we face is not in the tool, it is something we encounter very often here. It is an energy problem. I might have the document but I spend a week with frequent power outages. The patients come and we have to use hard files to see the patient. The tool is there but we cannot use it." (Doctor, facility coordinator)*

The majority (69%) of respondents said the resources at their facility were "adequate" to support the effective use of iSante and maintain up-to-date and accurate data. In the context of scaling iSante and CDS tools nationally, however, some respondents felt that CDS tools should be designed to address the limited or intermittent electricity and network access experienced by many facilities across Haiti, such as allowing for offline functionality and developing clear standard operating procedures for providers to follow in the absence of power or network connectivity.

Some participants noted that limited laboratory capacity in Haiti may reduce the usefulness of CDS alerts for prioritized viral load testing for patients identified as high-risk. Due to high patient loads and limited testing capacity nationally, prioritizing certain patients for viral loads may have negative impacts on non-prioritized patients. To address this concern, one participant suggested involving critical national stakeholders, such as the Laboratoire National de Santé Publique, in the design and implementation process to help address these limitations.

> *I think [the CDS tool] is a very good idea, but to implement the idea the national laboratory needs to be aware and be part of the discussions. Would they have the capacity? Because sometimes they have problems with equipment, we receive the results late." (Doctor, facility coordinator)*

2.5. Discussion

Our results showed that Haitian providers and MSPP stakeholders hold generally positive perceptions of the iSante system and CDS tools. Of respondents who routinely provide care to patients, all reported using iSante daily or several days a week and said that iSante use either did not affect or improved focus on the patients, and almost all said that CDS tools were beneficial to their work.

The primary motivator for iSante and tool use discussed by participants was a perceived benefit to quality of care. Respondents highlighted that system use can improve provider time use, efficiency, and decision-making ability, and, ultimately, patient outcomes (e.g., reduced viral load and better ART retention). This is an important finding, as perceived usefulness, defined in the Technology Acceptance Model as "the degree to which a person believes that using a particular system would enhance his/her job performance," of EMRs and CDS tools has been shown to be an important factor in adoption and use.[42] A number of studies from other resource-limited settings have echoed our findings, highlighting the importance of perceived usefulness on provider perceptions of CDS tools.[43–47]

Our results showed that provider autonomy was a common theme when discussing CDS tools, particularly about how such tools could not replace the clinical expertise of providers. A number of studies have identified threats to provider autonomy as a barrier to CDS implementation and adoption, although much of this research has been conducted in high-income settings where provider dynamics may differ from those in resource-limited settings.[48–50] Two studies of providers in Malaysia found that intention to adopt CDS tools was negatively impacted by threats to provider autonomy, defined by the authors as “the degree to which a physician believes that using a particular system decreases his/her control over the conditions, processes, or contents of his/her work.”[32,51] In our data, however, relatively few providers framed threats to autonomy as necessarily being a barrier to adoption; instead, providers were careful to position CDS tools as an additional source of information to supplement their knowledge and expertise in informing their clinical decision-making process. In addition, only one participant said that they would disregard CDS recommendations that went against their professional judgement. Hendriks et al. proposed shifting our view of autonomy to focus on “enabling the physician to make decisions in accordance with their professional goals and values and the goals and values of the patient,” which does not conflict with the idea of CDS tools supporting clinical decision making.[52] Research on provider perceptions of CDS tools in Bangladesh and Mali found that expectations of threats to provider autonomy recorded at baseline significantly predicted perceived threats to autonomy after tool use, suggesting that purposeful framing of CDS tools as a support for providers rather than a replacement for their expertise, in other words as facilitating rather than decreasing provider autonomy, may improve level of adoption and impact of the tools.[53]

In our data, respondents highlighted the importance of data quality on quality of care and expressed concerns over potential negative impacts to patient care and trust in providers if inaccurate or incomplete data resulted in false CDS tool alerts or recommendations. Perceived accuracy has been shown to facilitate trust in and use of CDS tools, particularly for predictive, machine-learning algorithms, where the outcome has yet to occur and therefore cannot be verified and which often employ algorithms not well understood by the end user.[54,55]

One common theme throughout the interviews was an emphasis on the need for sufficient provider training and sensitization to CDS tools, particularly with providers who may struggle to incorporate new technology into established service routines. Insufficient training has been found to be a primary barrier to successful EMR and CDS tool implementation and adoption in both high-income and resource-limited settings.[7,30,33] Similar results to ours were found in a study of a CDS tool to promote viral load testing in Kenya, which found that routine care provision patterns were negatively associated with tool acceptance and use but that education on tool benefits decreased this barrier.[56] Interestingly, technological literacy, which has been shown to be an important factor in prior CDS tool research, was only brought up by one respondent when asked about potential barriers to widespread CDS tool adoption in Haiti, although this may be due to our purposeful sampling of providers who were experienced iSante users.[7]

EMRs and EMR-informed CDS tools also benefit from functioning technical and health system infrastructure. In their systematic review of EMR-based CDS tools in resource-limited settings, Oluoch et al. found that limited access to electricity and network connectivity were major barriers to CDS tool implementation and adoption.[7] Our findings revealed that this was a primary concern of our respondents as well, with limited technical infrastructure being the most commonly cited perceived barrier to large-scale adoption and routine use of iSante and CDS tools. While most respondents reported that they had sufficient resources to support the effective use of iSante and maintain up-to-date and accurate data at their facilities, this may not be the case for many health facilities in Haiti, with an estimated 24% of all facilities and 42% of clinics not having regular access to power.[57]

CDS alerts and reminders need to be actionable in the context of the broader care system; the full benefits of CDS tools will not be realized if providers are unable to follow tool guidance due to health system limitations. Such concerns about health system constraints were raised in the interviews, particularly how limited laboratory capacity may negatively impact the ability of providers to request prioritized viral loads when prompted by a CDS tool. Related to this, a number of participants emphasized the importance of including providers and other stakeholders, such as the national laboratory, in the CDS tool design and implementation process to ensure the tools are user-friendly, relevant to actual on-the-ground care provision (i.e., using up-to-date treatment regimens and care guidelines as well as incorporating the realities of stockouts, etc.), and take into account broader health system limitations to avoid further overburdening systems which could, in the context of differentiated HIV care, cause decreased quality of care for non-prioritized patients.

Directly incorporating the views of users can help inform current and future efforts to develop, implement, and scale EMR-informed CDS tools in resource-limited settings. Trinkley et al. proposed an implementation science-informed, user-centered design approach to CDS tool development and implementation, including multilevel stakeholder engagement (e.g., providers, ministry officials, national laboratories, etc.), an iterative development process, and "thoughtful deployment" (e.g., providing necessary support for implementation, such as end user training and sensitization), all approaches highlighted by our respondents as key to facilitating CDS tool implementation and adoption.[58]

Strengths and Limitations

To promote transparency and methodological rigor, this study utilized the Consolidated Criteria for Reporting Qualitative Research (COREQ) framework, a 32-point checklist for qualitative data analysis that covers eight constructs under three domains: research team and reflexivity (personal characteristics and relationship with participants), study design (theoretical framework, participant selection, setting, and data collection), and analysis and findings (data analysis and reporting).[59] A completed COREQ report can be found under Supplemental Table 2.2.

Respondents were selected in part due to their knowledge and expertise in the Haiti HIV program and experience with iSante and therefore their views may not be representative of all providers throughout the country, which may account for the decreased focus on data quality and technical literacy as compared to similar studies. However, their expertise gives them valuable insight into EMR and CDS tools in the national context. Finally, the limited sample size precluded statistical testing or meaningful disaggregation (e.g., by provider type) of the quantitative results.

2.6. Conclusion

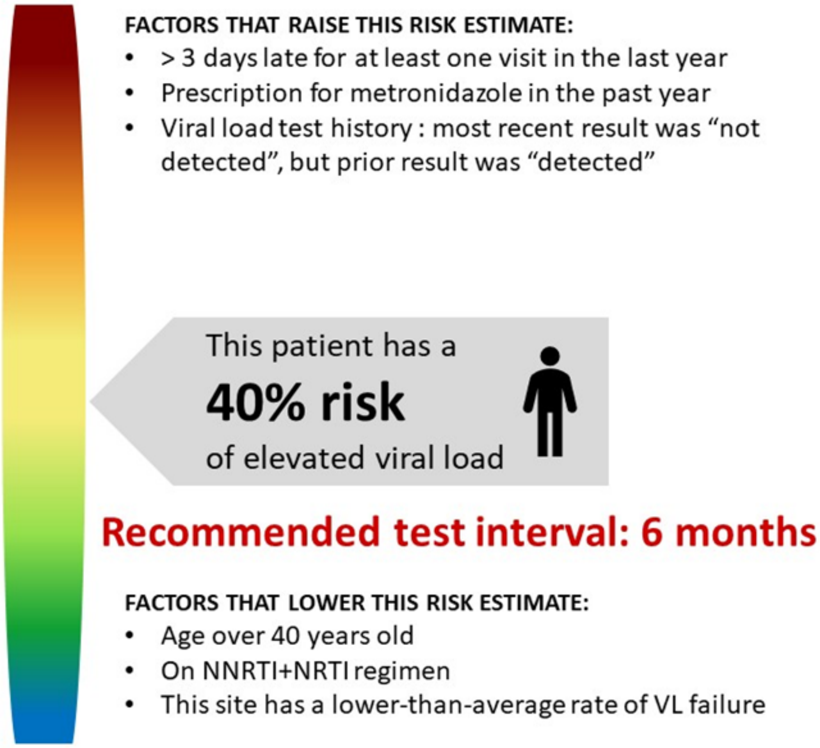
Respondents had a high level of iSante use and most had positive perceptions of iSante and CDS tools. Key motivators to tool use included perceived benefits to quality of care, including improved efficiency, decision-making ability, and patient outcomes. Participants highlighted the need for sufficient provider training/sensitization, inclusion of providers in the system design process, and prioritization of tool user-friendliness as key mechanisms to drive tool use and impact. However, systemic issues, such as access to electricity and network as well as laboratory capacity, may limit the adoption and impact of these tools.

2.7. Appendix

Supplemental Table 2.1. Coding schema

Domain	Code	Sub-code (if applicable)
Technical	IT system/reporting form complexity	
	iSante system performance	
	System up-to-date and in line with modern standards of care	
	Provider input on system/tool design	
	CDS tool accuracy	
Organizational	Availability of resources	
	Provider training/sensitization	
Behavioral	Provider familiarity with iSante/CDS	
	Provider burden from using system	
	Technological competence	
	Motivation	Quality of care: Patient outcomes
		Quality of care: Patient-centered care
		Quality of care: Time use/efficiency
		Quality of care: Patient tracking/follow-up
		Quality of care: General quality of care
		Provider habits/routine
		Professional autonomy
		General perceptions of iSante/CDS
Data quality	Data accuracy	
	Data completeness	
Systems-level	Health system functionality	
	Electricity and network access	

Supplemental Figure 2.1. Example of proposed high viral load risk prediction tool



FACTORS THAT RAISE THIS RISK ESTIMATE:

- > 3 days late for at least one visit in the last year
- Prescription for metronidazole in the past year
- Viral load test history : most recent result was “not detected”, but prior result was “detected”

This patient has a

40% risk

of elevated viral load

Recommended test interval: 6 months

FACTORS THAT LOWER THIS RISK ESTIMATE:

- Age over 40 years old
- On NNRTI+NRTI regimen
- This site has a lower-than-average rate of VL failure

Supplemental Table 2.2. Consolidated criteria for reporting qualitative studies (COREQ) checklist

No	Item	Guide questions/description	Response
Domain 1: Research team and reflexivity			
Personal Characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	JJ and CT
2.	Credentials	What were the researcher's credentials? *E.g., PhD, MD*	AS – MPH JJ – MA CT – MD JH – MD SK – BA KBS – PhD, MPH AW – PhD, MPH JP – PhD, MPH NP - PhD, MPH
3.	Occupation	What were their occupations at the time of the study?	AS – PhD Student JJ – Psychologist Mentor CT – Clinical Specialist JH – Executive Director SK – Student Researcher KBS – Acting Assistant Professor AW – Assistant Professor JP – Associate Professor NP – Assistant Professor
4.	Gender	Was the researcher male or female?	The research team was of mixed gender
5.	Experience and training	What experience or training did the researcher have?	All research team members have extensive experience conducting qualitative health research
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	Yes
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e*.g., personal goals, reasons for doing the research*	At the beginning of each interview, we explained the primary motivations for the research project and the interviewer's role in the study
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g., *Bias, assumptions, reasons and interests in the research topic*	Organizational affiliation of the interviewers was reported in the manuscript. The interviewers were highly familiar with the study context (HIV care in Haiti and iSante/CDS tool development and implementation) and had engaged with some participants in a professional capacity prior to the study.
Domain 2: Study Design			
Theoretical framework			

9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis*	Directed content analysis
Participant selection			
10.	Sampling	How were participants selected? *e.g., purposive, convenience, consecutive, snowball*	Purposive, based on their knowledge of and experience with HIV care in Haiti and the iSante system as well as their interest and experience in advising the Ministère de Santé Publique et de la Population on HIV care norms and guidelines
11.	Method of approach	How were participants approached? e*.g., face-to-face, telephone, mail, email*	Participants were initially approached to participate in this round of data collection by email and/or by phone
12.	Sample size	How many participants were in the study?	15 participants completed both the quantitative survey and qualitative interview
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	Two participants completed the quantitative survey but not the qualitative survey for personal reasons
Setting			
14.	Setting of data collection	Where was the data collected? e*.g., home, clinic, workplace*	The location varied by participant depending on their preferences and availability
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16.	Description of sample	What are the important characteristics of the sample? *e.g., demographic data, date*	Relevant demographics are presented in Table 1, including cadre and experience engaging with the iSante system. More detailed information was not reported on to maintain confidentiality.
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	The tools were not pilot tested. The interviews were semi-structured, with interviewers guiding the discussion to sufficiently cover the primary questions of interest.
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	Yes – audio recordings were taken of each interview with the permission of the participants

20.	Field notes	Were field notes made during and/or after the interview or focus group?	No
21.	Duration	What was the duration of the interviews or focus group?	Duration varied, ranging from 16 to 70 minutes
22.	Data saturation	Was data saturation discussed?	Yes
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	There were two data coders in this study.
25.	Description of the coding tree	Did authors provide a description of the coding tree?	All codes used have been provided in the supplemental materials
26.	Derivation of themes	Were themes identified in advance or derived from the data?	Both. Primary codes were derived from the PRISM framework, but inductive coding was used to develop more detailed sub-codes within the framework's constructs as well as codes not covered by the framework
27.	Software	What software, if applicable, was used to manage the data?	ATLAS.ti and Excel (qualitative) and R (quantitative)
28.	Participant checking	Did participants provide feedback on the findings?	No
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.*g., participant number*	Quotes were identified based on participant cadre and professional role
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Diverse cases were mentioned where applicable (e.g., "…only one participant said that they would disregard CDS recommendations that went against their professional judgement")

Chapter 3: Associations between Electronic Medical Record Data Missingness and Interruption in Antiretroviral Therapy among Adults and Children Living with HIV in Haiti

3.1. Abstract

Introduction: Children (aged 0-14 years) living with HIV (CLH) often have lower rates of HIV diagnosis, treatment, and viral load suppression. In Haiti only 63% of CLH know their HIV status (compared to 85% overall), 63% are on treatment (compared to 85% overall), and 48% are virally suppressed (compared to 73% overall). Electronic medical records (EMRs) can improve HIV care and patients, but these benefits are largely predicated on providers having access to high quality data. We hypothesize that data missingness will be associated with greater interruption in ART treatment (IIT) and that this relationship will be larger among CLH.

Methods: We assessed associations between patient intake record data missingness and IIT status at 6- and 12-months post ART initiation using patient-level data drawn from iSante, the most widely used EMR in Haiti. Missingess was assessed for TB stage, WHO HIV stage, and weight using a composite score indicator (number of indicators missing). Effect estimates were marginal parameters from multilevel modified Poisson models with robust error variances and random intercepts for facility to account for clustering.

Results: Data were drawn from 50 facilities and comprised 31,457 PLHIV patient records, of which 1,306 (4.2%) were pediatric. Pediatric patients were more likely than adult patients to experience IIT (33.0% vs. 23.4% at 6 months, p<0.001) and their patient records had higher data missingness (55.5% of pediatric records had no indicators of interest missing, compared to 74.1% of adult records, p<0.001). Among pediatric patients, each one additional indicator missing was associated with 1.34 times greater likelihood of being IIT at 6 months (95%

confidence interval [CI] = 1.08–1.66, p = 0.008) and 1.24 times greater likelihood of being IIT at 12 months (95% CI = 1.05–1.46, p = 0.010). These relationships were not statistically significant for adult patients. Compared to pediatric patients with zero missing indicators, pediatric patients with one, two, or three missing indicators were 1.59 (95% confidence interval [CI] = 1.26–2.01, p < 0.001), 1.74 (95% CI = 1.02–2.97, p = 0.041), and 2.25 (95% CI = 1.43–3.56, p = 0.001) times more likely to be IIT at 6 months, respectively. Among adult patients, compared to patients with zero indicators missing, having all three indicators missing was associated with being 1.32 times more likely to be IIT at 6 months (95% CI = 1.03–1.70, p = 0.030), while there was not association with IIT status for the other levels of missingness.

Conclusion: These findings suggest that improving EMR data quality may enable better quality of care and lead to greater care and treatment engagement, and that efforts to improve data quality should consider prioritizing pediatric patients.

3.2. Introduction

Despite improvements in HIV testing, care, and treatment and reduced HIV incidence over the last three decades, Haiti has the largest population of people living with HIV (PLH) in the Caribbean, with an estimated 1.8% of the population (150,000 persons), including nearly 6,000 children (aged 0-14 years) living with HIV (CLH).[60] CLH often have lower rates of HIV diagnosis, treatment, and viral load suppression.[61] In Haiti, CLH fare worse across all steps of the care cascade, with only 63% of knowing their HIV status (compared to 85% overall), 63% on treatment (compared to 85% overall), and 48% virally suppressed (compared to 73% overall).[60] Reviews of patient records in Haiti revealed that CLH were significantly less likely to initiate

ART in a timely manner as compared to adults aged 25-34 years, and, once initiated, were less likely than adults to be retained in ART treatment.[62,63]

Electronic medical records (EMRs) can improve HIV patient care and outcomes in multiple ways, including: 1) directly informing individual patient care, such as tracking clinical outcomes, ART adherence and retention, and patient follow-up, and 2) promoting provider compliance with treatment and care guidelines.[7,11,25,27,64–68] However, these benefits are largely predicated on providers having access to high quality data (i.e., reliable, timely, and non-missing).[69–71] Data missingness is both an element of quality of care (vis-à-vis non-compliance with reporting guidelines) and can itself lead to lower quality of care as missing data cannot be used to inform patient care.[72] Despite the importance of data quality in the value proposition of EMRs, the evidence base exploring the association between data missingness and patient outcomes is limited, especially in the LMIC context; while many studies of EMRs include both data quality and patient outcomes as indicators of interest, a direct association between the two is rarely assessed. In addition, no studies reviewed for this paper assessed this relationship by age cohort.

We hypothesize that data missingness will be associated with greater interruption in ART treatment (IIT) and that this relationship will be larger among CLH. We used ART patient data extracted from the iSante EMR system to explore the association between age group, data missingness and interruption in ART treatment (IIT).

3.3. Methods

Study design

This was a retrospective longitudinal study using patient-level routine EMR data.

Data source

We used patient-level clinical and pharmacy data extracted from iSanté, the most widely used EMR in Haiti and which covers over 1.8 million primary care patients and more than 200,000 unique records for PLH.[35,73] iSanté records include data on key HIV care cascade processes (e.g., clinical history, WHO HIV staging, etc.) and electronic pharmacy data (ART dispensing and continuation).

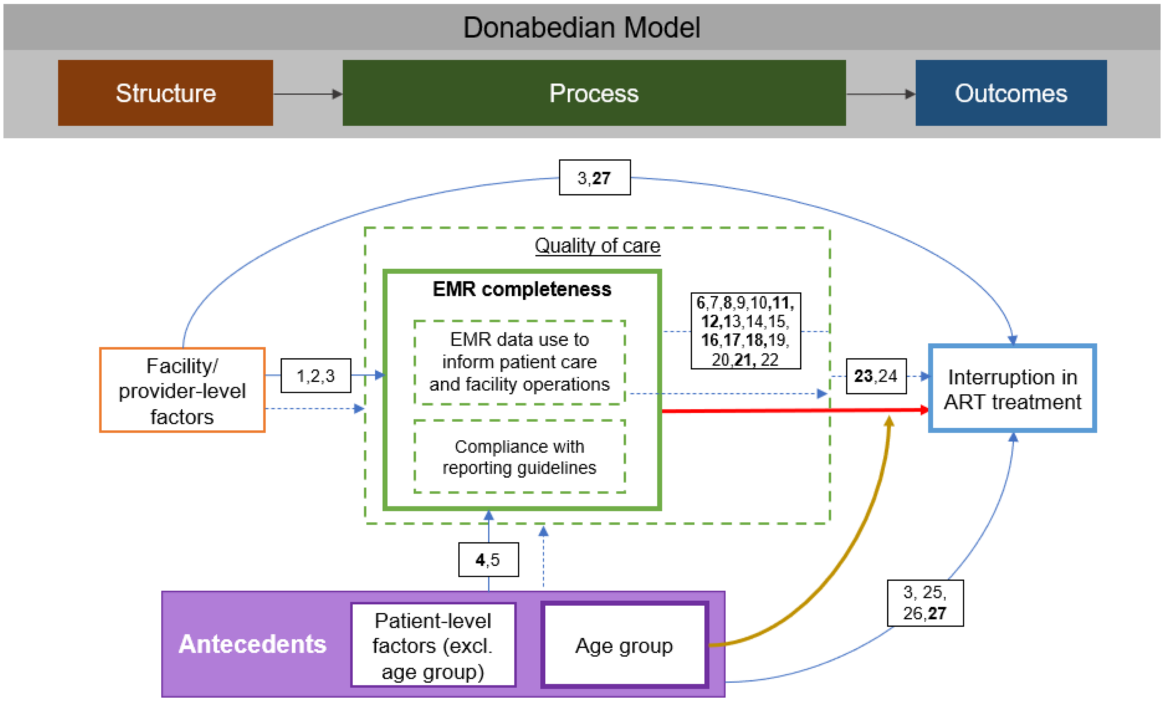
Sample

This analysis included data from 50 facilities and covered individuals who initiated ART between June 2016 and December 2021. Our analyses had a number of data exclusions. Twenty-four facilities were excluded from the analysis due to being prison-based facilities, had >20% of records entered more than 90 days after the visit date, or the mean number of prescription records per patient was less than five. Data before June 2016 were excluded to account for changes in treatment patterns following adoption of the test-and-treat approach to HIV care in mid-2016. The population included in the analysis were restricted to patients who initiated ART at least *n+2* months before the data extraction date (end of July 2022) to allow for sufficient follow up time to observe the outcome as well as to account for any delay in entry of patient files (e.g., for the 6-month retention outcome, data were restricted to those who had initiated ART by December 2021). Individuals without date of birth data (3.2%) were excluded as correct age group categorization was essential for the analysis. Additionally, to better assess the relationship between data missingness at intake and 6- and 12-month IIT, patients who completed their intake visit more than three months prior to initiating ART were excluded from the analysis (9.0%). A CONSORT flow diagram can be found under Supplemental Table 3.1.[74]

Conceptual model

Figure 3.1 shows our proposed causal model, which is situated within the Donabedian framework for quality of care as modified by Coyle and Battles to include medical antecendents.[75,76] The Donabedian framework divides care into three primary components: structure (i.e., the context in which care is delivered), process (i.e., actual service delivery), and outcome. In the context of HIV care and EMRs, these can be understood as: the facility/organizational context in which HIV care is delivered as well as the system aspects of the EMR (e.g., accessibility, usability); the provision of HIV care, including the use of the EMR to both document and inform care provided; and HIV outcomes (e.g., ART retention). The Donabedian model has been criticized for failure to account for antecedents, such as environmental and patient-level factors, which our analysis partially addresses by exploring the association between data missingness and interruption in treatment by age group.[76]

Figure 3.1. Conceptual model



Blue lines indicate proposed causal pathways; Red line indicates observed association of interest; **Yellow** line indicates effect modification by age; *Dashed* lines indicate unobserved pathways or variables

References (**bold** indicates systematic review): (1) Puttkammer 2016; (2) van der Bij 2017; (3) Forster 2008; (4) **Cook** 2022; (5) Terry 2019; (6) **Albagmi** 2021; (7) DesRoches 2008; (8) **Kruse** 2018; (9) Yates 2020; (10) Grissinger 2020; (11) **Jawhari** 2016; (12) **Oluoch** 2012; (13) Oluoch 2014; (14) Oluoch 2015; (15) Oluoch 2016; (16) Oluoch 2021; (17) **Gatiti** 2021; (18) **Campanella** 2016; (19) **Holroyd-Leduc** 2011; (20) Matheson 2012; (21) **Chaudhry** 2006; (22) King 2014; (23) **Hargreaves** 2019; (24) Ojikutu 2014; (25) Puttkammer 2018; (26) Abelman 2020; (27) **Frijters** 2020

Analysis

Outcome variable

The primary outcomes of interest were 6- and 12-month interruption in ART treatment (IIT) at their current facility, defined as being more than 28 days late in picking up ART medication as of the date 6- or 12-months after initiating ART. These definitions for IIT have been used in prior research in Haiti and other settings.[77–79]

Covariates

Age

Age groups were categorized as pediatric (0-14 years) and adult (≥15 years) as of the time of ART initiation.

Data missingness

Data missingness was defined as an indicator not being collected during the patient's intake visit. Assessment of missingness was restricted to indicators that were shared between both pediatric and adult intake forms and where missingness could be differentiated from absence of that issue (e.g., the headache symptomology field may be missing due to a patient not presenting with a headache or due to the provider failing to document that issue, whereas the World Health Organization [WHO] HIV stage indicator is expected to be completed for all patients).[80] Within these stipulations, we assessed missingness for weight, current WHO HIV stage, and current TB diagnosis. As the importance and impact of missingness for particular indicators may vary by age group (e.g., routine documentation of weight is generally of higher importance for pediatric patients), missingness was analyzed as both individual indicators (binary, missing or non-missing) and through a composite score indicator (continuous and categorical, number of indicators of interest missing).

Models

Associations between data missingness (exposure) and interruption in ART treatment at a patient's current facility (outcome) were assessed through marginal parameters from multilevel modified Poisson models with robust error variances. Modified Poisson models have been shown to provide unbiased estimates of the risk ratio (RR), important for non-rare binary outcomes where odds ratios estimated through logistic regression will over-estimate the risk ratio and potentially lead to improper interpretation of the results.[81,82] Random intercepts for facility were used to account for clustering. Sex, facility type and ownership, duration of iSante use at a given facility, and facility patient volume were included as fixed effects to control for potential confounding. Models were stratified by age group to understand the relationship between data missingness and IIT status within each age group. Additional models were run with age group as an interaction term with the continuous composite indicator to assess the statistical significance of age group as an effect modifier in the association between missingness and IIT.

Ethics approval

The secondary use of de-identified patient data from the iSanté EMR was approved by the University of Washington Human Subjects Division as non-engaged research (STUDY00016591 'Patient Risk Profiles for Interruption in Treatment (IIT) among People Living with HIV (PLHIV) in Haiti: Leveraging Health Information Systems and Prediction Models to Identify

Patients at High Risk'). The research was also reviewed and approved by the Haiti Ministry of Public Health and Population's National Bioethics Committee (Ref # 2223-26).

3.4. Results

In total, data were drawn from 50 facilities across 9 departments (of 10 total in Haiti) and comprised 31,457 PLHIV patient records. Of these, 30,151 (95.8%) were adult patients and 1,306 (4.2%) pediatric. The majority of patients (62.1%) were female. Most patients received care at health centers (60.6%) and hospitals (31.4%), while attendance at public versus private facilities was roughly equal (40.2% and 36.4%, respectively) and higher than at mixed ownership facilities (23.3%). The median duration of iSante use at each health facility was 17.5 years (IQR 15.8, 18.3), and median monthly patient volume was 348 (IQR 172 – 544). Table 3.1 further details participant and facility characteristics.

Table 3.1. Participant characteristics*

	Overall (n = 31,457)		**Adult** (n = 30,151, 95.8%)		**Pediatric** (n = 1,306, 4.2%)	
	n (%) / Med (IQR)		n (%) / Med (IQR)		n (%) / Med (IQR)	
Sex						
Female	19,544	(62.1%)	18,855	(62.5%)	689	(52.8%)
Male	11,913	(37.9%)	11,296	(37.5%)	617	(47.2%)
Age (years)	35	(27, 44)	35	(28, 44)	3	(0, 9)
Facility type						
Health Center	19,051	(60.6%)	18,319	(60.8%)	732	(56.0%)
Hospital	9,883	(31.4%)	9,406	(31.2%)	477	(36.5%)
Dispensary	2,523	(8.0%)	2,426	(8.0%)	97	(7.4%)
Facility ownership						
Mixed	7,337	(23.3%)	7,008	(23.2%)	329	(25.2%)
Private	11,466	(36.4%)	11,109	(36.8%)	357	(27.3%)

Public	12,654	(40.2%)	12,034	(39.9%)	620	(47.5%)
Duration of iSante use	17.5	(15.8, 18.3)	17.5	(15.3, 18.3)	18.1	(17.0, 18.3)
Monthly patient volume	348	(172, 544)	348	(172, 544)	408	(200, 626)

* Facility-related characteristics are described at the patient-level (e.g., proportion of patients initiating ART at a health center versus hospital or dispensary)

IIT status and indicator missingness are detailed in Table 3.2. Across all age groups, the proportion of patients IIT at 6 and 12 months were 23.8% and 29.3%, respectively. Overall, the weight indicator had the highest level of missingness (17.1% of patient records were missing weight data) while TB diagnosis had the lowest (4.5%). Both IIT status and data missingness were higher among pediatric patients. Pediatric patients were more likely than adult patients to be IIT at 6 months (33.0% vs. 23.4%, p<0.001) and 12 months (42.2% vs. 28.8%, p<0.001). Looking across age groups, only 55.5% of pediatric patient records had no indicators of interest missing, compared to 74.1% of adult records. Pediatric patient records were also more likely to have at least 3 indicators missing compared to adult records (3.1% vs. 1.3%, p<0.001). Variation in missingness across age group was greatest for WHO HIV stage, with 32.5% of pediatric records missing this indicator compared to 11.1% of adult records (p<0.001).

Table 3.2. IIT and indicator missingness

	Overall (n=31,457)		**Adult** (n=30,156)		**Pediatric** (n=1,310)		
	n	(%)	n	(%)	n	(%)	p-value*
IIT status							
6-month	7,477	(23.8%)	7,046	(23.4%)	431	(33.0%)	<0.001
12-month	9,222	(29.3%)	8,671	(28.8%)	551	(42.2%)	<0.001
Indicator Missingness							
Weight	5,365	(17.1%)	5,100	(16.9%)	265	(20.3%)	0.001
WHO HIV stage	3,780	(12.0%)	3,355	(11.1%)	425	(32.5%)	<0.001

TB diagnosis	1,417	(4.5%)	1,338	(4.4%)	79	(6.0%)	0.006
Composite missingness score (categorical)							
0	23,064	(73.3%)	22,339	(74.1%)	725	(55.5%)	<0.001
1	6,666	(21.2%)	6,232	(20.7%)	434	(33.2%)	<0.001
2	1,285	(4.1%)	1,179	(3.9%)	106	(8.1%)	<0.001
3	442	(1.4%)	401	(1.3%)	41	(3.1%)	<0.001

* Pearson's Chi-squared test

Results from continuous composite score models are in Table 3.3. Assessed as a continuous variable, higher values of the composite missingness score indicator were statistically significantly associated with greater likelihood of being IIT both 6 and 12 months among pediatric patients, while no association was observed among adult patients for either outcome. Among pediatric patients, each one additional indicator missing was associated with 1.34 times greater likelihood of being IIT at 6 months (95% confidence interval [CI] = 1.08–1.66, p = 0.008) and 1.24 times greater likelihood of being IIT at 12 months (95% CI = 1.05–1.46, p = 0.010). Our interaction models (not shown) revealed that the relationship between the composite score indicator and IIT status was statistically significantly larger among pediatric patients as compared to adult patients at both 6 months, where pediatric patients had a 25% greater risk of IIT for each additional missing element compared to adult patients (95% CI 1.02–1.53, p = 0.032), and 12 months, where pediatric patients had 18% greater risk of IIT for each additional missing element compared to adult patients (95% CI = 1.01–1.38, p = 0.040).

Table 3.3. Multivariable regression of 6- and 12-month IIT against composite missingness score (continuous) by age group

	Adult						**Pediatric**					
	6-month IIT			**12-month IIT**			**6-month IIT**			**12**		
	aRR	**95% CI**	**p-val.**	**aRR**	**95% CI**	**p-val.**	**aRR**	**95% CI**	**p-val.**	**aRR**	**95% CI**	**p-val.**
Composite missingness score	1.03	(0.92, 1.15)	0.579	1.02	(0.94, 1.10)	0.618	1.34	(1.08, 1.66)	0.008	1.24	(1.05, 1.46)	0.010
Sex												
Female	Ref	-	-	Ref	-	-	Ref	-	-	Ref	-	-
Male	1.05	(0.98, 1.11)	0.158	1.02	(0.97, 1.07)	0.396	0.93	(0.81, 1.08)	0.335	0.99	(0.88, 1.11)	0.870
Facility type												
Health Center	Ref	-	-	Ref	-	-	Ref	-	-	Ref	-	-
Hospital	0.84	(0.60, 1.16)	0.284	0.94	(0.59, 1.49)	0.795	0.86	(0.64, 1.15)	0.306	0.92	(0.67, 1.26)	0.609
Dispensary	0.81	(0.56, 1.17)	0.264	0.78	(0.54, 1.11)	0.166	1.13	(0.79, 1.62)	0.505	0.89	(0.62, 1.28)	0.533
Facility ownership												
Mixed	Ref	-	-	Ref	-	-	Ref	-	-	Ref	-	-
Private	0.95	(0.71, 1.28)	0.757	1.04	(0.74, 1.47)	0.811	0.87	(0.53, 1.44)	0.589	0.87	(0.60, 1.24)	0.435
Public	0.90	(0.65, 1.24)	0.513	0.96	(0.65, 1.42)	0.832	0.91	(0.69, 1.18)	0.462	0.85	(0.66, 1.10)	0.224
Duration of iSante use (years)	1.02	(0.97, 1.07)	0.526	1.04	(0.99, 1.08)	0.120	0.98	(0.93, 1.04)	0.496	1.00	(0.95, 1.04)	0.874
Monthly patient volume average (log)	0.82	(0.67, 1.00)	0.046	0.74	(0.58, 0.94)	0.012	0.98	(0.74, 1.28)	0.863	0.92	(0.75, 1.14)	0.460

Our composite score was also assessed as a categorical variable (Table 3.4) to understand the estimates of excess risk in absence of the assumption of a linear relationship in the risk of IIT with each additional level of missingness. Compared to pediatric patients with zero missing indicators, pediatric patients with one, two, or three missing indicators were 1.59 (95% confidence interval [CI] = 1.26–2.01, $p < 0.001$), 1.74 (95% CI = 1.02–2.97, $p = 0.041$), and 2.25 (95% CI = 1.43–3.56, $p = 0.001$) times more likely to be IIT at 6 months, respectively. At 12 months, pediatric patients with one, two, or three missing indicators were 1.54 (95% CI = 1.34–1.78, $p < 0.001$), 1.34 (95% CI = 0.82–2.20, $p = 0.241$), and 1.75 (95% CI = 1.08–2.85, $p = 0.023$) times more likely to be IIT, respectively, although this association was no longer significant for those with two indicators missing. Among adult patients, compared to patients with zero indicators missing, having all three indicators missing was associated with being 1.32 times more likely to be IIT at 6 months (95% CI = 1.03–1.70, $p = 0.030$), while having three indicators missing was not associated with IIT at 12 months and having one or two indicators missing was not associated with IIT at either 6 or 12 months.

Of note, none of the other patient or facility factors were statistically significantly associated with IIT status, except increasing facility volume being inversely associated with IIT status for adult patients in some models.

Table 3.4. Multivariable regression of 6- and 12-month IIT against composite missingness score (categorical) by age group

	Adult						Pediatric					
	6-month IIT			12-month IIT			6-month IIT			12		
	aRR	**95% CI**	**p-val.**	**aRR**	**95% CI**	**p-val.**	**aRR**	**95% CI**	**p-val.**	**aRR**	**95% CI**	**p-val.**
Composite missingness score												
0	Ref	-	-	Ref	-	-	Ref	-	-	Ref	-	-
1	0.94	(0.77, 1.15)	0.570	0.96	(0.85, 1.08)	0.484	1.59	(1.26, 2.01)	<0.001	1.54	(1.34, 1.78)	<0.001
2	1.14	(0.87, 1.51)	0.343	1.11	(0.91, 1.35)	0.295	1.74	(1.02, 2.97)	0.041	1.34	(0.82, 2.20)	0.241
3	1.32	(1.03, 1.70)	0.030	1.21	(0.95, 1.55)	0.122	2.25	(1.43, 3.56)	0.001	1.75	(1.08, 2.85)	0.023
Sex												
Female	Ref	-	-	Ref	-	-	Ref	-	-	Ref	-	-
Male	1.05	(0.98, 1.12)	0.196	1.02	(0.97, 1.07)	0.413	0.93	(0.81, 1.06)	0.291	0.99	(0.86, 1.13)	0.876
Facility type												
Health Center	Ref	-	-	Ref	-	-	Ref	-	-	Ref	-	-
Hospital	0.84	(0.57, 1.24)	0.380	0.94	(0.61, 1.46)	0.795	0.85	(0.61, 1.18)	0.340	0.92	(0.68, 1.25)	0.605
Dispensary	0.82	(0.56, 1.20)	0.304	0.79	(0.57, 1.09)	0.144	1.16	(0.86, 1.56)	0.335	0.90	(0.65, 1.25)	0.541
Facility ownership												
Mixed	Ref	-	-	Ref	-	-	Ref	-	-	Ref	-	-
Private	0.95	(0.71, 1.26)	0.719	1.04	(0.74, 1.45)	0.832	0.88	(0.58, 1.35)	0.566	0.87	(0.60, 1.26)	0.470
Public	0.90	(0.68, 1.20)	0.473	0.96	(0.62, 1.48)	0.852	0.92	(0.72, 1.18)	0.511	0.86	(0.69, 1.08)	0.195
Duration of iSante use (years)	1.01	(0.97, 1.06)	0.475	1.03	(0.99, 1.08)	0.098	0.98	(0.92, 1.03)	0.435	0.99	(0.95, 1.04)	0.796
Monthly patient volume average (log)	0.81	(0.68, 0.97)	0.022	0.74	(0.60, 0.90)	0.003	0.98	(0.74, 1.30)	0.882	0.91	(0.74, 1.13)	0.406

For the individual missingness indicators (Supplemental Table 3.1), only the WHO HIV stage indicator was associated with IIT status among pediatric patients, where pediatric patients with missing WHO HIV stage data on their intake form were 2.17 times more likely to be IIT at 6 months (95% CI = 1.79–2.64, $p < 0.001$) and 1.79 times more likely to be IIT at 12 months (95% CI = 1.54–2.08, $p < 0.001$) as compared to pediatric patients with non-missing WHO HIV stage data. Missingness for WHO stage among adult patients and missingness for weight and TB status among either age group were not associated with IIT status at either 6 or 12 months.

3.5. Discussion

In this retrospective longitudinal study of EMR data drawn from the iSante system in Haiti, we found that both data missingness and interruption in ART treatment were higher for pediatric patients as compared to adult patients; nearly one-third of pediatric patients were IIT at 6 months compared to just over one-fifth of adults, and nearly half of pediatric patients had missing values on their intake forms among the indicators of interest compared to just over one-quarter of adult patients. Data missingness showed a substantial and significant association with greater interruption in treatment, with adult patients being 30% more likely and pediatric patients more than twice as likely to be IIT at six months when all three indicators of interest were missing. The relationship between missingness and IIT status was stronger and more consistent among pediatric patients; pediatric patients showed statistically significantly greater likelihood of being IIT at 6 and 12 months for the composite score indicator both overall (continuous) and across all levels of missingness (categorical), while for adult patients this relationship was only significant at 6 months and for the highest level of missingness in the categorical analysis. Individual indicator missingess showed little association with IIT status, except for WHO HIV stage among pediatric patients. Within the modified Donabedian quality of care framework, our results show a link between the process of care provision (vis-à-vis compliance with reporting guidelines and/or data use for clinical decision making) and patient outcomes (IIT status) after adjusting for structural elements (facility characteristics), with the association being highly dependent on medical care antecedents (patient age group).[75,76]

There is a rich evidence base showing the potential impact of EMR use on HIV service provision and quality of care by promoting adherence to care guidelines, enabling higher quality patient data, improving provider efficiency, and informing patient care, tracking, and follow up.[7,11,25,27,64–68] The benefits of EMRs, however, are largely predicated on providers having access to quality data (i.e., reliable, timely, and non-missing) in order to inform their work, and there is a growing evidence base on the importance and impact of patient record quality (electronic or otherwise) on quality of care, care engagement, or health outcomes.[69–71] Prior research has shown that poor data quality can lead to lower quality of care, such as prescription errors, and poorer engagement with care.[83,84] Particularly relevant to this analysis, one study of over six thousand patient records collected from the National Clinical Audit for Rheumatoid and Early Inflammatory Arthritis found that missing baseline patient data was significantly associated with the odds of timely initiation of treatment being halved.[84] In a qualitative study of healthcare professionals in South Africa, participants reported viewing data quality as an critical element in the provision of quality healthcare services, including one nurse who noted that poor EMR information integrity can lead “to errors that endanger patient safety or decrease the quality of care.“[85] A systematic review found that data missingness was a commonly cited barrier to the use of EMRs to inform population health efforts.[67] In another systematic review, Albagmi et al. found that EMRs were associated with both better documentation and higher quality of care, although a direct causal relationship between data quality and quality of care was not directly assessed.[66] This limitation is common to much of the literature on EMR data quality; while many studies of EMR implementation include both data quality and quality of care indicators as outcomes or indicators of interest, few directly assess the relationship between data quality and quality of care or patient outcomes. Our results, then, contribute to this limited evidence base, providing evidence that EMR data quality is associated with interruption in ART treatment.

However, while we have established a temporal sequence for the relationship between data quality and IIT status, due to the fact that other elements of quality of care were not measured it is not possible to discern if the observed association is due to poor data quality itself or data quality as a proxy for broader quality of care. Data quality could be a marker of lower provider competence, poorer supplies and infrastructure at the health facility, higher provider patient ratio, lower contact time between providers and patients, or possibly other phenomena associated with IIT status. Further research is necessary to understand the role data missingness plays in care provision.

Our finding that overall missingness was higher among pediatric patients and that the association between missingness and IIT status was stronger among pediatric patients supports our hypothesis that there may be differential quality of care among pediatric patients leading to poorer retention in care. Pediatric HIV populations have unique care needs, and poorer engagement for pediatric patients across the HIV care cascade is a multifaceted issue, involving behavioral, psychosocial, pharmacokinetic, and structural factors.[86,87] Relevant to this analysis, prior research has shown direct links between quality of care, care engagement, and patient outcomes for this population. In their analysis of CLH in Nigeria, Ojikutu et al. found that higher quality care, measured as a composite score exploring TB screening, adherence measurement and counseling, CD4 and weight documentation, and medication prescription, was significantly associated with lower likelihood of pediatric and adolescent patients being lost to follow up and mortality.[88] Improving quality of care for CLH, including better patient record quality, is necessary to address the gaps in HIV testing and treatment among CLH.

Limitations

At present, it is not possible to track patients between facilities within our analysis data. As such, it is not possible to distinguish patients who transferred to a new facility but remained on ART and those who interrupted or fully discontinued treatment. As a result, our ART retention outcome was defined as interruption in treatment at a patient's current facility rather than interruption overall. This outcome still fits within our causal model, with lower quality of care being feasibly associated with either actual interruption in treatment or transfer to another facility for higher quality care, and still represents a meaningful proxy indicator for clinical outcomes, as facility transfer may be associated with ART treatment gaps or discontinuation. Patient transfers are also not a limitation specific to this study; a systematic review of ART retention studies found that nearly 20% of patients classified as lost to follow up had actually self-transferred to another facility.[89]

Additionally, our results may be confounded if missingness of the indicators is associated with values of that indicator as well as our outcome. For example, if higher WHO HIV stage is associated with both greater likelihood of being missing as well as greater likelihood of interruption in treatment, the observed association may be due to the latent WHO HIV stage rather than the data missingness. Of note, while integrated with iSante, pharmacy data used to calculate the IIT outcome variables are collected through different mechanisms and staff, including greater data quality oversight in part due to their inclusion in routine PEPFAR monitoring, evaluation, and reporting. Therefore, we do not anticipate that misclassification of the IIT outcome due to missing pharmacy data will be highly correlated with our exposure (missingness among indicators of interest) and will therefore not present a substantial risk of bias.

Strengths

While this was an observational study and therefore cannot assess a causal relationship between data missingness and interruption in treatment, our hypothesis is strengthened by the robust sample size and analytical design; strong association observed between missingness and IIT status; a dose response relationship wherein greater missingness was associated with greater likelihood of a patient being IIT; and established temporal sequence as the intake data is completed prior to ART initiation and therefore the IIT outcomes.

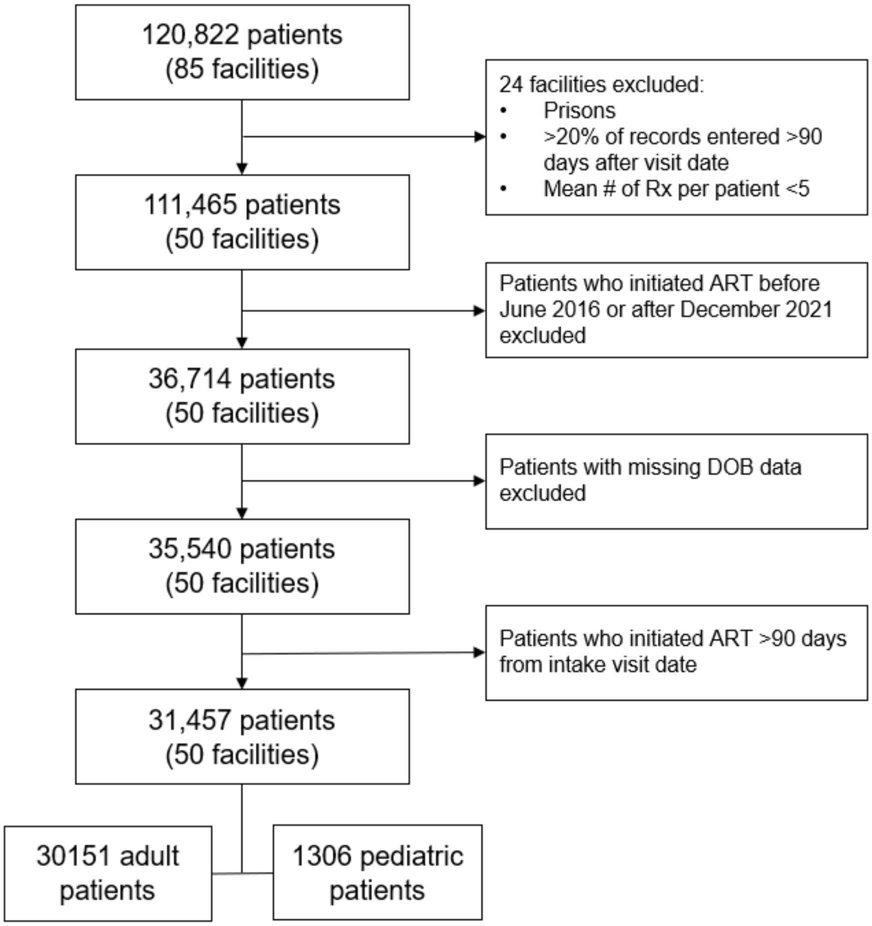
3.6. Conclusion

Our analysis showed that both patient record data missingness for key indicators and interruption in ART treatment were common among patients, with nearly one-quarter of patients being IIT at

6 months and over one-quarter missing at least one indicator of interest in their patient record. Both IIT status and data missingness were more common among pediatric patients. Greater data missingness was associated with a higher likelihood of being IIT at 6 and 12 months for both pediatric and adult patients, although the association was stronger among pediatric patients. These findings suggest that improving EMR data quality may enable better quality of care and lead to greater care and treatment engagement, and that efforts to improve data quality should consider prioritizing pediatric patients.

3.7. Appendix

Supplemental Figure 3.1. CONSORT flow diagram



Supplemental Table 3.1. Multivariable regression of 6- and 12-month IIT against indicator missingness (binary, missing vs. non-missing), by age group

	Adult						**Pediatric**					
	6-month IIT			**12-month IIT**			**6-month IIT**			**12-month IIT**		
	aRR	**95% CI**	**p-val.**	**aRR**	**95% CI**	**p-val.**	**aRR**	**95% CI**	**p-val.**	**aRR**	**95% CI**	**p-val.**
Weight missingness	0.95	(0.79, 1.14)	0.556	1.01	(0.83, 1.23)	0.910	0.91	(0.67, 1.25)	0.564	0.87	(0.63, 1.21)	0.414
WHO HIV stage missingness	1.15	(0.93, 1.41)	0.193	1.03	(0.92, 1.14)	0.639	2.17	(1.79, 2.64)	<0.001	1.79	(1.54, 2.08)	<0.001
TB diagnosis missingness	1.03	(0.86, 1.24)	0.749	1.03	(0.87, 1.23)	0.713	1.03	(0.78, 1.38)	0.821	1.01	(0.65, 1.57)	0.972
Sex												
Female	Ref	-	-	Ref	-	-	Ref	-	-	Ref	-	-
Male	1.05	(0.97, 1.12)	0.217	1.02	(0.97, 1.07)	0.439	0.92	(0.79, 1.06)	0.238	0.98	(0.86, 1.11)	0.748
Facility type												
Health Center	Ref	-	-	Ref	-	-	Ref	-	-	Ref	-	-
Hospital	0.83	(0.58, 1.21)	0.335	0.94	(0.60, 1.47)	0.788	0.83	(0.65, 1.07)	0.148	0.89	(0.70, 1.12)	0.318
Dispensary	0.81	(0.56, 1.18)	0.275	0.78	(0.55, 1.11)	0.162	1.14	(0.88, 1.48)	0.335	0.92	(0.69, 1.23)	0.574
Facility ownership												
Mixed	Ref	-	-	Ref	-	-	Ref	-	-	Ref	-	-
Private	0.95	(0.72, 1.26)	0.739	1.04	(0.75, 1.45)	0.804	0.97	(0.73, 1.30)	0.850	0.90	(0.68, 1.19)	0.456
Public	0.90	(0.65, 1.25)	0.541	0.96	(0.64, 1.42)	0.834	1.00	(0.78, 1.28)	0.979	0.89	(0.72, 1.11)	0.303
Duration of iSante use (years)	1.01	(0.97, 1.06)	0.596	1.04	(0.99, 1.08)	0.135	0.98	(0.94, 1.02)	0.302	0.99	(0.95, 1.04)	0.760
Monthly avg. patient volume (log)	0.82	(0.68, 1.00)	0.052	0.74	(0.60, 0.91)	0.004	0.94	(0.77, 1.15)	0.543	0.91	(0.75, 1.10)	0.336

Chapter 4: Does HIV Index Testing and Partner Services Bring Patients into Treatment at Earlier Stages of HIV Disease? Results from an Observational Study in Ukraine

4.1. Abstract

Introduction: Over one-third of people living with HIV (PLHIV) in Ukraine are not on treatment. Index testing and partner services (IT/PS) are scaling up in Ukraine and could potentially close this gap. We investigated two research questions using routine EMR data: 1) did individuals who entered HIV testing and treatment through IT/PS (i.e., as named partners) initiate antiretroviral therapy (ART) at an earlier stage of HIV disease progression compared to other ART initiators; and 2) did a technical assistance program to strengthen and expand IT/PS services increase the number of patients newly starting ART.

Methods: This observational study used data from the national HIV Medical Information System. Data from patients ≥18 years who initiated ART at an IT/PS intervention facility between October 2018 and May 2021 were included in the analyses. Differences between named partners and other ART initiators were assessed through marginal parameters from mixed-effects multivariable Poisson regression, and an interrupted time series (ITS) was used to assess the technical assistance program's impact on number of new of ART initiators.

Results: After adjustment for age, sex, and facility type, named partners were less likely to have a confirmed TB diagnosis (adjusted risk ratio [aRR]=0.56, 95% confidence interval (CI)= 0.40, 0.77, p<0.001), a CD4 count less than 200 cells/mm^3 (aRR=0.84, 95% CI=0.73, 0.97, p=0.017), or be categorized as WHO HIV stage 4 (aRR=0.68, 9% CI=0.55, 0.83, p<0.001) at the time of ART initiation compared to other ART initiators. After adjustment for age, sex, facility type, TB diagnosis, and HIV stage, named partners were also significantly more likely than other ART initiators to initiate ART within seven days of testing for HIV (aRR=1.36, 95% CI=1.22, 1.50, $p<0.001$). Our ITS analysis showed a modest 2.34% (95% CI=0.26%, 4.38%; p=0.028) month-on-month reduction in mean ART initiations comparing the post-intervention period to the pre-intervention period, although this reduction may have been due to disruptions in HIV services due to onset of the COVID-19 pandemic shortly after program implementation.

Conclusion: Our findings suggest that IT/PS services may be beneficial in bringing PLHIV into treatment at an earlier stage of HIV disease and decreasing delays between HIV testing and ART initiation.

4.2. Introduction

HIV remains a major public health concern in Ukraine, with an estimated 245,000 cases and an incidence of 0.21 per 1,000 person-years at risk in 2021.[90,91] Prevention efforts have been hindered by low rates of testing and treatment; it is estimated that only 75% of people living with HIV in Ukraine know their status, 83% aware of their status are receiving treatment, and 94% on treatment are virally suppressed.[91] Testing and treatment coverage are even lower among hard-to-reach populations, such as sex workers, people who inject drugs (PWID), and men who have sex with men (MSM), who are estimated to make up over one-third of people living with HIV (PLHIV) in Ukraine.[92] These numbers fall short of the UNAIDS 95-95-95 targets: 95% of people living with HIV are aware of their status, 95% of those aware receive antiretroviral therapy (ART), and 95% of those on treatment achieve viral suppression.

Identifying and linking PLHIV to ART is essential if these targets are to be achieved. HIV index testing, also known as partner notification services (IT/PS), is a long-standing strategy to achieve this goal.[93] While IT/PS has traditionally been used more commonly in high-income settings, the World Health Organization estimates that 128 nations around the world now have IT/PS programs and a growing evidence base supports the effectiveness of this strategy in low- and middle-income settings.[94–96] IT/PS works by identifying potentially exposed partners (named partners) of patients living with HIV (index patients) and connecting those partners with testing, pre-exposure prophylaxis, and HIV treatment services. IT/PS may be especially beneficial among marginalized and hard-to-reach populations, where legal and social barriers may result in lower uptake of testing and treatment.[97] The WHO considers IT/PS to be part of a "comprehensive package of testing and care offered to persons with HIV" and the Centers for Disease Control (CDC) and President's Emergency Plan for AIDS Relief (PEPFAR) have promoted scale-up of IT/PS in multiple countries, including Ukraine.[93]

In Ukraine, scale-up of IT/PS services began in 2018 through PEPFAR support, with the Public Health Center of Ukraine (PHC) naming it as a priority intervention in the 2019-2030 National HIV Testing Strategy.[92] However, implementation and scale-up of IT/PS services were not standardized, leading to sub-optimal implementation. In response to the need for standardization and strengthening of IT/PS services, the International Training and Education Center for Health (I-TECH), a center in the University of Washington's Department of Global Health, collaborated with CDC Ukraine and PHC Ukraine to provide targeted financial and technical assistance to 35 health facilities across 11 priority regions (oblasts) starting in October 2019 and fully implemented by January 2020. Specifically, I-TECH activities sought to strengthen IT/PS services by developing and refining standard operation procedures, health care worker training on IT/PS services, supporting program monitoring and evaluation, identifying areas for targeted improvement, and monitoring standards adherence.

IT/PS is hypothesized to increase HIV case-finding and to connect people with HIV testing and treatment at an earlier stage of HIV disease progression, reaching partners who might otherwise not seek testing and treatment services on their own.[93,98–100] However, the extent to which IT/PS as implemented actually increases the identification of people with HIV – versus just changing how one's reason for testing is classified – is unknown. Likewise, while the idea that IT/PS would result in identification of people with HIV earlier in their course of infection is intuitive, scant data exist to support that hypothesis, including in the above-cited studies. We investigated two research questions: 1) did ART initiators who came into testing and treatment through IT/PS tend to initiate treatment at an earlier stage of disease progression compared to other ART initiators; and 2) did the IT program result in an increase in the number of patients newly starting ART.

4.3. Methods

Study Design

This observational study used routine data sources from Ukraine's HIV index testing and ART programs from October 2018 to May 2021. To answer the first research question, the study compared indicators of HIV disease stage at ART initiation among named partners identified through IT/PS services versus other ART initiators, using a non-experimental comparative cohort analysis. To answer the second research question, the study used an interrupted time series design to estimate the effect of introducing scaled IT services on the number of ART initiators per month.

Data Sources

The Socially Important Diseases Medical Information System (SID MIS) is a routine, patient-level electronic health system used by all public facilities providing HIV care in Ukraine.[101] It captures data on patient demographics, HIV diagnosis and treatment, and lab results (e.g., CD4 count) and is filled out by infectious disease doctors and other clinic personnel at the point of service when delivering HIV services. Data on IT service provision was extracted from an IT registry, an electronic spreadsheet developed to enable more robust tracking of IT services and to support IT program reporting and includes indicators on data of IT services such as named partner demographics and method of notification. Clinicians complete the IT registry using paper-based patient files either at the point of service or retrospectively. Both tools track patients through a patient-level unique identifier generated by the SID MIS (the MIS ID), enabling merging of the two datasets. For these analyses, SID MIS data were available from October 2018 to May 2021 and IT registry data were available from January 2020 to May 2021. Analysis variables are detailed in Table 4.1.

Table 4.1. Analysis outcomes and exposure

	Indicator	**Definition/Notes**
Outcome	Number of new ART initiators	Aggregate number of patients who initiated ART at a given facility in a given month (facility-month).
	Confirmed tuberculosis (TB) diagnosis at the time of ART initiation	Confirmed diagnosis of pulmonary or extrapulmonary TB.
	WHO HIV stage at the time of ART initiation	Defined by the WHO clinical stages of HIV, ranging from stage 1 (asymptomatic) to stage 4

		(severe symptoms).[80] Parameterized as a binary indicator – stage 4 or not.
	CD4 count (cells/mm^3)	Restricted to lab results obtained within 365 days before or 90 days after date of ART initiation. Parameterized as a binary indicator – CD4 count under 200 cells/mm^3 or not.
	ART initiation timeliness	Patients without a recorded HIV test date were excluded from analyses involving ART initiation timeliness. Parameterized as a binary indicator – ART initiation within seven days of a confirmatory positive HIV test or not.
Exposure	Referral to treatment through IT/PS services (vs. referral through other means; i.e., named partner vs. other ART initiators)	Patients who were referred to treatment through IT/PS services as a named partner by an index case prior to initiating ART were categorized as named partners. All other ART initiators were categorized as other ART initiators (including those named by index cases but after they had already initiated ART).

Statistical analysis

We used multivariable Poisson regression models with robust error variance to estimate risk ratios and test the hypothesis that IT/PS would identify PLHIV earlier in their course of infection.[81,82] These models used WHO HIV stage (stage 4 vs. not), CD4 count (below 200 vs. not), and TB status (confirmed TB diagnosis vs. not) at the time of ART initiation as binary dependent variables, with patient identification through IT/PS services (i.e., named partner vs. other ART initiators) as the primary exposure variable, and controlled for age, sex, and facility type. Multivariable Poisson regression models with robust standard errors were also used to assess differences in ART initiation timeliness, using initiation of ART within seven days of a confirmatory positive HIV test as a binary outcome, patient referral to treatment through IT/PS services (i.e., named partner vs. other ART initiators) as the primary exposure variable, and controlling for age, sex, and facility type, TB status, and WHO HIV stage. To assess the impact of IT/PS services on number of new ART initiation, we conducted an interrupted times series

(ITS) analysis looking at the number of new HIV diagnoses per month using a negative binomial regression with an AR1 correlation structure to address observed overdispersion and serial correlation, respectively, in the outcome and censoring data between October and December 2019 to account for the rolling program rollout period. All models used complete case analysis and included random intercepts for facility to account for clustering.

Data were analyzed using R (v 4.1.1) [41]. Regression models were run using the GLMMadaptive (Poisson models) and glmmTMB (ITS models) packages.[102,103]

Inclusion criteria

Data from patients were included in the analysis if they were: 18 years or older, initiated ART at an intervention facility, and were recorded within the SID MIS system regardless of IT/PS services engagement. The ITS analysis included patients who initiated between October 2018 and May 2021, while the analyses exploring clinical factors and ART initiation timeliness by IT/PS service engagement (i.e., named partners vs. other ART initiators) included patients who initiated ART between January 2020 and May 2021 (i.e., dates for which both SID MIS and IT registry data were available).

Ethics statement

This study was granted a non-research designation due to minimal risk after review of the evaluation protocol by the University of Washington Human Subjects Division, and the US CDC. The Ukraine Ministry of Health Center for Public Health reviewed the protocol and scope of work and provided a letter of support for the project.

4.4. Results

In total, data were drawn from 35 facilities across 11 oblasts (of 24 total in Ukraine) and comprised 14,554 ART initiator patient records from October 2018 to May 2021, of which 5,851 were from the post-intervention time period (January 2020 to May 2021). The following summary statistics are specific to participants who initiated in this post-intervention time period. Over half of included patients were male (58.4%) and aged 25 to 44 (67.9%). The majority of patients presented with a WHO HIV clinical stage of III or lower (82.0%) and did not have a confirmed TB diagnosis (89.3%). ART initiation timeliness varied, with most patients (60.1%) initiating ART within seven days of a confirmatory positive HIV test.

A minority of ART initiators in the post-intervention period were named partners (1,024, 17.5%). Almost half of named partners also served as index cases (41.8%), and almost all were named by a single index case (97.5%). Most named partners were linked to index cases through sexual connection (93.0%) rather than needle sharing (7.0%). Named partners were slightly less likely to be male compared to other ART initiators (53.5% vs. 59.4%). Additionally, named partners were less likely to initiate ART at a city or regional AIDS center as opposed to other ART sites (i.e., ART sites based in hospitals, STI clinics, or other primary health care centers) (50.3% vs. 63.5%). Participant characteristics are detailed in Table 4.2.

Table 4.2. Participant demographic and clinical characteristics (among patients who initiated ART between January 2020 and May 2021)

	Overall (n=5,851)	**Named partners (n=1,024)**	**Other ART initiators (n=4,827)**
	n (%)†	n (%)†	n (%)†
Sex			

Female	2,435	(41.6%)	476	(46.5%)	1,959	(40.6%)
Male	3,416	(58.4%)	548	(53.5%)	2,868	(59.4%)
Age (mean, SD)	40.8	(9.2)	41.2	(9.1)	40.7	(9.2)
Facility type						
City AIDS Center	672	(11.5%)	94	(9.2%)	578	(12.0%)
Regional AIDS Center	2,910	(49.7%)	421	(41.1%)	2,489	(51.6%)
Other ART site	2,269	(38.8%)	509	(49.7%)	1,760	(36.5%)
TB status (at time of ART initiation)						
Confirmed	322	(5.7%)	40	(4.0%)	282	(6.1%)
Suspected	97	(1.7%)	13	(1.3%)	84	(1.8%)
No	5,227	(92.6%)	956	(94.7%)	4,271	(92.1%)
(Missing)	205		15		190	
WHO HIV stage (at time of ART initiation)						
Acute HIV infection	13	(0.2%)	3	(0.3%)	10	(0.2%)
Clinical stage 1	2,575	(44.1%)	503	(49.3%)	2,072	(43.0%)
Clinical stage 2	789	(13.5%)	135	(13.2%)	654	(13.6%)
Clinical stage 3	1,408	(24.1%)	233	(22.8%)	1,175	(24.4%)
Clinical stage 4	1,053	(18.0%)	147	(14.4%)	906	(18.8%)
(Missing)	13		3		10	
CD4 value (at time of ART initiation)						
>=500	1,293	(25.2%)	229	(25.0%)	1,064	(25.3%)
350-499	984	(19.2%)	198	(21.6%)	786	(18.7%)
200-349	1,170	(22.8%)	203	(22.1%)	967	(23.0%)
<200	1,677	(32.7%)	287	(31.3%)	1,390	(33.0%)
(Missing)	727		107		620	
ART initiation timeliness						
Same day	2,033	(36.9%)	466	(47.9%)	1,567	(34.6%)
1-7 days	1,279	(23.2%)	237	(24.4%)	1,042	(23.0%)
8-30 days	825	(15.0%)	164	(16.9%)	661	(14.6%)
31-60 days	157	(2.9%)	23	(2.4%)	134	(3.0%)
61-120 days	68	(1.2%)	10	(1.0%)	58	(1.3%)
>120 days	1,146	(20.8%)	73	(7.5%)	1,073	(23.7%)
(Missing)	343		51		292	

† Percentages were calculated by column (i.e., within each IT/PS engagement group), and missing observations were excluded from percentage calculations

Clinical factors

Our multivariable regression models (Table 4.3) revealed that named partners were less likely to have markers of advanced HIV disease at ART initiation compared to other ART initiators. Compared to other ART initiators, named partners were less likely to have a confirmed TB diagnosis (adjusted risk ratio [aRR] = 0.56; 95% confidence interval (CI) = 0.40, 0.78; p<0.001), be categorized as WHO HIV stage 4 (aRR = 0.68; 95% CI = 0.54, 0.85; p<0.001), or have a CD4 count less than 200 cells/mm^3 (aRR = 0.84; 95% CI = 0.73, 0.97; p=0.015) at the time of ART initiation. Bivariable model results can be found in Supplemental Table 4.1.

Table 4.3. Multivariable regression of clinical factors at time of ART initiation

	Confirmed TB diagnosis			**WHO HIV Stage 4**			**CD4 count (<200)**		
	(n=5,646)			(n=5,838)			(n=5,124)		
	aRR	95% CI	p-value	aRR	95% CI	p-value	aRR	95% CI	p-value
IT/PS participation									
Other ART initiators	Ref	-	-	Ref	-	-	Ref	-	-
Named partners	0.56	(0.40, 0.78)	<0.001	0.68	(0.54, 0.85)	<0.001	0.84	(0.73, 0.97)	0.015
Age (years)	1.02	(1.01, 1.03)	<0.001	1.03	(1.02, 1.04)	<0.001	1.03	(1.02, 1.03)	<0.001
Sex									
Female	Ref	-	-	-	-	-	-	-	-
Male	1.48	(1.19, 1.86)	<0.001	0.92	(0.76, 1.12)	0.416	1.00	(0.92, 1.09)	0.966
Facility type									
Other ART site	Ref	-	-	Ref	-	-	Ref	-	-
City AIDS Center	0.40	(0.14, 1.14)	0.087	0.95	(0.56, 1.62)	0.856	0.93	(0.80, 1.08)	0.329
Regional AIDS center	0.55	(0.32, 0.96)	0.035	0.72	(0.47, 1.13)	0.152	0.73	(0.59, 0.90)	0.003

Timing of ART initiation

As shown in Table 4.4, as compared to other ART initiators named partners were more likely to initiate ART within seven days of a confirmatory positive HIV test (aRR = 1.36; 95% CI = 1.23, 1.50; p<0.001). Bivariable model results can be found in Supplemental Table 4.2.

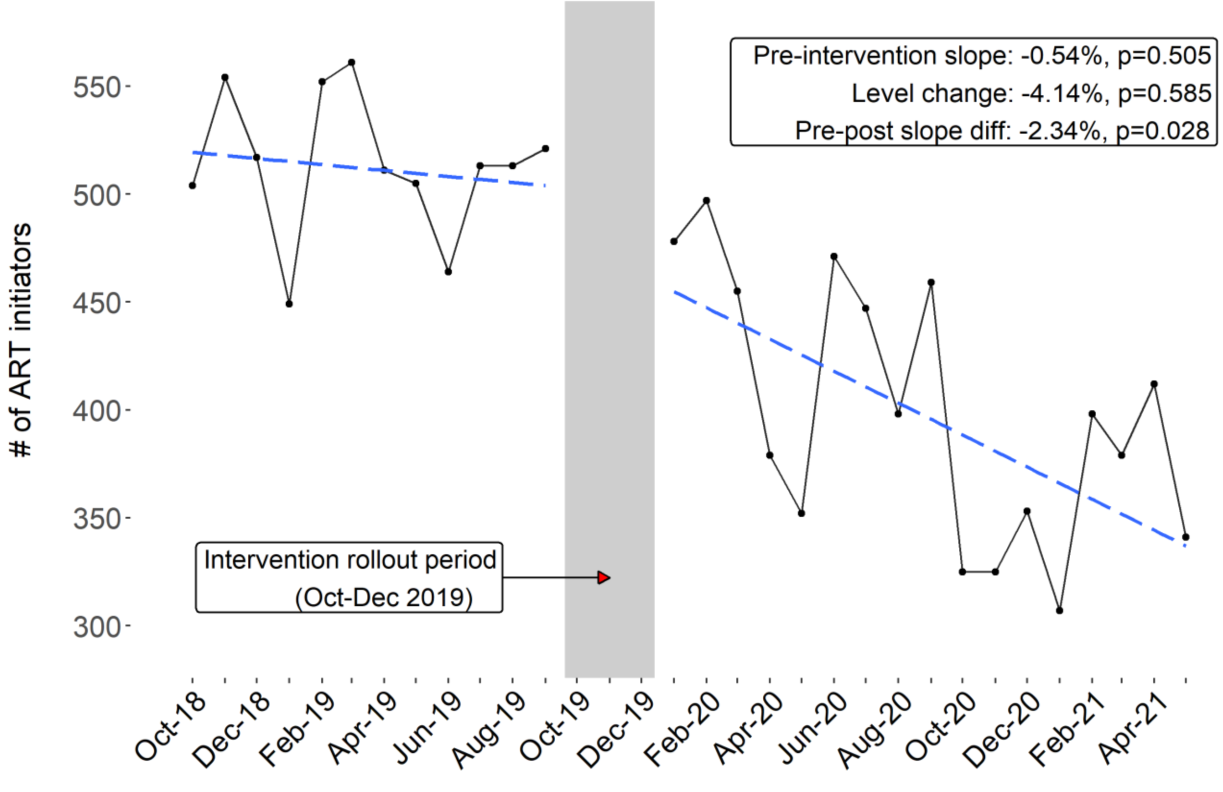
Table 4.4. Multivariable regression of ART initiation timeliness

	Timely ART initiation (<7 days) (n=5,224)		
	aRR	95% CI	p-value
IT/PS participation			
Other ART initiators	Ref	-	-
Named partners	1.36	(1.23, 1.50)	<0.001
Age (years)	1.00	(1.00, 1.00)	0.659
Sex			
Female	Ref	-	-
Male	1.07	(0.99, 1.16)	0.070
Facility type			
Other ART site	Ref	-	-
City AIDS Center	1.19	(0.97, 1.46)	0.104
Regional AIDS center	1.27	(1.01, 1.60)	0.042
TB diagnosis	0.78	(0.61, 1.00)	0.051
WHO HIV Stage 4	0.73	(0.62, 0.86)	<0.001

ITS results

In 2018, there was an average of 525 ART initiators per month, compared to 517 in 2019, 411 in 2020, and 367 in 2021. As shown in Figure 4.1, during the pre-intervention period (October 2018 to September 2019), there was a non-significant month-on-month decrease in the number of ART initiators (-0.54%, p=0.505). There was no significant step change in ART initiations comparing directly before to after implementation (-4.14%, p=0.585). The post-intervention time period (January 2020 to May 2021) was associated with a modest additional month-on-month decrease (-2.34%, 95% CI = -0.26%, -4.38%; p=0.028) in mean ART initiations above and beyond what would have been expected based on the pre-intervention period.

Figure 4.1. Trends in ART initiation and ITS model results at intervention facilities (October 2018 – May 2021)†



† Black dots and lines indicate observed ART initiation data. Blue dotted lines represent linear trend from ITS model fitted values.

4.5. Discussion

Our analysis found differences in clinical indicators at the time of ART initiation between ART initiators who were named partners and those not referred to treatment through IT/PS services. Named partners were significantly less likely to have a confirmed TB diagnosis, present with Stage 4 HIV, or have a CD4 count below 200 cells/mm^3 at the time of ART initiation. Our results further showed that named partners were significantly more likely than other ART initiators to initiate ART within seven days of a confirmatory positive HIV test. Our findings suggest that IT/PS services may be beneficial in bringing PLHIV into treatment at an earlier stage of HIV disease and decreasing delays between HIV testing and ART initiation.

Baseline CD4 count has been shown to be correlated with CD4 recovery, adverse events, and mortality [104–108]. Palella et al. found that baseline CD4 $\geq$200 cells/mm^3 compared to <200 was associated with a nearly five-fold greater likelihood of achieving CD4 >750.[106] A systematic review and meta-analysis covering 13 observational studies found significantly reduced mortality and progression to AIDS and significantly increased immunologic recovery comparing ART initiators with baseline CD4 counts $\geq$500 cells/mm^3 compared to <500.[107] In their study of 22,937 treatment-naive adult ART initiators from the North American AIDS Cohort Collaboration on Research and Design study, Samji et al. found life expectancy estimates to be nearly 16 years higher among ART initiators with baseline CD4 $\geq$350 cells/mm^3 compared to those with CD4 <350 (54.6 years vs. 38.8).[105] Additionally, a large-scale, multi-country RCT of 4,685 participants showed a 57% relative reduction in serious AIDS-related events, serious non–AIDS-related events, or death from any cause comparing ART initiators with a CD4+ count >=500 cells/mm^3 to those <350.[108] In the context of treatment as prevention, initiating patients on ART earlier in HIV infection (i.e., closer to HIV testing, at earlier HIV stages, and when CD4 values are higher) can also dramatically reduce HIV transmission.[109,110] This is particularly salient in Ukraine, where prior research has indicated that over one-third of Ukrainian PLHIV who enrolled in HIV care did so at a late stage of infection.[111]

Our findings about the timing of ART initiation in index testing programs are in line with prior research, which has shown similar associations between timely linkage to ART care for patients diagnosed through index testing programs as compared to other testing modalities, perhaps due to the personalized and proactive approach of IT/PS as well as improved quality of care through additional training providers may receive as part of IT/PS implementation.[99,100,112,113] Timely ART initiation can reduce HIV-associated morbidity and mortality and decrease the likelihood of HIV transmission by more quickly achieving viral suppression.[114–117] A Cochrane systematic review and meta-analysis of RCTs in LMIC settings found that rapid ART initiation ($\leq$7 days from testing) among adult PLHIV was significantly associated with increased likelihood of both viral suppression and retention in care at 12 months post-initiation.[117] Studies of HIV positive adults in Thailand and West Africa also found significant associations between timely introduction and viral suppression, although neither found early ART initiation to be significantly associated with retention.[115,116] Although our results are unable to explore likelihood of ART initiation after testing as our sample was limited to just those who initiated ART, IT/PS services driving more timely ART initiation may also decrease the likelihood of a patient being lost to follow up after HIV diagnosis but prior to initiating ART. With an estimated one-in-eight Ukrainian PLHIV aware of their status but not on treatment, increasing engagement throughout the HIV testing and treatment cascade is vital.[90,91]

Regarding the ITS results, I-TECH's collaboration with the MOH to standardize and intensify IT/PS service implementation occurred at a dynamic time for the health system due to the onset of the COVID-19 pandemic, which greatly disrupted health services shortly after implementation of the program. The WHO reported reductions in both HIV testing (24% reduction in median number of people testing) and ART initiation (15% reduction) in high HIV burden areas in Ukraine in early 2020.[118] Uncontrolled ITS analyses assume that the pre-intervention secular trend would have continued if the intervention was not introduced, an assumption that is violated in the presence of history, or events that impact the outcome and happen contemporaneously with the intervention or post-intervention observation period.[119] As these documented disruptions in HIV services aligned with the post- but not pre-intervention period, we suspect that the observed reductions in ART initiations in the ITS model were likely due to the COVID-19 pandemic rather than the intervention itself.

Limitations

Use of complete case analysis and exclusion of patients who experienced a registration event after initiating ART (e.g., due to a facility transfer) may result in a final analysis sample that is not fully representative of all new ART initiators. However, generalized linear mixed models can provide robust estimates under complete case analysis provided the missingness is ignorable (i.e., missing completely at random or missing at random), although it is not possible to verify if those assumptions hold.[120] The IT/PS strategy was included in Ukraine's health sector policy prior to our program implementation, although it was not widely implemented at that time. As such, the ITS analysis describes the impact of the technical assistance program to standardize, improve, and accelerate implementation of IT/PS services in practice versus simply having in place a policy recognizing IT/PS as standard of care.

4.6. Conclusion

Our analysis showed that named partners, as compared to ART initiators not referred to treatment through IT/PS services, were significantly less likely to initiate ART with baseline TB diagnosis, HIV clinical stage 4, or CD4 count <200 cells/mm^3 and were more likely to initiate ART within seven days of a confirmatory positive HIV test. As baseline opportunistic infections, lower CD4 count, stage 4 HIV, and delayed ART initiation are associated with poorer retention, CD4 recovery, and morbidity and mortality, our findings suggest that IT/PS services may be beneficial in bringing PLHIV into treatment at an earlier stage of HIV disease and decreasing delays between HIV testing and ART initiation.

4.7. Appendix

Supplemental Table 4.1. Bivariable regression of clinical factors at time of ART initiation

	Confirmed TB diagnosis			**WHO HIV Stage 4**			**CD4 count (<200)**		
	(n=5,646)			(n=5,838)			(n=5,124)		
	RR	95% CI	p-value	RR	95% CI	p-value	RR	95% CI	p-value
IT/PS participation									
Other ART initiators	Ref	-	-	Ref	-	-	Ref	-	-
Named partners	0.56	(0.40, 0.77)	0.001	0.67	(0.56, 0.81)	<0.001	0.83	(0.73, 0.95)	0.006
Age (years)	1.02	(1.01, 1.03)	<0.001	1.03	(1.03, 1.04)	<0.001	1.03	(1.02, 1.03)	<0.001
Sex									
Female	Ref	-	-	Ref	-	-	Ref	-	-
Male	1.50	(1.20, 1.88)	<0.001	0.93	(0.77, 1.12)	0.447	1.01	(0.92, 1.10)	0.857
Facility type									
Other ART site	Ref	-	-	Ref	-	-	Ref	-	-
City AIDS Center	0.41	(0.14, 1.21)	0.107	0.97	(0.56, 1.68)	0.927	0.93	(0.80, 1.07)	0.294
Regional AIDS center	0.55	(0.31, 0.97)	0.039	0.70	(0.45, 1.09)	0.115	0.69	(0.56, 0.86)	<0.001

Supplemental Table 4.2. Bivariable regression of ART initiation timeliness

	Timely ART initiation (<7 days) (n=5,224)		
	RR	95% CI	p-value
IT/PS participation			
Other ART initiators	Ref	-	-
Named partners	1.38	(1.24, 1.54)	<0.001
Age (years)	1.00	(1.00, 1.00)	0.278
Sex			
Female	Ref	-	-
Male	1.06	(0.99, 1.15)	0.106
Facility type			
Other ART site	Ref	-	-
City AIDS Center	1.20	(0.94, 1.54)	0.148
Regional AIDS center	1.28	(1.03, 1.60)	0.029
TB diagnosis	0.69	(0.54, 0.88)	0.003
WHO HIV Stage 4	0.69	(0.59, 0.81)	<0.001

Chapter 5: Conclusions

5.1. Summary of findings

In this dissertation we provided insights on how routine EMR data and CDS tools can be used to evaluate and strengthen HIV care. We used mixed-methods and quasi-experimental designs, using primary data as well as routine patient record data for 44,397 patients extracted from the Haiti iSante EMR and Ukraine Socially Important Diseases Medical Information System (SID MIS). We found that providers had generally positive views of EMR-informed CDS tools, particularly their potential to improve decision-making and patient outcomes; that EMR data missingness is associated with poorer retention in care, particularly among children living with HIV, suggesting that data quality is a crucial element of quality of care; and that EMR data can enable large-scale analyses of public health interventions, here showing that named partners who are engaged in HIV services through index testing do so earlier stages of HIV. More specifically, we found that:

1. Providers and national health policy stakeholders in Haiti had positive perceptions of iSante and CDS tools. Key motivators to tool use included perceived benefits to quality of care, including improved efficiency, decision-making ability, and patient outcomes. Participants highlighted the need for sufficient provider training/sensitization, inclusion of providers in the system design process, and prioritization of tool user-friendliness as key mechanisms to drive tool use and impact. However, systemic issues, such as access to electricity and network as well as laboratory capacity, may limit the adoption and impact of these tools.

2. Both EMR patient record data missingness for key indicators and interruption in ART treatment were common among patients in Haiti, with nearly one-quarter of patients being IIT at 6 months and over one-quarter missing at least one indicator of interest in their patient record. Both IIT status and data missingness were more common among pediatric patients. Greater data missingness was associated with a higher likelihood of being IIT at 6 and 12 months for both pediatric and adult patients, although the association was stronger among pediatric patients. These findings suggest that improving EMR data quality may enable better quality of care and lead to greater care and treatment engagement, and that efforts to improve data quality should consider prioritizing pediatric patients.
3. Named partners, as compared to ART initiators not referred to treatment through IT/PS services, were significantly less likely to initiate ART with baseline TB diagnosis, HIV clinical stage 4, or CD4 count <200 cells/mm^3 and were more likely to initiate ART within seven days of a confirmatory positive HIV test among ART initiators in Ukraine. As baseline opportunistic infections, lower CD4 count, stage 4 HIV, and delayed ART initiation are associated with poorer retention, CD4 recovery, and morbidity and mortality, our findings suggest that IT/PS services may be beneficial in bringing PLHIV into treatment at an earlier stage of HIV disease and decreasing delays between HIV testing and ART initiation.

5.2. Implications

Substantial time and resources have been put towards advancing the digitization of health data, including development and implementation of EMRs and EMR-informed CDS tools, in order to improve patient care and outcomes. However, there is a research gap relating to these systems in LMICs as compared to high income countries, including on the perceptions of and willingness to use these systems among providers. Understanding the barriers and facilitators to EMR and CDS implementation and use is crucial in achieving high levels of adoption and consistent use. Better understanding the context in which these tools are implemented is also important, as CDS alerts and reminders need to be actionable in the context of the broader care system; the full benefits of CDS tools will not be realized if providers are unable to follow tool guidance due to health system limitations. Additionally, the benefits of EMRs and CDS tools are largely predicated on having access to high quality data, including non-missing values for essential indicators. There has been limited research to date on the associations between data missingness and retention in ART treatment in resource-limited settings, particularly among children living with HIV. Our findings expand this limited evidence base to show that data quality is an important component of data quality, and that lower data quality may be a factor in the lower HIV care and treatment engagement seen among pediatric patients. Finally, our results show the potential for EMRs to inform program implementation and evaluation without the need for costly primary data collection. However, appropriate methodologies are necessary to overcome inherent limitations to these data (e.g., lack of randomization), as well as foresight to design program data systems to enable linkages with routine data systems, such as leveraging patient IDs from the routine systems.

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