Using Data from the iSanté National Electronic Medical Record System to Strengthen Haiti's HIV Antiretroviral Therapy Program

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Abstract

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The scale-up of electronic medical records (EMR) in low resource settings offers opportunities to improve patient care and health outcomes through improved information to guide decision-making at individual patient, facility, and national levels. In this dissertation, we explored use of data relevant for quality improvement in Haiti's national HIV care and treatment program, at each of these three levels of decision-making.

Our first analysis was relevant to improved clinical decision making for individual patients. We developed a simple prediction model for risk of therapeutic failure among patients on HIV antiretroviral therapy (ART), using pharmacy-based adherence data and other patient characteristics. This model strongly differentiated patients at high, medium and low risk and could be help providers identify which patients to target with intensive adherence support services. We concluded that targeting patients according to their predicted risk could help providers to reach the greatest number of patients with high need in the context of constrained resources.

Our second analysis examined attrition from the ART program in two large departmental hospitals in Haiti and identified patient demographic, clinical, temporal, and health service-related factors associated with ART attrition. This analysis was relevant to improved management of services at the facility level. We found that at 12 months after ART initiation 26.6% of ART patients were no longer retained in care (95% CI: 24.6-28.7%). Location of patient residence in communes distant from the health care facility was strongly associated with attrition, as was briefer duration of enrollment within HIV care and treatment prior to ART initiation, having a non-standard ART regimen, and having no counseling sessions prior to ART initiation. We concluded that quality improvement interventions which address these risk factors merit further testing within the two facilities.

Our third analysis examined the performance of 95 facilities using the iSanté electronic medical record system with respect to a series of 14 priority data quality indicators. In this analysis, we examined consistency of performance across the indicators, as well as site and system use characteristics associated with strong vs. weak data quality. This analysis offers insight on where and how efforts to strengthen data quality should focus, and on which system "ingredients" may be necessary to produce strong data quality.

Together our analyses demonstrate the value of using data from the iSanté EMR system to identify improvements in individual patient follow-up, organization of services, quality of information, and allocation of system-wide resources. There are tremendous on-going pressures to expand access to HIV care and treatment, to assure quality of services, and to optimize efficiency in Haiti and other low-resource settings. Our analyses of iSanté EMR data represent three examples of data use which address these pressures. Building upon the momentum of the present analyses by translating the findings into on-ground program improvements, and by

exploring other data uses which answer timely health services research questions is of great importance.

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Chapter 1: Introduction

This dissertation examines data from Haiti's national HIV care and treatment program, and considers use of data to improve quality of care and patient health outcomes. Our research takes place within the context of been a massive scale-up of donor investment in the health sector in low-resource settings since 2001. Development assistance for health increased from 10.8 billion USD per year in 2001 to 28.2 billion USD per year in 2010. In Haiti, the focus of this dissertation, annual development assistance for health increased from 37.8 million to 1.53 billion per year (IHME 2012).

There have been two important and inter-related trends within these investments, which further frame the context of this dissertation. The first is the growth in investment in programs for HIV prevention, care and treatment, which made up about one-third of all development assistance for health by 2010 (IHME 2012). Globally, HIV/AIDS ranked fifth among causes of disease burden in 2010 (Ortblad, Lozano, and Murray 2013). In Haiti, HIV/AIDS was responsible for 22.8% of deaths and 15.0% of disability-adjusted life years among adults aged 15-49 in Haiti in 2005 (IHME 2014). In the early 2000s, several small-scale programs in Haiti demonstrated that it was possible to successfully stem HIV-related mortality by treating patients with antiretroviral therapy (ART), inspiring rapid scale-up of ART treatment programs globally (Mukherjee et al. 2006). By 2012 in Haiti, approximately 60% of all treatment-eligible people living with HIV, or about 42,000 patients, were on ART, similar to the ART coverage level in other low-resource settings (MSPP/PNLS 2012; UNAIDS 2013). Yet, despite tremendous progress in scale-up of HIV care and treatment, investments have stagnated since 2010 in the context of the global economic slowdown. UNAIDS currently estimates a shortfall of

approximately 5 billion USD per year to meet targets for HIV prevention, care and treatment in low and middle-income countries (UNAIDS 2013; IHME 2012).

A second trend is the scale-up of investments in health information systems, including electronic medical records (EMRs). The World Health Organization has identified health information systems as one of six building blocks for strengthening health systems (WHO 2007). These systems are seen as essential for demonstrating program results to donors (Nash 2009). In low-resource settings, routine facility-based information systems are beset by many challenges including: poor documentation practices at the point of service delivery; weak use of information to inform clinical care delivery and program management; lack of skilled human resources for data management and analysis; existence of health information "silos" within vertical health programs; and a high burden of reporting requirements, often with irrelevant or duplicative health indicators (Odhiambo-Otieno 2005; Aqil, Lippeveld, and Hozumi 2009; Pappaioanou et al. 2003; AbouZahr, Adjei, and Kanchanachitra 2007; Nash 2009). Compared with traditional paper-based systems, EMRs offer the potential to improve documentation practices, render information more timely and usable, and reduce reporting burdens. In Haiti, the Ministry of Health and donors have invested significant resources in scale-up of the iSanté EMR. Originally piloted in a single facility in 2005, iSanté was deployed in more than 95 facilities by 2013. The system currently contains longitudinal clinical data from more than 100,000 patients with HIV (Lober et al. 2008; Matheson et al. 2012).

Against the backdrop of these two trends, this dissertation explores the use of data from the iSanté EMR in order to inform improvements in HIV/AIDS care and treatment services. We consider use of data and information at three levels: the individual, group, and population levels. The first level refers to information use to guide clinical decision-making during the course of

individual patient care. The second level refers to information use to shape the organization of care services for groups of patients. The third level refers to information use for the core purposes of public health: assessment, assurance, planning, policy development, and research (Kukafka et al. 2007; Lippeveld and Sauerborn 2000). When health information systems comprise inaccurate, outdated, incomplete, or inaccessible information, then decisions taken at any one of these levels can result in poor health outcomes and inefficient use of resources. Improving information systems and information use seeks to achieve: greater completeness and accuracy of patient records; clinical decision making in keeping with evidence-based guidelines; timely retrieval of patient information for care delivery; greater alignment of services to patient needs; and optimized investments of public health resources (Tierney, Overhage, and McDonald 1997; Poissant 2005; Chaudhry 2006; Shekelle, Morton, and Keeler 2006; Clifford et al. 2008; Clifford et al. 2008).

The three objectives of this dissertation align with the three levels of information use. First, we develop and validate an alert for patients at risk of therapeutic failure of ART using Haiti's iSanté EMR data, demonstrating the use of data to guide care at the individual patient level. Second, we identify patient and service-delivery factors associated with in attrition from the national ART program at 2 facilities, demonstrating use of data to guide organization of care delivery at the group level. Finally, we undertake a mixed methods assessment of quality of HIV patient data within the iSanté EMR system and explore system-level factors associated with strong vs. weak data quality, demonstrating use of data at the population level to guide systems strengthening efforts.

The results of these analyses provide pragmatic insights into ways to improve care for patients as well as quality of information available to Haiti's national HIV care and treatment

program. The alert for risk of ART failure has potential to guide providers in selecting patients who would benefit most from in-depth ART adherence support as well as in tailoring communication messages to level of risk. The results of the ART attrition study indicate potentially fruitful quality improvement steps which could be taken within the facilities to reduce attrition. The results of the iSanté data quality assessment have implications in informing how to direct efforts for strengthening this information system, so that it can best contribute to health assessment and monitoring at a national level.

With no viable vaccine or cure likely to be available in the coming decade, HIV/AIDS will remain an important public health issue in Haiti and globally in the coming years. Much progress remains necessary to reach targets for ART coverage, and expanded coverage will continue to place heavy demands on health care delivery systems in settings where many fundamental system weaknesses persist. Despite growing need, the global economic slow-down since 2010 has meant constraints on development assistance for health. The penetration of information technology (IT) offers potential to strengthen health information systems, enhancing access, quality, and efficiency of health care programs and services. This dissertation explores the potential of one health information system—the iSanté EMR in Haiti—to contribute to these access, quality, and efficiency goals.

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Chapter 2: Development and Validation of an Electronic Medical Record Based Alert for Risk of ART Failure in a Low-Resource Setting

Introduction

HIV antiretroviral therapy (ART) requires adherence levels of >90% in order to optimize therapeutic benefit (Chaiyachati et al. 2011; Simoni et al. 2006). Patients with lesser adherence run the risk of incomplete HIV viral suppression and developing resistance to ART medications. In resource-limited settings, the high cost and limited availability of second-line ART regimens make it critical to minimize ART therapeutic failures for first-line regimens.

Early identification of gaps in ART adherence can help prevent ART failure. However, measuring ART adherence is a challenge (Chesney et al. 2000). Many of the techniques considered to be most valid, such as examination of drug concentrations in tissue samples, medication electronic monitoring system caps, and unannounced pill counts during home visits, are costly to implement and impractical in resource-limited settings(Thompson et al. 2012; Liu et al. 2001). Self-reported measures gathered on a routine basis during clinic visits are more practical, but may be biased due to poor recall or social desirability (Chaiyachati et al. 2011; Kunutsor et al. 2010; Garfield et al. 2011; McMahon et al. 2013). Pharmacy-based adherence measures derived from ART dispensing data can also be practical in resource-limited settings, depending on availability and quality of data (McMahon et al. 2011; McMahon et al. 2013).

The adoption of electronic medical record systems in resource-limited settings can help clinicians monitor patients' ART adherence and identify patients at risk of future ART failure, allowing resources to be targeted to those most at risk. This study used data from the iSanté electronic medical record system in Haiti to develop and validate a prediction model for risk of

ART failure, based upon self-reported and pharmacy-based adherence measure as well as other patient demographic and clinical data.

Methods

Study setting and patient population

The study cohort included adult (age ≥ 15 years) HIV patients from Hôpital St. Michel in Jacmel (HSM) and Hôpital St. Antoine in Jérémie (HSA) who initiated a life-long ART regimen from January 1, 2005 – June 30, 2013. ART regimens used for prevention of mother-to-child HIV transmission or other prophylaxis were not considered to be life-long regimens and were excluded from the analysis (although patients using ART for prophylaxis had the opportunity to enter the analysis later, upon initiating a life-long regimen).

Both hospitals provide primary and secondary levels of service and serve as the main referral hospitals in their respective departments, both rural and mountainous regions of Haiti. Adult HIV prevalence is estimated to be 2.1% in the region served by HSM and 1.5% in the region served by HSA (Cayemittes et al. 2013). Both facilities began their ART programs in early 2005, and by mid-2013 had together enrolled 2,510 patients on ART.

Data Source

All study data came from the consolidated server for the Haitian Ministry of Health's iSanté data system. This data system is used in more than 90 health care facilities and contains data on approximately half of the 42,000 Haitians receiving ART in 2012 (Matheson et al. 2012; Lober et al. 2008; MSPP/PNLS 2012). The system was first used in Haiti in April 2005, based upon data captured in standardized HIV encounter forms originally disseminated in October 2004. First use of iSanté began in March 2006 in Jérémie and April 2006 in Jacmel, and the system captured data for ART patients who initiated treatment as early as January 2005 in

Jérémie and March 2005 in Jacmel. The ART adherence assessment form was added to the system later, in February 2008. Data were de-identified and the study close date was June 30, 2013.

ART Adherence Measures

We explored five types of adherence measures using iSanté data. The first three were pharmacy-based measures: 1) medication possession ratio (MPR), or total quantity of medication of any type dispensed divided by the number of days in the calendar period; 2) proportion of days covered (PDC), or the proportion of days during the period which are covered by the most recently prescribed medication (a more conservative adherence estimate of adherence than MPR since it excludes left-over medication stockpiled from prior prescriptions); and 3) timely visit ratio (TVR), or the proportion of pharmacy refills collected no more than 2 days after the expected refill due date. . Our procedures for calculating MPR and PDC used dispense dates and the number of days of medication dispensed, based on standard definitions (Raebel et al. 2013; Hess 2006) and methods of calculation (Chu, Kawatkar, and Gu). Since MPR can exceed 100% when patients pick up refills before exhausting earlier medication supplies, we truncated our measure of MPR measure at 100% to represent maximum possible adherence. The remaining two were self-reported measures collected by clinicians or pharmacists using a standard adherence assessment form during regular clinical visits. These were: 4) the average level of medications taken during the past 30 days, based on a visual analogue scale (VAS); and 5) the proportion of adherence assessments where patients reported no missed doses during the last 3 days (%NoMD). The VAS used a standard, validated instrument translated from English (Giordano et al. 2004). Baseline adherence measures during the first 6 months on ART were

used in the analyses, as early adherence has been shown to be highly correlated with later adherence.

Study Outcome

The outcome of interest was ART failure, based on based on World Health Organization (WHO) immunologic and clinical criteria. A patient was considered to have failed ART if they met any of the following criteria: 1) fall in CD4 cell count to the baseline level or below; 2) fall in CD4 to below 50% of the peak value following ART initiation; 3) having a persistent CD4 cell count of <100 cells/µl; or 4) onset of a new WHO stage 4 diagnosis not reflective of immune reconstitution syndrome (WHO 2013). According to Haitian national treatment guidelines, presence of any of these criteria after 6 months of ART use can trigger consideration of a switch to a second-line ART regimen (Balan 2013). Clinical diagnosis data within iSanté were fairly incomplete, and could not be used in absence of CD4 data to differentiate ART failures from non-failures. For this reason, we restricted the primary and secondary analyses to patients with both baseline and follow-up CD4 measures.

Our primary analysis considered ART failure outcomes observed during months 7-12 following ART initiation, while our secondary analysis considered ART failure outcomes observed during months 7-42 following ART initiation (**Figure 2.1**). The baseline CD4 level was the measure occurring closest in time to the ART start date, during the period from 180 days before ART initiation to 7 days after ART initiation.

Covariates

Covariates considered in the analysis were: hospital facility, gender, marital status, age at ART initiation, location of residence relative to the hospital, type of initial ART regimen, duration of enrollment in HIV care prior to ART initiation, baseline CD4 cell count, baseline

body mass index (BMI), number of ART adherence assessments conducted during the first 6 months on treatment, and whether any ART adherence assessment was done by a clinician. We had data available on commune of residence, so location of residence was grouped into 3 categories: residence in the same commune as the hospital, residence in an adjacent commune bordering the commune of the hospital, and residence in a non-adjacent commune.

Data Cleaning

We applied a limited set of data validation and cleaning rules, suitable for eventual use within an automated algorithm to be run in real-time against patient data within the live iSanté database (rules available upon request from corresponding author). These rules were applied to patient registration dates, visit dates, medication dispense dates, patient BMI, and patient ages.

The minimum quantity of medication dispensed for any single drug within a multi-drug regimen was used to calculate ART regimen refill due dates. For dispenses with missing quantities of medication dispensed, the between-visit time interval was excluded from both the numerator and denominator of the pharmacy-based adherence measures. Covariates with missing data were treated as categorical variables with a missing data category.

Statistical methods

Descriptive statistics

We examined patient characteristics and baseline ART adherence measures among those with and without ART failure at 12 months, and compared observed values between the two groups using Pearson's Chi-square test, Student's t-test, or the Wilcoxon rank sum test for continuous variables with skewed distributions. We also compared patient characteristics and baseline adherence among patients included vs. excluded from our analyses, to identify any selection issues.

Primary analysis: ART failure by 12 months

Step 1: Selection of adherence measure

First, we assessed how well each of the five baseline adherence measures predicted ART failure during months 7-12. Patients retained within the 12-month analysis had at least 182 days of study follow-up after ART initiation and had a follow up CD4 measure taken from 182-365 days after ART initiation (n=923, see **Figure 2.1**). Logistic regression models using continuous forms of each measure were used to test prognostic accuracy, using the area under the receiver operating characteristic curve (AUC) (Pepe 2003; Pepe, Longton, and Janes 2009). The best performing measure was considered to be the measure which offered the highest AUC.

Step 2: Selection of patient characteristics

Next, we considered enrichment of the prediction model using additional covariates beyond the selected adherence measure. Patients with 12-month outcomes were split randomly into 50:50 training and validation sub-samples. A forward stepwise selection procedure, using the Akaike Information Criterion (AIC), was used to identify a robust yet parsimonious prediction model in the training sub-sample (Burnham 2004). The performance of the resulting prediction model was then assessed in the validation sub-sample. For continuous covariates retained in the model following the stepwise procedure, we categorized continuous covariates into deciles in order to identify the dichotomous level of the covariate at which predicted risk increased markedly, and then compared performance of continuous and binary forms of the covariates to assess whether performance degraded with simplified, binary versions of the covariates. We used dichotomous versions of each covariate in the final prediction model.

Step 3: Formulation of a risk score and risk groupings

A risk score, taking into account the relative weight of each covariate, was constructed by multiplying the estimated coefficients from the logistic model by 10 and rounding to the nearest decimal place and then multiplying this quantity by the covariate value (Fan et al. 2002; Wand et al. 2011; Plews 2010). We assessed the performance and calibration of the risk score in the validation sample, using the AUC and the Hosmer-Lemeshow goodness of fit test (Hosmer and Lemeshow 2000). Finally, we created a risk grouping with low, medium and high categories based on tertiles of the risk score distribution, and examined performance and calibration of the risk groupings using similar methods.

Secondary analysis: ART failure by 42 months

Our goal in this secondary analysis was to further validate the formulation of the risk score and risk groupings and to assess their performance in predicting ART failure over a longer time frame, through 42 months following ART initiation. For this analysis, we used time-to-event, or survival analysis, methods (Hosmer, Lemeshow, and May 2007). Patients retained within the 42-month analysis had at least 365 days of study follow-up after ART initiation (n=1,302, see **Figure 2.1**). Each patient contributed up to seven 6-month periods to the analysis and time to first ART failure was the right-censored outcome. Patients were followed from the date of ART initiation until the period of ART failure, the period prior to the study close date, or the period where loss to follow-up occurred, whichever was first. Loss to follow-up was defined as having 180 days pass with no clinical encounter.

To compare the performance of the adherence measures in the survival analysis framework, we created standardized versions of the baseline adherence measures using z-scores. Then we assessed each measure's ability to predict ART failure in separate Cox regressions. The standardized adherence measure with the largest magnitude regression coefficient was taken to

offer strongest prediction capability. Next, we applied the risk score and risk groupings derived in the primary analysis to the survival data. We stratified the Kaplan-Meier survival curves by risk groupings and used the log-rank test to assess differences in the survival curves across the groups over the extended 42-month time frame.

Sensitivity analyses

We explored the robustness of the results in the context of incomplete baseline CD4 cell count data. Specifically, we relaxed the requirement for a baseline CD4 measure to be available, assuming that these patients could still be observed to fail based on WHO criteria 2-4. All the steps in the primary and secondary analysis were repeated; however, baseline CD4 was modeled with a missing value category.

Ethical Review

The study protocol was reviewed by the University of Washington and received a human subjects exemption based upon use of existing de-identified patient data. It was also reviewed by the US Centers for Disease Control and Prevention and approved as a non-research program evaluation, and was reviewed and approved by the Haiti National Bioethics Committee.

Results

Adherence levels

In the overall cohort of 2,510 patients, mean adherence within the first 6 months was estimated to be highest based on the VAS measure (91.4%), followed by MPR (77.0%), TVR (76.1%), %NoMD (76.0%), and finally PDC (75.1%) (**Figure 2.2**). Only 24/2,510 (3%) patients lacked a value for MPR or PDC and only 48/2,510 (5%) lacked a value for TVR in the first 6 months on ART. In contrast, 1,005/2,510 patients overall (40.0%) and 317/1,814 patients

(17.5%) enrolled on ART after the introduction of the adherence assessment form lacked any self-reported adherence measures during the first 6 months on ART.

MPR and PDC were lower among those who were excluded from the primary 12-month analysis than among those who were included. Patients with no self-reported measures had markedly lower pharmacy-based adherence measures than those with self-reported measures available. Among those enrolled on ART after the introduction of the adherence assessment form and included in our primary analysis (n=643), mean PDC was 88.7% among those with a self-reported measure but only 66.2% among those without one ($p<0.001$ by t-test). In other words, those who never provided self-reported adherence data tended to have poorer adherence as estimated by pharmacy data.

Primary analysis: ART failure by 12 months

There were 923 patients within the primary analysis of ART failure at 12-months (**Figure 2.1**). More than half of patients in the original cohort lacked baseline CD4 results, follow-up CD4 results, or both, and were excluded from the analysis. Among the 923 patients, 196 (21.2%) met ART failure criteria by 12 months. Of the failure cases, 75% had a follow-up CD4 below the baseline value, 19% had a follow-up CD4 below 100 cells/µl, 5% met both of these CD4 criteria, and <1% had a new stage IV clinical diagnosis.

Patient characteristics are shown in **Table 2.1**. ART failure was more typical among male patients ($p=0.04$), among those who started ART in 2005-06 ($p<0.01$), among those with higher baseline CD4 level ($p<0.001$), and among those with no adherence assessments conducted during the first 6 months on treatment ($p=0.03$). Characteristics which were marginally significantly associated with ART failure were use of zidovudine + lamivudine + efavirenz (AZT+3TC+EFV)

or a non-standard initial regimen (p=0.06), younger age (p=0.07), and shorter duration of enrollment within the HIV care and treatment program prior to ART initiation (p=0.07).

The MPR and PDC measures differentiated cases of ART failure from non-failure, with non-overlapping 95% confidence intervals for mean measures in these 2 groups (**Figure 2.2**). Mean MPR and PDC levels were approximately 9 percentage points lower among cases of failure vs. non-failure ($p<0.001$ for each). The TVR measure had slightly overlapping 95% confidence intervals for the mean measure in the ART failure vs. non-failure groups. In contrast, the self-reported measures did not differentiate the 2 groups and the 95% confidence intervals for the mean measures were largely overlapping.

In the first step of identifying a robust prediction model--that of selecting the best-performing adherence measure from among the five available measures--PDC demonstrated the best performance (AUC=0.61; 95% CI: 0.56 – 0.66) (**Table 2.2**). In the second step, the stepwise covariate selection procedure conducted in the training dataset revealed several significant predictors of ART failure over and above PDC. These were male sex, higher baseline CD4 level, and lower duration of enrollment in HIV care prior to starting ART ("pre-ART duration"). The prediction model with both baseline adherence and these other patient characteristics performed better than models with only adherence or with only patient characteristics in the validation dataset (**Table 2.3**). The covariates for age, marital status, hospital site, proximity of residence, ART start year, initial ART regimen, baseline BMI, number of adherence assessments, and having any adherence assessment done by a clinician all failed to improve the AIC and were dropped from the prediction model. Predicted risk jumped with PDC<80%, with baseline CD4 values of >250 cells/µl, and with pre-ART duration of less than 160 days (data not shown).

A simplified prediction model using binary versions of each covariate performed as well as a model using continuous versions of covariates (**Table 2.3**). The risk score had possible values 0-32.5 and followed the equation:

$$Risk\ Score \quad = 7.7(pdc \leq 0.80) + 9.6(cd4 \geq 250) + 8.9(duration \leq 160) + 6.3(male\ sex)$$

Grouping the risk score into tertiles for high, medium, and low risk also resulted in predictive discrimination in the validation sample, with an AUC of 0.63 (95% CI: 0.58-0.68). The proportion of patients experiencing ART failure by 12 months was 10.1% in the low risk group, 14.4% in the medium risk group, and 28.7% in the high risk group. The odds of ART failure at 12 months was 1.5 times higher for patients in the medium risk group (OR=1.50; 95% CI: 0.66 – 3.40, p=0.37) and 3.6 times higher for patients in the high risk group (OR=3.58; 95% CI: 1.76 – 7.30, p<0.0001), compared to those in the low risk group (results not shown).

The implications of using each different risk grouping as a cut-off for a positive "risk test" are shown in **Table 2.4**. Using the low group as the cut-off would treat 100% patients as positive for the "risk test" and would be equivalent to no test. Using the medium group as the cut-off would identify approximately 75% of patients as positive for the risk test, while using the high group as the cut-off would classify approximately 50% of patients as positive for the risk test. The sensitivities, specificities, positive and negative predictive values for each risk test strategy, derived from the validation sample of the 12-month outcome study, are shown in **Table 2.4**. The implications of applying each risk test strategy to a hypothetical population of 1,000 patients, with and without resource constraints for actually targeting those with a positive risk test, are also shown in **Table 2.4**. In the absence of resource constraints, using no risk test would result in catching all eventual cases of ART failure, and would be the preferred strategy.

However, when resource constraints are present and only half of all patients can be targeted, the fewest cases of ART failure would be missed when only those in the high risk grouping are defined as having a positive risk test and are targeted for services.

Secondary analysis: ART failure by 42 months

The 42-month outcome analysis supported the findings of the 12-month analysis. An additional 441 patients were able to be included in the 42-month study based upon having a follow-up CD4 available after 12 months, for a total cohort of 1,302 patients (**Figure 2.1**). Among the 441 additional patients, baseline PDC was slightly higher than among patients in the 12-month study (89.4% vs. 86.5%, p=0.01), but no other patient characteristics were different. During the 42 months after ART initiation, 376 patients (28.9%) were observed to experience ART failure.

In the time-to-event analyses using standardized versions of the adherence measures, PDC was again the most predictive measure of ART failure. Kaplan-Meier survival curves stratified by the low, medium and high risk groupings showed a higher rate of ART failure in the high risk group compared to low and medium groups, and the curves suggest that this relationship between predicted risk and observed rate of failure holds even at time points up to 3.5 years after ART initiation (**Figure 2.3**). The difference in survival estimates among the groups was highly statistically significant (log rank $p<0.0001$).

Sensitivity analyses

Our sensitivity analyses also yielded consistent results. When patients without baseline CD4 values were included in the 12-month analysis, the number of included patients increased modestly from 923 to 1,005 patients. PDC continued to be the best-performing adherence measure. In an enriched prediction model, hospital site emerged as an additional predictive

covariate beyond PDC, sex, baseline CD4 and pre-ART duration. Still, the original risk score demonstrated good discrimination beyond chance in the sensitivity analysis. Relaxing the requirement for a baseline CD4 increased the number of patients in the 42-month analysis from 1,302 to 1,511. As in the original analysis, stratification by risk grouping produced dramatic differences in the Kaplan-Meier survival curves (log-rank $p<0.001$).

Discussion

Our study estimated that approximately one-fifth of ART patients met the WHO immunologic or clinical criteria for ART failure at 12 months. Pharmacy refill data, particularly the PDC adherence measure, had high informational value in predicting ART failure. In contrast, self-reported adherence measures were frequently missing and, when they were captured, they offered little value in discriminating patients who experienced ART failure. Male sex, higher CD4 level at baseline, and less time enrolled in care before initiating ART were also important predictors of ART failure. A risk score based on the baseline PDC measure together with these patient characteristics strongly discriminated patients at risk of ART failure. Whereas only 10.1% of patients in the lowest risk score grouping experienced ART failure, 28.7% in the highest risk score grouping did so. The risk grouping was robust in predicting failure up to 42 months following ART initiation, and also performed well in the context of missing baseline CD4 results.

Our results confirm PDC to be a viable proxy for adherence. The relative completeness of pharmacy-based data on medication regimen types, dispense dates, and amounts of medication dispensed, and the low likelihood that patients sought medications from sources outside their primary facility, all support use of iSanté pharmacy data to estimate ART adherence. Several additional patient characteristics enriched the prediction model by reflecting dimensions of

adherence not captured in the PDC proxy measure. For example, patients with higher baseline CD4 may have been less motivated to consistently take the medication they had in their possession, based upon a better overall level of health. Patients with longer duration of pre-ART enrollment may include those who are inherently likely to remain in care and comply with recommended care behaviors (since others may drop out before initiating ART), while patients with brief duration of pre-ART enrollment may include patients with a mix of inherent tendencies toward compliance. Lower pre-ART duration has been identified as a risk factor for ART attrition in Haiti (Puttkammer et al. 2013). The higher risk of ART failure we found among males is consistent with evidence of elevated ART attrition risk among males in Haiti and elsewhere in the Caribbean region (Koenig et al. 2012).

In a resource-limited setting like Haiti, our risk score has an important role to play in helping providers target patients for adherence support services before ART failure occurs. Such services could include in-depth counseling sessions with social workers or psychologists, adherence reminder phone calls or text messages, outreach visits by community health workers, or other types of supportive interventions. In the context of highly constrained human and material resources, it may not be possible to offer these interventions on a universal basis. This reality is underscored by the fact that nearly 40% of patients in our study population had no adherence assessment and counseling form completed. That these very patients tended to have lower adherence levels by pharmacy-based refill data, indicates that providers seemed to be missing patients with high levels of need. When resources are constrained, using the information about which patients are at higher risk of ART failure could help to decrease the number of eventual cases of ART failure which are missed. In a hypothetical cohort of 1,000 ART patients

of whom only half can be reached with intensive adherence support services, targeting these services to high risk patients would result in missing 40% fewer of these critical cases. Even if universal coverage with adherence support interventions is possible, knowing a patient's risk grouping could still help providers customize their communication messages according to risk grouping. For example, counseling for a patient at lower risk could focus on reinforcing positive behaviors. For those at higher risk, counseling could focus on identifying and overcoming barriers to adherence and could include referrals to other intensive adherence support services. This type of targeted communication strategy is identified as a best practice in HIV adherence support (Amico and Orrell 2013).

The first recommendation arising from our study is to use the validated risk scoring algorithm to program an automated provider alert within the iSanté electronic medical record system. The alert could be used in either an active or passive manner. For an iSanté alert to be successful, providers would need to receive training on how to interpret the alert and integrate its use within their care delivery processes. Well-designed electronic clinical alerts and reminders have been shown to improve quality of care and patient health outcomes (Oluoch et al. 2012; Robbins et al. 2012; Pearson et al. 2009; Damiani et al. 2010; Were et al. 2011).

A second recommendation arising from our study is to drop routine, universal documentation of self-reported adherence measures by providers. Leveraging automated adherence estimates derived from pharmacy refill data would allow for more efficient use of health worker and patient time, eliminating the need for providers to collect and record self-reported adherence data for patients with already-strong adherence by pharmacy data. Pharmacy personnel, who were responsible for completing about half of the adherence assessments for patients in our study, could shift their attention toward assuring strong data quality in the

pharmacy dispense and refill data, as well as toward following up with patients who are late for pharmacy refills. Having providers ask patients about adherence levels and barriers could have value as a cue to favorable adherence behaviors among patients, so it is important to be clear that the recommendation is not to abandon these conversations but rather to drop universal data collection of the self-reported adherence measures.

Strengths and limitations

A strength of our study is the exploration of several types of adherence measures in order to identify the measure which performed best in predicting ART failure. Another strength is that in evaluating various prediction models, we looked for a balance between the simplicity of the model and the robustness of its statistical performance. For an automated alert to be effective in Haiti, it is important that it be well-understood and trusted by Haitian providers. Our four-factor model, using binary thresholds for PDC, baseline CD4, and pre-ART duration, can be easily understood as representing a common "profile" of patients at high risk of ART failure. The risk groupings with low, medium, and high categories are also intuitive. A final strength of our study is the use of a randomly split sample in developing and validating the risk score. The strong performance of the risk score and risk grouping within the validation sample speaks favorably to the generalizability of our results to other patient populations and at other sites.

A key limitation of our study is the fact that many patient records lacked either baseline or follow-up CD4 values, meaning they lacked data on the ART failure outcome. Both our secondary and our sensitivity analyses supported the primary findings when including patients with follow-up CD4 results beyond 12 months and patient with no baseline CD4 results. Further, the distribution of sex and the average levels of baseline CD4 and pre-ART duration did not differ between patients included vs. excluded from the primary analysis. This gives modest

evidence for the generalizability of our findings to patients who were excluded from the primary analysis.

A second concern related to generalizability of our findings is that our study examined ART patients from only two facilities, representing approximately 6% of all ART patients within the iSanté data system. ART patients in Jérémie and Jacmel may be different from patients in other sites. Other iSanté sites might not share the relatively high completeness of pharmacy data we found in our cohort. Other sites may also have implemented the self-reported adherence assessments in a different manner, rendering the information more useful.

A third limitation of our study is that AUC values of above 0.70 are typically considered desirable for screening and diagnostic tests. An algorithm for ART failure risk developed for several large-scale electronic medical record systems in Boston demonstrated an AUC of 0.78, indicating strong discrimination (Robbins et al. 2010). ART adherence measures in South Africa had AUC values of 0.67-0.74 in predicting virologic failure at 6 or 12 months (Bisson et al. 2008). Our study found slightly lower AUC values, indicating weaker ability to discriminate ART failures from non-failures. Still, our risk score grouping was notably better than chance in predicting ART failure and would be useful in targeting patients, particularly since no harmful procedures would be triggered by false positive results of the risk test.

HIV viral load testing, the "gold standard" measure of ART failure, is not widely available in Haiti. There can be substantial misclassification of ART failure status when only immunologic and clinical status is known, and no confirmatory viral load testing is available (Gsponer et al. 2012; Keiser et al. 2009; van Oosterhout et al. 2009; Mee et al. 2008). Still, the WHO immunologic and clinical criteria for ART failure represent the available information upon which clinicians in Haiti must act. If viral load becomes more available in the future in Haiti, it

would be possible to repeat the study methodology to validate a simple and robust prediction model for this "gold standard" outcome.

Several important patient-level factors which might be important predictors of ART adherence and ART failure—such as employment status, socioeconomic status, food security, level of education, mental health status, and drug and alcohol use—were also not available iSanté. Data on whether patients were infected with a drug-resistant strain of HIV before initiating ART, and data on timing and frequency of ART stock-outs at the health facilities were also unavailable.

Conclusion

There is a critical need to support high ART adherence among patients placed on first-line ART regimens in resource-limited settings, to avoid cases of ART failure. Electronic medical record systems like iSanté can return relevant, actionable information to clinicians so that they can identify patients with problematic adherence and high risk of ART failure. Our study results support the development of an automated alert, leveraging iSanté pharmacy refill data as well as other patient characteristics, to predict risk of ART failure before it occurs. Such an alert could help in targeting patients with greatest need for in-depth ART adherence counseling and other supportive services. It would also help providers customize counseling messages according to the patient's level of risk. In the context of limited resources, there is high informational value in an alert which can improve targeting of patients in these ways.

Figure 2.1: Flow Chart for Participants in the 12-Month and 42-Month Analyses

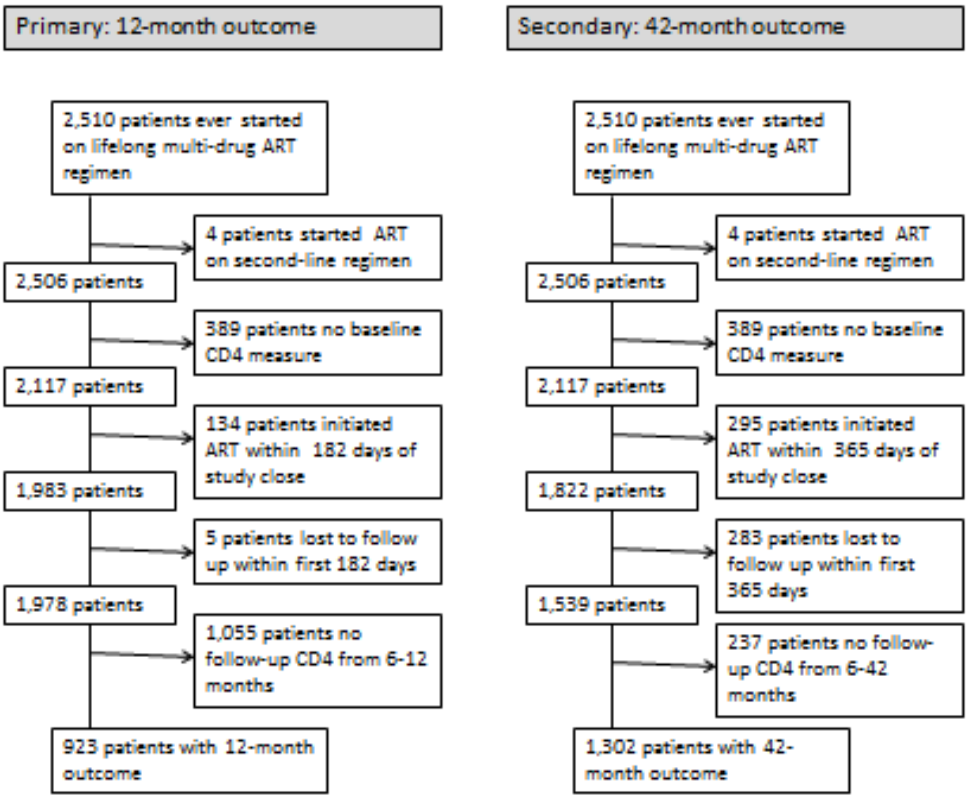


Table 2.1A: Patient Characteristics (Categorical Variables)

	All patients (n=923)		Failure cases within each sub-group	
	n	%	n	%
Site				
HSA Jérémie	453	49.1%	100/453	22.1%
HSM Jacmel	470	50.9%	96/470	20.4%
Sex[a]				
Male	382	41.4%	94/382	24.6%
Female	541	58.6%	102/541	18.9%
Marital status				
Single	227	24.6%	49/227	21.6%
Married / cohabitating	539	58.4%	116/539	21.5%
Widowed / separated	121	13.1%	21/121	17.4%
Unknown	36	3.9%	10/36	27.8%
ART start year[b]				
2005-06	135	14.6%	42/135	31.1%
2007-08	296	32.1%	58/296	19.6%
2009-10	225	24.4%	37/225	16.4%
2011-12	267	28.9%	59/267	22.1%
Proximity of residence to site				
Same commune	355	38.5%	77/355	21.7%
Adjacent commune	124	13.4%	29/124	23.4%
Non-adjacent commune	431	46.7%	88/431	20.4%
Missing	13	1.4%	2/13	15.4%
ART starting regimen				
AZT-3TC-EFV	464	50.3%	111/464	23.9%
AZT-3TC-NVP	293	31.7%	56/293	19.1%
Other standard	143	15.5%	21/143	14.7%
Non-standard	23	2.5%	8/23	34.8%
Number of adherence assessments (months 1-6)[a]				
None	340	36.8%	88/340	25.9%
One	62	6.7%	10/62	16.1%
2 or more	521	56.4%	98/521	18.8%
Any adherence assessment by clinician (months 1-6)				
No	641	69.4%	138/641	21.5%
Yes	282	30.6%	58/282	20.6%

Chi-square test p-values for difference in proportions between ART failures and non-failures: [a]p<.05, [b] p<0.01 ;
AZT=zidovudine, 3TC=lamivudine, EFV=efavirenz, NVP=nevirapine

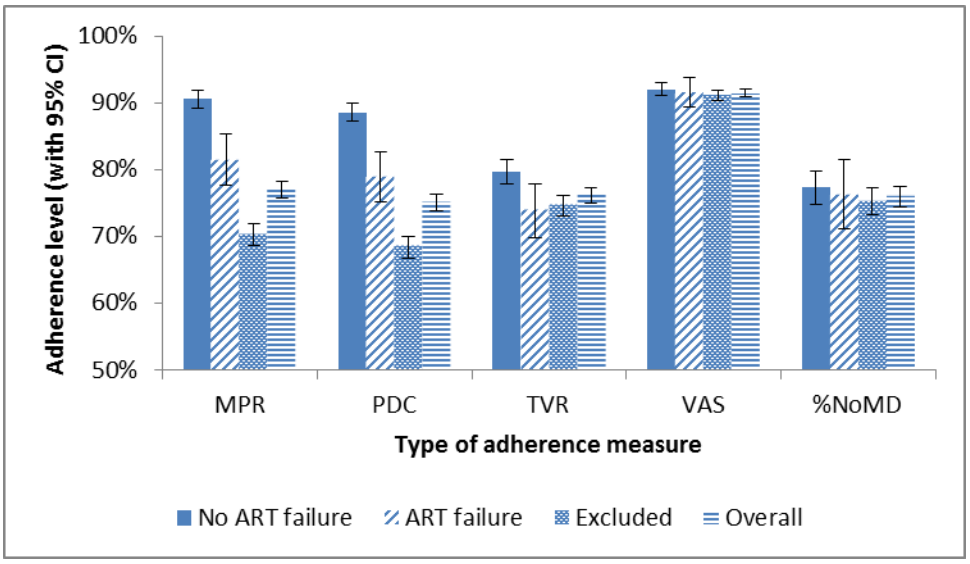
Table 2.1B: Patient Characteristics (Continuous Variables)

	All patients (n=923)			ART failure (n=196)			No ART failure (n=727)		
	n	mean	sd	n	mean	sd	n	mean	sd
Age at ART start[a]	923	38.7	10.9	196	37.3	11.3	727	39.0	10.8
Baseline CD4[1]	923	207.8	183.1	196	267.1	266.7	727	191.8	149.2
Baseline BMI	727	20.8	3.1	150	20.9	3.0	577	20.8	3.1
Pre-ART enrollement (days)	923	299.9	437.7	196	247.8	373.4	727	314.0	452.7

[a] p<.05 by Student t-test for difference in means between ART failures and non-failures.

[1] p<0.001 by Wilcoxon rank sum test (non-parametric test) for equality of distributions between ART failures and non-failures.

Figure 2.2: Baseline ART Adherence Levels (Months 1-6)



Pharmacy-based measures

MPR=Medication possession ratio; sample size: n=2,458

PDC=Proportion of days covered; sample size: n=2,458

TVR= Timely visit ratio; sample size: n=2,242

Self-reported adherence measures

VAS=Visual analogue scale; sample size: n=1,496

%NoMD=Proportion of visits with no missed dose reported; sample size: n=1,505.

Comparison groups

No ART failure (n=727) and ART failure (n=196) groups refer to patients in the primary analysis. Exluded group refers to patients excluded from the primary analysis (n=1,587). Overall group refers to the full population of adult ART patients (n=2,510).

Table 2.2: Performance of Baseline Adherence Measures as Predictors of ART Failure at 12 Months

Measure	Functional form	n	AUC	95% CI
MPR	continuous	899	0.60	(0.56, 0.65)
PDC	continuous	899	0.61	(0.56, 0.66)
TVR	continuous	875	0.56	(0.52, 0.61)
%NoMD	continuous	583	0.52	(0.46, 0.57)
VAS	continuous	582	0.50	(0.44, 0.56)

MPR: Medication possession ratio; PDC: Proportion of days covered; TVR: Timely visit ratio; VAS: Visual analogue scale; %NoMD: Proportion of visits with no missed dose reported; AUC: Area under the receiver operating curve; CI: confidence interval.

Table 2.3: Comparison of Prediction Models for ART Failure (12-month outcome)

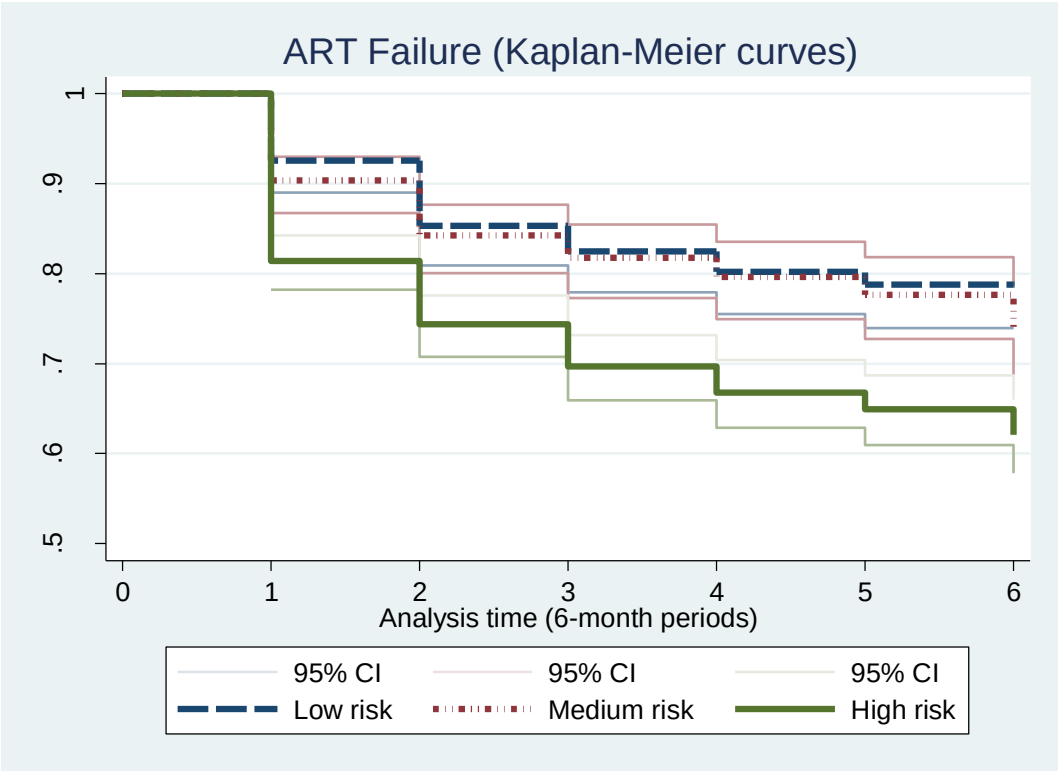
	PDC only			Patient characteristics only			Both PDC and patient characteristics			Simple model (binary covariates)			
	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value		OR	95% CI	p-value
PDC (untransformed continuous)	1.02	(1.01, 1.03)	0.002				1.01	(1.00, 1.02)	0.02	<80%	2.16	(1.27, 3.65)	0.00
Male				1.76	(1.11, 2.81)	0.02	2.12	(1.30, 3.47)	0.003	Male	1.87	(1.15, 3.05)	0.01
Baseline CD4				1.03	(1.01, 1.04)	<0.001	1.02	(1.01, 1.04)	0.001	>=250	2.60	(1.54, 4.38)	0.00
Pre-ART duration				0.99	(0.99, 1.00)	0.02	0.99	(0.99, 1.00)	0.06	<160	2.43	(1.54, 4.38)	0.00
Constant	0.20	(0.15, 0.27)	<0.001	0.36	(0.18, 0.42)	<0.001	0.23	(0.15, 0.35)	<0.001		0.07	(0.06, 0.16)	0.00
AIC	448.5			468.3			432.5				430.5		
	n	AUC		n	AUC		n	AUC			n	AUC	
Training sample	446	0.58		462	0.63		446	0.67			446	0.68	
Validation sample	453	0.64		461	0.64		453	0.69			453	0.69	

AIC: Akaike Information Criterion; PDC: Proportion of days covered; OR: Odds ratio; CI: Confidence interval.

Table 2.4: Diagnostic "Risk Test" Characteristics under Different Strategies

	Low + medium + high groups have positive "risk test" (no "risk test")	Medium + high groups have positive "risk test"	High group has positive "risk test"
Test classification characteristics			
Sensitivity	100.0%	89.6%	70.8%
Specificity	0.0%	24.4%	53.7%
PPV	20.8%	23.8%	28.7%
NPV	NA	89.9%	87.5%
Correctly classified	20.8%	38.0%	57.3%
Hypothetical population of 1,000 with unlimited resources for targeting			
Total targeted	1000	785	514
Cases of failure among targeted	208	186	147
Cases of non-failure among targeted	792	599	367
Cases of failure missed	0	22	61
Hypothetical population of 1,000 but with resources to target only 500			
Total targeted	500	500	500
Cases of failure among targeted	104	119	143
Cases of non-failure among targeted	396	381	357
Cases of failure missed	104	89	65

Figure 2.3: Kaplan Meier Curves for ART Failure by Risk Category (42-month outcome)



Log-rank test: p<0.001; CI: Confidence interval

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Chapter 3: Using an Electronic Medical Record System to Identify Factors Associated with ART Attrition at Two Hospitals in Haiti

Introduction

Haiti has the most extensive HIV epidemic in the Caribbean region, with a national adult HIV prevalence rate of 2.2% (IHE 2012). In the early 2000s, several small-scale programs in Haiti demonstrated success in treating patients with HIV antiretroviral therapy (ART), inspiring rapid scale-up of ART programs both within Haiti and globally (Mukherjee et al. 2006). As of the end of 2011, 34 927 Haitians were receiving ART, representing approximately 60% of the numbers of adults and children needing therapy (MSPP/PNLS 2012). Retention of patients within the ART program is critical to its success at individual and population levels.

The Haitian Ministry of Public Health and Population's (MSPP) iSanté electronic medical record (EMR) system, deployed in Haiti since 2004, contains longitudinal health records for patients living with HIV (Matheson et al. 2012). A concerning level of ART attrition is evident in iSanté data, with approximately 25% of ART patients recorded as officially discontinued. The earthquake of January 2010, which devastated the already-fragile health services infrastructure in and around the capital Port-au-Prince, may have exacerbated ART attrition. Prior studies have examined ART attrition in patient cohorts in Port-au-Prince prior to the earthquake (Koenig et al. 2012; Severe et al. 2005; Leger et al. 2009), but their findings do not necessarily reflect ART outcomes in other parts of Haiti or outcomes during the post-earthquake period. This retrospective cohort study examined factors associated with ART attrition among patients who initiated ART from 2005-2011 at two large public-sector Departmental hospitals in peripheral regions of Haiti.

Materials and Methods

Study setting and patient population

The study cohort included ART patients at Hôpital St. Michel in Jacmel and Hôpital St. Antoine in Jérémie. Both sites are the leading secondary hospitals in their respective Departments, which are rural and mountainous. The 2010 earthquake was centered < 30 km from Hôpital St. Michel; it destroyed several buildings on the hospital campus and killed approximately 300-500 people in the town of Jacmel (Wikipedia 2013). In contrast, Hôpital St. Antoine is located >150 km from the earthquake epicenter, and did not experience direct damage from the earthquake.

The study cohort included patients who were 15 years or older at the time of HIV program registration, and who started a multidrug ART regimen. The study excluded several two-drug ART regimens in women, which were presumed to represent time-limited therapies for preventing mother-to-child HIV transmission under prevailing treatment guidelines.

Data source

All study data came from the consolidated server for MSPP's iSanté EMR system. iSanté is one of three EMRs in in Haiti, and is used in more than 85 HIV care and treatment sites covering more than half of all ART patients in Haiti. Data are typically captured on standard paper-based iSanté patient encounter forms and then retrospectively data entered to the system. In addition to capturing data within an EMR, sites are also required to keep paper-based registers with summary data on all ART patients. iSanté data extracts were obtained on February 1, 2012. The average lag time for electronic data entry was less than 1 week, meaning that the data extract was an up-to-date representation for the cohort. Data cleaning involved inspection and adjudication of elements which violated field validation rules or plausible data relationships.

Elements that could not be adjudicated or which were determined to be errors were coded as missing.

Outcome variable

The outcome variable was time in days from ART start to attrition. ART start date was defined as the first dispense date for the multi-drug ART regimen. A variety of definitions of ART attrition have been used in international research (Chi et al. 2011; Koenig et al. 2012; Fox and Rosen 2010; Fatti, Grimwood, and Bock 2010). Our primary definition of attrition was the failure to return for pharmacy pick-up within 30 days of the expected ART refill date ("30+ day pharmacy definition"). The 30+ day pharmacy definition takes advantage of iSanté's detailed routine pharmacy data, reflects the continuity of actual ART use, and measures interruptions of clinical significance. In sensitivity analyses, we considered three alternative definitions: 1) no return pharmacy pick-up within 60 days ("60+ day pharmacy definition"); 2) no return for any type of outpatient HIV visit within 90 days ("90+ day encounter definition"), the MSPP's standard definition; and 3) no return for any type of outpatient HIV visit within 180 days ("180+ day encounter definition"), a proposed universal definition suggested by empirical findings on loss-to-follow-up among more than 180 000 patients in 19 countries (Chi et al. 2011).

To calculate ART attrition from pharmacy data, ART refill due dates were defined for every interval between pharmacy visits, based on dispense dates and number of dose-days dispensed. Missing dispense dates (missing in 4.1 % of pharmacy records) were imputed using the date of the clinical visit where the prescription was made (concordant in 97.8% of cases where both dates were available). The minimum number of dose-days dispensed for any single medication within a regimen was used to calculate the refill due date for the overall regimen. Missing dose-days dispensed (missing in 3.9% of pharmacy records) were imputed using the

patient-specific median dose-days or, if this was unavailable, the median dose-days for the study cohort.

Patients were counted as cases of attrition upon the first incident of failure to return in a timely manner. To partially account for patient transfers within the network of iSanté sites, we used a matching algorithm to identify those who presented for care at another iSanté site before the pharmacy refill or encounter "due date." These patients were then counted as transfer cases rather than ART attrition cases, and their observations were censored as of the "due date." We could not verify transfers of care to facilities outside of the iSanté data system. Haiti lacks a national death registry for ascertainment of mortality, and the two hospitals had limited resources to trace patients who failed to return to care, meaning that official ART disenrollment forms citing the reason for disenrollment were only available for a small fraction of patients who failed to return for care. For these reasons, we could not distinguish deaths from cases of loss to follow up. In sum, the outcome measure represented a composite of several possible reasons for attrition, with accounting for patient transfers to other facilities in the iSanté network.

Covariates

Factors assessed for association with ART attrition included: temporal factors, patient demographic factors, patient clinical factors, and service utilization factors (see **Figure 1**). CD4, BMI, WHO stage, tuberculosis (TB) status, and presence of symptoms associated with WHO stage IV were entered into analytic models as baseline covariates, measured during a baseline period of 180 days prior to ART initiation. TB status was a binary variable indicating a confirmed TB diagnosis, use of TB prophylaxis, or suspicion of TB during the baseline period. ART regimen was the initial regimen prescribed. Proximity of patient residence to the hospital

used the commune of residence at initial registration in HIV care, and defined categories of residing in the same, adjacent, or non-adjacent (more distant) commune as the hospital.

Statistical methods

This study used time-to-event analysis methods (Hosmer, Lemeshow, and May 2007). Observations of patient outcomes were censored for transfer cases or for patients not meeting the attrition definition as of January 1, 2012. Descriptive statistics were used to characterize the sample and identify the number of patients meeting the primary and alternative ART attrition definitions. The Kaplan-Meier method was used to estimate average rates of attrition, attrition levels at specific time points, and attrition levels by patient sub-groups. Unadjusted and adjusted semi-parametric Cox regression models were used to obtain hazard ratio (HR) estimates for all observed independent variables. In the adjusted model, we included a post-earthquake indicator as a time-varying exposure, in order to allow for different attrition risk before and after the earthquake. We also included an interaction term for hospital site and the post-earthquake period, in order to test for a differential earthquake effect by site. To avoid assumptions of linearity in relationships, several covariates were classified as categorical variables with logical or clinically-relevant cut-points.

To handle missing data on the covariates proximity of residence (<1% missing), WHO stage (3.0% missing), BMI (7.7% missing), and CD4 (17.0% missing), we used multiple imputation using chained equations. This method has been shown to minimize bias in risk estimates relative to other possible methods for handling missing covariate data (Groenwold et al. 2012; Schafer and Graham 2002; Knol et al. 2010). The imputation model included all model variables, and 5 imputed datasets were created (Buuren, Boshuizen, and Knook 1999). Categorical variable constructs were tested with joint testing of coefficients. To assess the

sensitivity of our findings to this strategy for handling missing data, we compared models using complete case analysis, missing indicator dummy variables for covariates with missing data, and manual imputation using extreme values, for each of the attrition definitions. All analyses were performed using STATA 12.0 statistical software (StataCorp, College Station, TX).

Ethical review

The study protocol was reviewed and approved by the University of Washington, the Haiti National Bioethics Committee, and the US Centers for Disease Control and Prevention.

Results

The study cohort included 2 023 patients who received a multidrug ART regimen at the 2 hospital sites by the end of 2011. The cohort excluded 113 pediatric patients, 15 patients of unknown age or year of birth, and 1 patient of unknown gender. Characteristics of the patient population are shown in **Table 1**. Overall, 694 patients (34.3%) met the 30+ day pharmacy attrition definition, 331 (16.4%) met the 60+ day pharmacy attrition definition, 966 (47.8%) met the 90+ day encounter definition, and 321 (15.9%) met the 180+ day encounter defintion. Only a small number of patients who stopped receiving care at the two sites made timely transfers to an alternative facility (1 timely transfer under the 30+ day pharmacy definition, and 4 timely transfers under the alternative definitions).

Under all definitions, attrition was dramatic during the first 12 months after ART initiation, with 26.6% of patients abandoning ART under the 30+ day pharmacy definitions (95% CI: 24.6%-28.7%, see **Figure 2**). While attrition tapered considerably after 12 months under the 30+ day pharmacy definition, it increased more steadily over time under the 90+ day encounter definition. Attrition under the 60+ day pharmacy definition was about half of that under the 30+ day pharmacy definition at each time point. This indicates that a sizable proportion of attrition

reflected temporary interruptions in care. Attrition under the 60+ day pharmacy definition and the 180+ encounter definition was similar. ART attrition was notably higher in Jérémie compared to Jacmel, for every definition and for every time point.

Rates of attrition per 100 person years by patient subgroups are shown in **Table 1**, based on the 30+ day pharmacy definition. In unadjusted analyses, factors associated with greater attrition risk were: care in Jérémie ($p<0.001$); residing outside the commune of the hospital ($p<0.0001$); starting ART during an earlier calendar year ($p<0.0001$); ART regimen ($p<0.05$); not having a WHO stage IV symptom reported ($p=0.01$); and having less time between enrollment and ART initiation ($p<0.01$). There were no meaningful differences in rates of attrition by gender, age, BMI, WHO stage, TB status, and number of counseling sessions prior to ART initiation, in unadjusted analyses.

In the adjusted analysis, there was no evidence that the relative risk of attrition between the 2 hospitals changed following the quake ($p=0.66$ for interaction term). The results of the main-effects adjusted Cox model are presented in **Table 2**. After adjustment for all covariates, proximity of residence, hospital site, and year of ART start (representing a cohort effect by calendar year) were each strongly associated with ART attrition. Adjusted ART attrition risk was 69% higher for patients residing in an adjacent commune (HR: 1.69, 95% CI: 1.39-2.06; $p<0.001$) and 89% higher for patients residing in a non-adjacent commune (HR: 1.89, 95% CI: 1.54-2.33; $p<0.001$), compared to patients residing in the same commune as the hospital. Adjusted ART attrition risk was meaningfully lower in Jacmel vs. Jérémie both before and after the quake (HR: 0.58, 95%CI: 0.49-0.70; $p<0.001$). The adjusted model showed a risk of attrition that decreased successively with calendar time of ART start ($p<0.001$), but there was no evidence of a specific temporal effect related to the earthquake (HR: 0.94 for post-earthquake

compared to pre-earthquake, 95%CI: 0.73-1.22; p=0.66). Having shorter duration of enrollment in HIV care prior to ART initiation ($p<0.01$), having a non-standard ART regimen ($p<0.05$), having no counseling sessions prior to ART initiation ($p<0.10$), and having a BMI >18.5 ($p<0.10$) were also associated with higher attrition risk in the adjusted analysis.

The findings of elevated attrition risk by distance patient residence and by hospital site were robust across sensitivity analyses using alternative attrition definitions and alternative strategies for handling missing data. The findings on attrition risk by calendar period, ART regimen, and number of counseling sessions prior to ART initiation were more sensitive to the attrition definition and to the strategy for handling missing data. Calendar period was significantly associated with attrition risk in all models except the model using the 60+ day pharmacy definition for attrition outcome; however, ART regimen and number of counseling sessions were not significantly associated factors in the sensitivity analyses.

Discussion

This study, one of the first to use iSanté data for applied research, describes ART attrition both before and after the 2010 earthquake in 2 large public-sector hospitals in peripheral Departments of Haiti. These exploratory findings point to several quality improvement interventions with potential to improve ART program outcomes at the 2 hospitals.

That ART attrition risk was sharply higher in Jérémie compared to Jacmel is consistent with other studies from Haiti showing the heterogeneity of ART attrition in different facilities and regions. An unpublished study by the MSPP on patients initiating ART in 55 different facilities in 2010 found ART attrition to range from 12.8 – 47.8% after 1 year in facilities with at least 50 ART patients (MSPP/PNLS 2013). A study of outcomes of ART patients enrolled in 2003-09 at the GHESKIO clinic in the heavily urban environment of Port-au-Prince reported an

attrition rate of 26 per 100 person years (Koenig et al. 2012), somewhat higher than our observations both in Jérémie (21.5 per 100 person years) and in Jacmel (12.5 per 100 person years). The relatively high rate of ART attrition observed in Jérémie compared to Jacmel may reflect the relative disadvantage of the surrounding Grand-Anse Department, where fully half of the population is estimated to fall in the lowest quintile of wealth for Haiti (compared to 31% in the South East Department, where Jacmel is located) (Cayemittes et al. 2013).

The finding of elevated risk of attrition for patients residing at greater distance from the hospital was noteworthy. Since the start of the national ART program, Haiti has steadily decentralized ART services to bring services closer to people in need. The number of ART sites in Haiti grew from 2 sites in 2003 to more than 63 sites by 2011 (MSPP/PNLS 2012, 2013). However, as late as 2011, 36% of patients newly enrolling on ART in Jacmel and Jérémie still resided outside the commune of the hospital. Our finding is consistent with evidence from other low-resource settings on the role of patient travel distance and transport barriers in ART attrition. Studies in Malawi, South Africa, and Mozambique, have all demonstrated more favorable ART retention in decentralized primary care centers compared with larger centralized hospitals (Massaquoi et al. 2009; Fatti, Grimwood, and Bock 2010; Lambdin et al. 2011). While each of these studies did not necessarily measure and control for patients' travel distances, we can presume that travel distance plays a strong role in explaining these findings. A qualitative study in Uganda identified transportation cost as a key structural barrier for ART program retention (Tuller et al. 2009).

In Haiti, as in other countries, the question of the right level of ART service decentralization is complex. There is a tension between the goal of increasing patient access to ART via decentralization, and the goal of maintaining quality of care via concentration of

resources in larger, regionalized care centers. Within the global health services literature, there is a compelling body of evidence indicating that greater patient volume is associated with improved health outcomes, in HIV care (Handford et al. 2012; Kitahata et al. 2003; Kitahata, Van Rompaey, and Shields 2000) as well as other areas such as surgery (Birkmeyer et al. 2003), cardiac care (Grumbach et al. 1995), and neonatal care (Phibbs et al. 1996). Given Haiti's limited health system resources to support ART program decentralization even into the smallest, most remote clinics, it is important that patients who travel long distances for ART services, whether by necessity or preference, are offered supportive services which counter balance their elevated risk of attrition.

The pattern of decreased attrition risk with maturation of the national ART program is consistent with evidence from other low-resource countries (Koenig et al. 2012; Fox and Rosen 2010; Auld et al. 2011; Sabapathy et al. 2012; Fatti, Grimwood, and Bock 2010), likely reflecting greater provider experience and access to medical technologies over time. While a Ugandan study reported no benefit of counseling sessions before ART initiation in improving ART outcomes (Siedner et al. 2012), we found that adjusted attrition risk was 26% lower for patients receiving 2 or more counseling sessions compared to those receiving no counseling before ART initiation. In the Haitian context, counseling sessions may effectively identify and resolve some care access barriers.

Together, our findings suggest several interventions to improve retention of patients on ART. First, the hospitals should target the efforts of their psychosocial counseling and community health worker staff toward enhanced retention support for patients accessing care from remote areas. It may also be important to mobilize greater material resources for transportation subsidies. Offering counseling for all patients prior to ART initiation could help

ensure that patients' access barriers are more universally and systematically identified. Scheduling timely outreach to patients who are late for ART refills, without waiting until 90 days after their last visit, could also mitigate attrition. Providing "bridging services" whereby community health workers accompany transferring patients to the new facility in a timely manner could also help ensure that ART use remains uninterrupted during the transfer process. Routine screening at each ART pick-up for anticipated inability to return in a timely manner for the next refill, such as due to upcoming travel, would allow providers to adjust the duration of ART dispenses accordingly. Finally, conducting medical case review for patients placed on non-standard ART regimens could help improve ART outcomes for these patients. Of course, the associations observed in this study cannot be interpreted as causal, due to the possibility that unmeasured patient characteristics drive the observed relationships. Still, the suggested quality improvement interventions are worthy of further testing at the two hospitals.

Limitations

Data quality within routine health information systems in low-resource settings, such as iSanté, is typically considered to be weak (AbouZahr, Adjei, and Kanchanachitra 2007). Within iSanté, misclassification of the presence of symptoms or diagnoses was possible, because absence of notation on symptoms or diagnoses could represent a provider's failure to assess for the condition rather than a "true negative" status; this could lead to some bias in covariate estimates (Jurek, Greenland, and Maldonado 2008). A data validation exercise comparing iSanté electronic data with data from paper charts and ART registers within a randomly selected sample of 200 ART patients from the two hospitals, found a high concordance (≥90%) of both outcome and covariate data between sources for patient demographic data, weight, CD4, and ART medication prescriptions (Puttkammer, Raphael, and Zamor 2013). Further, our estimates of

attrition closely matched estimates independently obtained by the MSPP from paper-based ART registers at each of the two sites, for the cohort of patients enrolled on ART in 2010 (MSPP/PNLS 2013). In sum, we have strong reason to believe that the iSanté data were fit for use for this study.

The lack of cause-specific information about attrition represents a second limitation. Our estimates of absolute attrition levels may be upwardly biased due to our inability to fully account for transfers of care to sites outside of the iSanté network. However, given that iSanté sites account for more than half of patients enrolled within Haiti's national ART program, the number of uncounted transfer cases in our cohort was likely small. This means that neither the absolute attrition estimates nor the hazard ratio estimates are likely to be strongly affected by missing information about patient transfers.

Finally, the iSanté system lacks information on some patient-level factors likely to influence ART attrition risk, including income, occupation, education, mental health status, provider experience level, receipt of ancillary services such as nutrition support or peer counseling, and experience of the effects of ART stock-outs (**Figure 1**). Nevertheless, iSanté represents a remarkably rich data source of for operational research and monitoring of quality improvement interventions.

Conclusion

ART attrition differed notably between the two hospitals and was very strongly associated with distance of patient residence from the facility. The later finding has important policy implications with respect to decentralization of services and argues for minimizing transportation-related barriers to accessing care. As Haiti's ART guidelines expand coverage to patients with higher CD4 counts and to all pregnant women regardless of CD4 count ("Option

B+"), the challenges of maximizing retention of ART patients will likely intensify. Quality improvement interventions which target retention support to patients residing in remote areas and which promptly provide outreach to patients who miss ART refills merit testing at the two facilities, as well as at similar facilities in Haiti. This study demonstrates the potential of the iSanté system not only to inform the design of such interventions for improved ART retention, but also to monitor and evaluate their success over time.

Figure 3.1: Conceptual Model for Factors Associated with ART Attrition

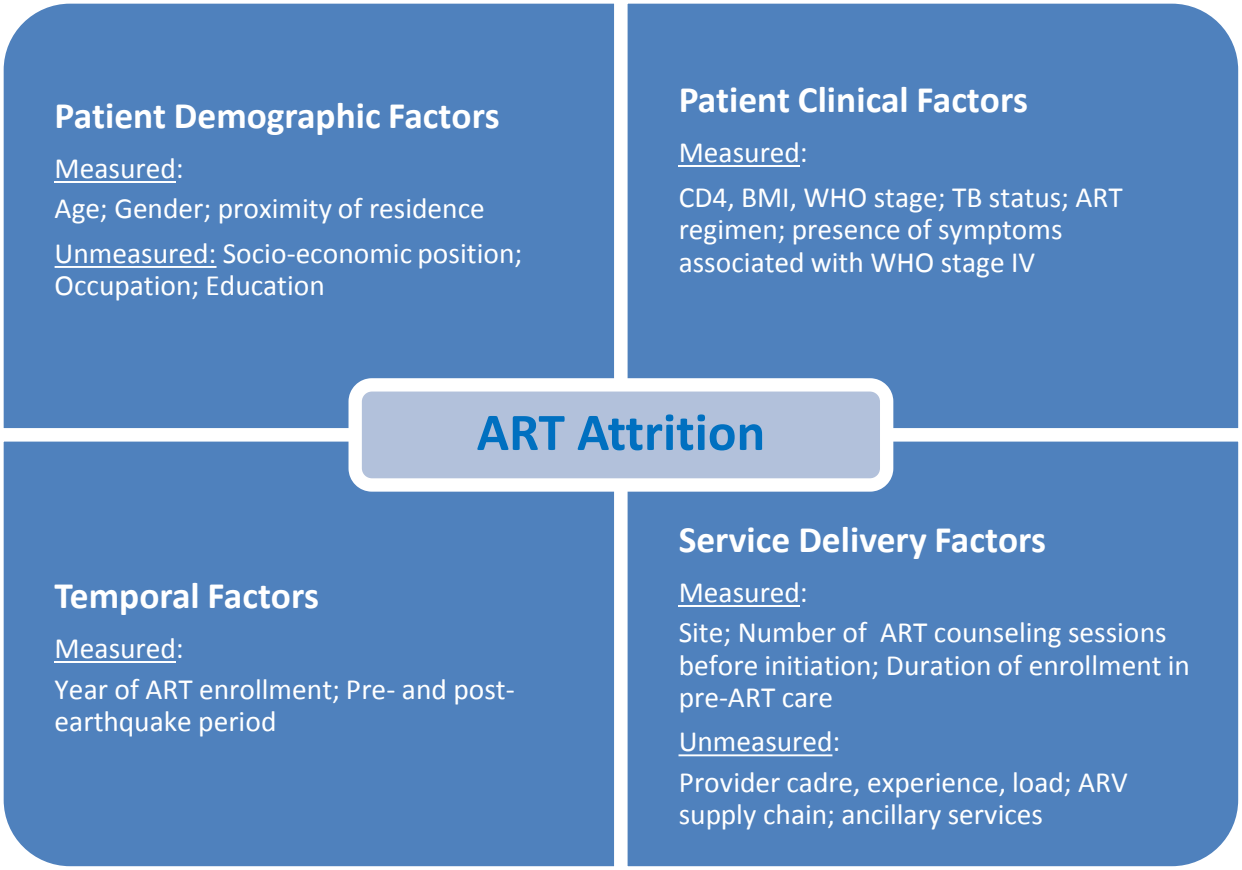
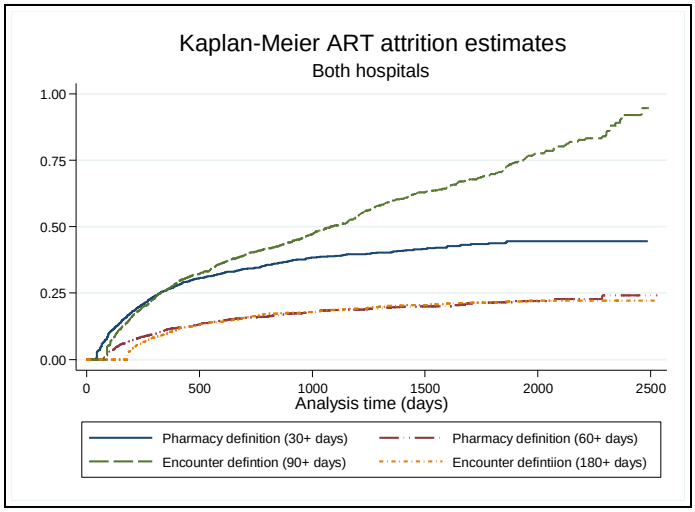


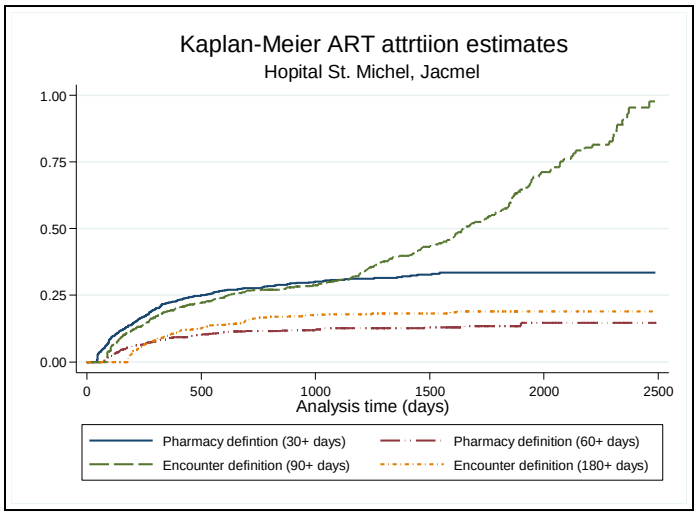
Table 3.1: Patient Characteristics and Rates of Antiretroviral Therapy (ART) Attrition at 2 Hospitals in Haiti, 2005-2011*

		Patients		Attrition	Rate per	95% CI	
		N	%	N	100 PY	Lower	Upper
Overall		2023	100%	694	17.0	(15.8,	18.3)
Site	HSA Jérémie	1052	52%	434	21.5	(19.6,	23.6)
	HSM Jacmel	971	48%	260	12.6	(11.1,	14.2)
Gender	Male	877	43%	295	16.2	(14.5,	18.2)
	Female (non-pregnant)	1043	52%	367	17.5	(15.8,	19.4)
	Female (pregnant)	103	5%	32	19.2	(13.6,	27.1)
Age group	<25	182	9%	62	17.2	(13.4,	22.1)
	25-44	1254	62%	428	16.6	(15.1,	18.3)
	>45	587	29%	204	17.8	(15.5,	20.4)
Residence	Same commune	1301	64%	389	13.4	(12.1,	14.8)
	Adjacent commune	419	21%	158	20.8	(17.8,	24.3)
	Non-adjacent commune	291	14%	140	34.0	(28.8,	40.1)
	Missing	12	1%	7	60.9	(29.1,	127.8)
BMI	<=18.5	529	26%	180	16.2	(14.0,	18.7)
	>18.5	1338	66%	471	17.4	(15.9,	19.1)
	Missing	156	8%	43	15.9	(11.8,	21.4)
ART start	2005-06	343	17%	192	18.1	(15.7,	20.8)
	2007-08	645	32%	261	14.6	(12.9,	16.4)
	2009-10	660	33%	208	19.8	(17.3,	22.7)
	2011	375	19%	33	18.3	(13.0,	25.8)
Baseline CD4	<100	485	24%	164	14.8	(12.7,	17.2)
	100-249	743	37%	253	15.9	(14.0,	18.0)
	250+	453	22%	129	18.4	(15.5,	21.9)
	Missing	342	17%	148	21.8	(18.6,	25.6)
ART regimen	AZT-3TC-EFV	1122	55%	371	16.4	(14.8,	18.2)
	AZT-3TC-NVP	690	34%	268	18.7	(16.6,	21.1)
	d4T-3TC-EFV or TDF-3TC-EFV	88	4%	18	9.8	(6.2,	15.5)
	d4T-3TC-NVP or TDF-3TC-NVP	89	4%	24	13.7	(9.2,	20.5)
	Non-standard	34	2%	13	36.6	(21.2,	63.0)
WHO stage	Stage 1 or 2	1187	59%	387	16.4	(14.8,	18.1)
	Stage 3 or 4	776	38%	280	17.4	(15.4,	19.5)
	Missing	60	3%	27	25.7	(17.6,	37.4)
TB status	No	1581	78%	530	17.7	(16.3,	19.3)
	Yes	442	22%	164	15.0	(12.8,	17.4)
Stage 4 symptom	No	1728	85%	630	17.1	(15.8,	18.5)
	Yes	295	15%	64	15.9	(12.5,	20.3)
Pre-ART duration	<1mo	677	33%	255	20.8	(18.4,	23.6)
	1-6mos	689	34%	239	15.9	(14.0,	18.0)
	>6mos	657	32%	200	14.7	(12.8,	16.9)
Counseling sessions	None	1332	66%	481	16.9	(15.4,	18.4)
	One	539	27%	166	17.5	(15.0,	20.4)
	Two+	152	8%	47	16.6	(12.5,	22.1)

*ART attrition is defined as being 30 or more days late for an ART pharmacy re-fill ("30+ day pharmacy definition")
ART= antiretroviral therapy; BMI=body mass index; TB=tuberculosis; PY=person-years; WHO=World Health Organization
ART regimen: ZDV=zidovudine; 3TC=lamivudine; EFV=efavirenz; NVP=nevirapine; d4T=stavudine; TDF=tenofovir.

Figure 3.2: ART Attrition Estimates at Two Hospitals in Haiti, 2005-2011





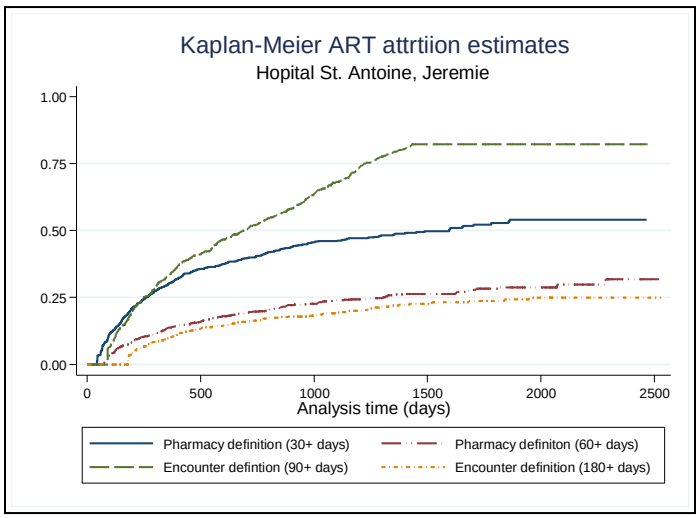


Table 3.2: Adjusted Hazard Ratios for ART Attrition at 2 Hospitals in Haiti, 2005-2011*

Risk Factor	Hazard ratio	95% confidence interval		p-value
Site				
Jacmel vs. Jeremie[d]	0.58	(0.49,	0.70)	<0.001
Post vs. pre-quake	0.94	(0.73,	1.22)	0.66
Gender (male=reference)				
Female (non-pregnant)	0.99	(0.81,	1.21)	0.92
Female (pregnant)	1.08	(0.72,	1.62)	0.71
Age (10 year greater)	1.05	(0.97,	1.13)	0.20
Proximity (same commune=reference)[c]				
Adjacent commune	1.69	(1.39,	2.06)	<0.001
Non-adjacent commune	1.89	(1.54,	2.33)	<0.001
BMI (<18.5=reference)[a]				
>18.5	1.19	(0.99,	1.42)	0.06
Year of ART start (2005-06=reference)[d]				
2007-08	0.66	(0.54,	0.81)	<0.001
2009-10	0.60	(0.44,	0.81)	0.001
2011	0.37	(0.23,	0.61)	<0.001
Baseline CD4 (<100=reference)				
100-249	1.06	(0.86,	1.30)	0.58
250+	1.15	(0.86,	1.54)	0.33
ART regimen (AZT-3TC-EFV=reference)[b]				
AZT-3TC-NVP	1.14	(0.92,	1.42)	0.23
d4T or TDF + 3TC-EFV	0.67	(0.42,	1.08)	0.10
d4T or TDF + 3TC-NVP	0.86	(0.55,	1.34)	0.51
non-standard regimens	2.04	(1.16,	3.59)	0.01
WHO Stage (stage I or II=reference)[a]				
stage III or IV	1.16	(0.99,	1.37)	0.07
TB status (No suspicion, prophylaxis or diagnosis=reference)				
Yes	0.91	(0.74,	1.10)	0.32
Any stage IV symptom (No=reference)				
Yes	0.84	(0.64,	1.11)	0.22
Pre-ART duration (30 day increase)[c]	0.99	(0.98,	1.00)	0.01
Counseling sessions prior to ART start (None=reference)[a]				
1 session	0.84	(0.70,	1.01)	0.07
2+ sessions	0.74	(0.54,	1.01)	0.06

*Main effects model using 30+ day pharmacy definition for ART attrition

p-values using joint testing of coefficients: [a] p≤0.10, [b]p≤0.05, [c] p≤0.01, [d] p≤0.001

ART= antiretroviral therapy; BMI=body mass index; TB=tuberculosis; WHO=World Health Organization

ART regimen: ZDV=zidovudine; 3TC=lamivudine; EFV=efavirenz; NVP=nevirapine; d4T=stavudine; TDF=tenofovir.

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Chapter 4: A mixed-methods assessment of data quality in Haiti's multi-site electronic medical record system

Introduction

In recent years, significant investment in resource-limited settings has been made to strengthen health information systems, including clinic-level electronic medical record (EMR) systems. These systems offer the potential to improve quality of care and population health by informing clinical decision making (Oluoch et al. 2012; Chaudhry 2006; Shekelle, Morton, and Keeler 2006; Buntin et al. 2011), health facility management (Nash 2009; Clifford et al. 2008; Chaudhry 2006), and health-sector surveillance, policy-making, and resource allocation (Nash 2009; Chaudhry 2006). However, both in low- and high-resource settings, data quality within routinely used health information systems can be problematic (Holve, Segal, and Lopez 2012; Parsons et al. 2012; AbouZahr, Adjei, and Kanchanachitra 2007). Poor DQ in EMRs can arise from systematic errors in software, non-intuitive user interfaces, transcription errors, lack of alignment between data collected and clinical practice, lack of provider clarity about how to use data fields, and many other EMR-specific issues. It can also come from issues beyond the EMR, including measurement error from poorly calibrated or functioning equipment, weak provider training, inadequate numbers of personnel to collect data, or other underlying weaknesses in the broader health care delivery system.

Strong DQ is a precursor to strong data use because consumers and users of the data must first trust the information (Nutley and Reynolds 2013). Multiple dimensions of DQ are important to data users, including timeliness, completeness, accuracy, relevance, accessibility, interpretability, flexibility, and conciseness, among others (Wang and Strong 1996; Weiskopf and Weng 2012). Numerous one-off studies have reported on results of DQ assessments (DQA)

for electronic databases in resource-limited settings (Lambdin et al. 2012; Gimbel et al. 2011; Makombe 2008; Ndira, Rosenberger, and Wetter 2008); however, the methods used are not realistic for routine internal assessment on a daily, weekly, or monthly basis. Methods for validating the accuracy of EMR data are particularly tricky and can require resource-intensive methods such as comparison of electronic data with patient exit interviews, video-recordings of patient encounters, or chart reviews (Thiru, Hassey, and Sullivan 2003; Chan, Fowles, and Weiner 2010). Because EMRs collect longitudinal patient data, it is possible to use automated database queries to assess timeliness, completeness, and accuracy of data by checking for plausible data relationships (Kahn et al. 2012; Maydanchik 2007). This can be an efficient process for routine internal DQA of EMRs in resource-limited settings.

The purpose of this study was to identify strategies for strengthening DQ within the iSanté EMR in Haiti. The iSanté system has been implemented by Haiti's Ministry of Health (MSPP) since 2005 (Lober et al. 2008; Matheson et al. 2012). Initially, iSanté focused on outpatient care for patients with HIV, but the system has since expanded to cover general outpatient primary care; women's health; and malaria and tuberculosis screening, prevention, and treatment (Lamothe et al. 2011). As of March 2014, iSanté had been deployed in 108 health care facilities in all geographic regions of Haiti. The system holds longitudinal data for more than 270,000 patients, including more than half of all patients receiving HIV care and treatment services in Haiti. There is anecdotal evidence from system users that DQ is perceived as weak across many of the hundreds of data elements within iSanté, leading to sub-optimal data use for patient care, health program management, and program reporting. Low use of data was evident in that 20% of sites actively using iSanté ran fewer than 30 automated reports of any type, including individual patient summary reports, reports on active vs. inactive patients, quality of

care indicator reports, and data quality reports during the 6-month period from January - June 2013. Our study contributes to the growing literature on the implementation of large-scale multi-site EMRs in resource-limited settings by providing a description of DQ, by identifying site- and system-level factors associated with strong DQ within the iSanté system, and by demonstrating efficient methods for conducting DQA.

Methods

We used mixed methods for the iSanté DQA. First, using a qualitative Delphi process, we established stakeholder consensus to determine the priority data elements to investigate. We then performed a retrospective quantitative analysis on the prioritized data elements. The analysis included only HIV patient data since these data had the longest history within the system.

Qualitative Assessment

The Delphi process involved two groups of local Haitians: 1) experts in HIV clinical care, and 2) experts in strategic information and HIV program reporting. The two groups identified the type of information that is crucial for competent clinical care and public health reporting, respectively. Delphi processes are useful for obtaining and building consensus on strategic questions where opinions matter, especially when competing options are present (Dalkey and Rourke 1971). Respondents participated in one in-person session and two follow-up on-line surveys. During the in-person session, stakeholders provided an open-ended, unprompted listing of information for which they perceived high levels of completeness, accuracy and timeliness to be highly important. They also responded to open-ended questions about their attitudes toward the iSanté system. During subsequent surveys, participants rated and ranked the

types of information, each time taking into account average group responses from the prior round. This method produced a limited set of priorities for DQ improvement within iSanté.

Quantitative Assessment

For the quantitative assessment, we first mapped the information priorities to specific data elements within the system. For example, to have high quality information on proportion of women eligible and receiving services for preventing mother-to-child HIV transmission, it is important to have accurate and complete data on pregnancy status, eligibility for HIV antiretroviral therapy (ART), and ART prescriptions. This mapping step yielded a set of specific DQ indicators for the quantitative analysis (**Table 4.1**).

Next we completed a retrospective quantitative DQA across all facilities using the iSanté system. The iSanté data system includes 20 possible encounter types, which match paper forms used for HIV care (registration, clinical intake and follow-up, counseling intake and follow-up, pharmacy, laboratory, home visit, referral tracking, ART selection committee, ART adherence assessment, and program discontinuation forms for adult and pediatric patients). Discontinuation forms are used to indicate the disposition of patients who have failed to return for care after more than 180 days. We included facilities that had collected and stored at least 100 encounters (forms) of any type for HIV patients within iSanté. Sites without their own local servers entered data over the Internet to a central server. Sites with local servers entered data to a local network and those data were replicated on a daily basis to the consolidated server as internet connectivity permitted. Data extracts were obtained from the national consolidated server.

Outcomes

Our outcome measures were 13 DQ indicators, focused on the dimensions of completeness, accuracy, and timeliness of data, shown in **Appendix 1**. All indicators were defined as binary variables for a specific encounter (form). Some indicators were relevant for only a single encounter per patient (such as age or sex, which were collected only once on the registration form), while others were relevant to multiple encounters per patient (such as weight, which could be collected at each clinical visit).

Completeness indicators considered the specific set of patients and encounters for which mandatory completeness would be relevant. For example, completeness of data on eligibility status for HIV antiretroviral therapy (ART) was derived from clinical intake and follow up forms for patients who had not yet received any ART prescription. Responses from the Delphi process guided when completeness was considered as mandatory. For example, ART eligibility assessment was considered mandatory at every clinical visit prior to ART initiation, while height was considered mandatory during every clinical encounter for pediatric patients but only at a single clinical encounter for adults.

Accuracy indicators also had specific rule sets, based on logic for plausible sequence of events and relationships between values (Kahn et al. 2012; Maydanchik 2007). Some of the rules detected impossible values such as "45" recorded for a day of the month, male patients with obstetric data or female-only laboratory data recorded, or visit dates falling before the creation dates for forms, while other rules signaled suspicious data where inconsistencies were present (such dispensing dates for ART medications falling more than 30 days after prescription dates, discrepancies of more than 2 years between age in years and date of birth, or CD4 cell count values of >2000). It is important to note that our DQ indicators for accuracy do not necessarily

reveal whether particular information is true or false, but rather they flag the presence of suspicious data.

The timeliness indicator was based on whether data entry for each encounter occurred three or more days after the visit date. During the Delphi process, stakeholders expressed consensus on this threshold as a local standard for timely data entry of iSanté data.

Covariates

Covariates used in the DQA included both site characteristics (department (region), urban vs. rural location, facility type, sector, and patient volume) and iSanté system characteristics (number of system users, presence of a local server for off-line use of iSanté, number of months of experience at the site in using the system, and overall maturity of the system at the time of use). Haiti is divided into 10 administrative departments, with the Port-au-Prince metropolitan area located within the West Department. There is no published standard urban vs. rural definition available from the Haiti Statistical Bureau, so the classification of sites by urban vs. rural was done by a Haitian professional responsible for training iSanté system users, who had physically visited each site. Facility type was grouped by categories: university hospitals, hospitals, health centers with and without beds, and dispensaries. Sector referred to ownership and governance of the site and was grouped by categories of public, private/non-profit, or mixed. Patient volume was considered to be a time-varying characteristic based on the cumulative number of HIV patients ever enrolled at the site by the end of each calendar month. All iSanté system characteristics were time-varying by month. The number of system users was derived from the number of distinct user logins used. The use of a local server was defined based on the first date of data replication from a local server to the consolidated server. The site experience and system maturity covariates were continuous integers based on calendar month.

Data management

Data extracts were obtained between August 2013 and March 2014. The closing date for the study was June 30, 2013. Data indicators were matched to a master file for the site and system characteristics, based on calendar month of data entry.

Analysis strategy

Descriptive analyses considered counts and proportions of encounters with incomplete data, flags for inaccurate or suspicious data, or late data entry, by site over the entire period of iSanté use as well as during the last 6 months of the study (January-June 2013). For data with accuracy flags, we explored the reasons for the flags based upon the pre-defined rule sets. Next, we ranked sites with respect to each DQ indicator, calculated each site's average rank across the 13 indicators (with a first place ranking assigned to all sites tied with zero values for DQ flags). We grouped sites by average DQ rank to explore consistency of performance across indicators. We also examined consistency by grouping the indicators along two dimensions: 1) type of indicator (completeness vs. accuracy); and 2) primary responsibility for data capture (data clerk vs. clinician).

In inferential analysis, we explored the associations between site and system characteristics and each DQ indicator. The indicators were treated as binary variables, and covariates were measured by site-month. For these analyses we used generalized linear models (GLM) with a logit link function and binomial errors. The models used binomial denominators as weights, such that sites with more observations carried greater weight (Crawley 2013), and clustered sandwich variance to adjust for multiple observations per site (Hardin and Hilbe 2012). These models provided adjusted estimates of the odds ratio for having incomplete, inaccurate, or late data for each covariate in the model. For categorical site characteristics, the category with

the largest number of patients was treated as the reference category. While our analysis involved multiple comparisons across the 13 DQ indicators, because this was an exploratory analysis intended to generate hypotheses, we considered associations to be important at the statistical significance level of $p<0.05$ and did not use a correction for multiple comparisons. All analyses were carried out using STATA 12.0 (College Station, TX).

Ethical issues

All data extracts were de-identified prior to analysis. The study protocol was reviewed and approved by the University of Washington, the Haiti National Bioethics Committee, and the US Centers for Disease Control and Prevention.

Results

In addition to producing consensus on DQ priorities, the Delphi process revealed several key themes of relevance to interpreting the quantitative findings. A total of 25 stakeholders (16 clinical and 9 strategic information experts) participated. In general, respondents conveyed appreciation for the support iSanté gives in providing health care services of high quality. As one clinician stated, "*The electronic version of iSanté creates a dynamic within the staff in favor of adequate follow-up of patients*." However, stakeholders also noted ways in which iSanté made work more difficult. In particular, respondents highlighted concerns with stability of the technology, based largely on inconsistent power supply but also on computer viruses, software bugs, and server maintenance problems. Respondents also indicated that certain factors external to iSanté's design and technology platform impaired effectiveness of the system, including failure by staff to enter data, different perspectives among providers on how to use the system and on the meaning of different pieces of information, and lack of training of providers on the specific system features.

For the quantitative analysis, 95 sites met the study inclusion criteria, and their characteristics are shown in **Table 4.2**. The majority of sites were located in the West (41 sites) or North (15 sites) Departments. There were 3 large university hospitals, 26 regular hospitals, 61 health centers, and 5 dispensaries, and sites were approximately equally distributed by sector. The first facility began using the system in April of 2005, and the median duration of use was 51 months as of the end of the study in June, 2013. In their most recent month of use, 47 sites serving 49.5% of HIV patients in iSanté relied upon a local server to access iSanté, while the remaining sites used the internet to access the system. The maximum number of system users per month per site ranged from 1–50; 39 sites (41.1%) had at most 3 or fewer users while 33 sites (34.7%) had >10 users. **Figure 4.1** shows a map of sites by number of HIV patient encounters captured within iSanté.

Average system-wide performance on DQ indicators was highly variable by indicator (**Figure 4.2**). There were few problems with completeness of age (<1%); however, age was flagged as inaccurate or suspicious in approximately 26% of registration forms. The proportion of encounters with accuracy flags was low for male sex, ART dispenses, CD4 values, and visit dates (≤3%). However, when number of patients (rather than number of encounters) was taken as the denominator for accuracy of male sex, it is notable that 4.5% of supposedly male patients had at least one encounter indicating female-only clinical or laboratory data. Data on weight was moderately incomplete (approximately 10%), while data on tuberculosis (TB) status and height were relatively incomplete overall (approximately 20–35%), but notably improved during the most recent 6 months. The incompleteness of pregnancy status and ART eligibility was high (approximately 35–40%), with limited or no improvement during the most recent 6 months. Discontinuation forms were only filled out for about half of all patients without visits for 180 or

more days, and the level of incomplete discontinuation forms increased with time, as cases of lost patients accumulated. More than 60% of encounters were entered 3 or more days after the visit date, though timeliness improved notably in the most recent 6 months.

The variability of site-by-site DQ performance is demonstrated in **Table 4.3**, showing the average level of DQ flags for a typical site (the site at the median) as well as the spread in performance across sites (the interquartile range). Variability in performance was particularly high for completeness of clinical data and for timeliness of data entry. For example, ART eligibility was incomplete for about 15% of clinical visits in the site at the 25th percentile but about 60% for the site at the 75th percentile. Timeliness of data entry was also highly variable across sites, ranging from about 40% in the site at the 25th percentile but nearly 90% for the site at the 75th percentile. There was notable improvement over time in the number of sites meeting absolute performance thresholds for completeness of height, pregnancy status, and TB status; accuracy of age, ART dispenses, visit dates; and timeliness (see **Table 4.3**).

The "heat table" in **Figure 4.3A** shows the level of DQ for the top 10, middle 10, and bottom 10 performing sites, ordered by average ranking across the 13 DQ indicators. This visual representation shows somewhat limited consistency in performance across the 13 indicators. For example, strong performers in terms of timely data entry tended to be weak in completeness of age and ART eligibility and in accuracy of CD4. **Figure 4.3B** shows clustering of performance when the indicators are separately grouped by completeness or accuracy, while **Figure 4.3C** shows the when the indicators are separately grouped by personnel primarily responsible for data capture. Both figures 3B and 3C indicate that strong sites tended to be strong and weak sites tended to be weak across all indicators within the grouping. Results in the most recent 6 months

were qualitatively similar to results from all time with respect to consistency of performance across DQ indicators.

The results from the adjusted analyses of site and system factors associated with strong vs. weak DQ are shown in **Table 4.4**. The adjusted model included geographic department, though these results are not shown. Compared to the West Department, one department had favorable DQ, while two departments had less favorable DQ for several indicators. All other departments had a mixed picture, with some favorable indicators, some unfavorable, and some that showed no association. Urban location was associated with unfavorable completeness of discontinuation forms in the adjusted analysis.

Facility type and site governance also showed a mixed pattern of associated with DQ, in the adjusted analysis (**Table 4.4**). Compared to regular hospitals, university hospitals had strong DQ in some areas (completeness of height, weight, and discontinuation data, and accuracy of CD4 data) but notably weaker DQ for completeness of TB status. Again compared to regular hospitals, dispensaries were strong on completeness of height, but markedly weak in multiple areas (completeness of pregnancy status, accuracy of ART dispensing data and CD4 cell count data). Compared to facilities in the public sector, those in the private sector performed better in several areas (completeness of weight and accuracy of ART dispense data), while those with mixed site governance performed worse in several areas of completeness of clinical data (height, pregnancy status, and TB status).

Using iSanté via a local server was strongly associated with favorable completeness of several indicators (age, pregnancy status, and discontinuation forms) (**Table 4.4**). Surprisingly, it was not significantly associated with timely data entry in the adjusted analyses. The temporal

variables of greater site and system maturity had generally favorable associations with DQ. Greater site-specific experience in using the system was associated with favorable performance in some areas (completeness of height, pregnancy status, and discontinuation data), while greater system maturity was associated with more favorable DQ in other areas (completeness of weight and TB status, and accuracy of age and male sex). Patient volume had little association with DQ performance in adjusted analyses. Having more unique user logins showed favorable associations in some areas (completeness of weight and pregnancy status), but unfavorable association with completeness of age.

Discussion

Our qualitative Delphi process identified information elements where high levels of completeness and accuracy of data were thought to be critical for quality of patient care and integrity of reporting, as well as a local standard for acceptable timeliness of data entry to the system. Our quantitative system-wide DQA demonstrated value by describing the variability in DQ within iSanté both within and across sites. Data quality for each of the 13 DQ indicators was highly variable across indicators and sites. Encouragingly, certain DQ indicators—particularly completeness of height and TB status; accuracy of age, male sex, ART dispense data, and visit dates; and timeliness of data entry—improved over calendar time. However, it is of concern that completeness of discontinuation forms worsened over calendar time. Across DQ indicators, site performance was more consistent when grouped by DQ attribute (completeness or accuracy) or by type of user responsible for data capture (data clerk or clinician), than when all DQ indicators were considered together. Site and system factors that emerged as having important associations with DQ were geographic department, site governance, facility type, presence of local server, and temporal factors of site experience and system maturity.

The strong performance of some sites indicated that excellent DQ is achievable within Haiti. Eight key themes related to improving DQ within the iSanté system arose from the study.

Theme 1: Each site has a unique pattern of DQ issues needing improvement. The heterogeneity in each site's performance across DQ indicators was evident in the "heat table" grouped by average performance. Among the top 10 performers by overall DQ, there were typically several indicators where the site performed among the bottom 40% of sites. The converse was true for sites among the bottom 10 performers. The fact that university hospitals and dispensaries had markedly stronger DQ for some elements but markedly weaker DQ for other elements when compared with regular hospitals, also underscores this point.

There would be high value in implementing a dynamic, site-specific "DQ dashboard" within iSanté, allowing site-level personnel to monitor their own performance on DQ indicators over time, to compare their performance to average performance at other sites, and to drill down to review and systematically cleanse problematic data. A variety of dashboards, report cards, and other audit and feedback tools have been embraced in order to bring transparency to performance and to motivate quality improvement in health care (Hibbard and Jewett 1997; van der Veer et al. 2010; Ivers et al. 2012; NYDOH 2014; Casalino et al. 2003). If transparency indeed motivates improvement, having a dynamic "DQ dashboard" within iSanté could, in itself, be a DQ improvement intervention prompting sites to work on the areas where they most need improvement.

Theme 2: Completeness of data for clinical follow-up needs strengthening. A key weakness of iSanté data was the high incompleteness of certain clinical data, especially pregnancy status and ART eligibility. Much work remains to be done to improve in these areas.

Missing data undermines the potential value of automated reports designed to facilitate care continuity and quality, such as the iSanté report on patients who are eligible for ART but not yet enrolled on treatment. Without further on-ground assessment, it is impossible to know if the missing clinical data reflects failure of clinicians to comprehensively evaluate patients or simply their failure to document what they have done. Improvement will certainly require increasing motivation and decreasing barriers for clinicians, both in comprehensive patient evaluation and in documentation.

Improving completeness of discontinuation forms should also be a priority, given the role of these forms in assuring continuity of care for HIV patients. Tracing patients can identify the need to transfer historical patient data when patients have moved to a new facility, or can facilitate re-entry to care for patients who have dropped out of care. Greater availability of human resources for patient tracing is likely necessary to improve completeness of these forms.

Theme 3: Interventions to improve DQ should take into account which personnel are primarily responsible for data capture. Within-site performance was most similar for DQ indicators grouped by primary responsibility (data clerks vs. clinicians). There may be widely different reasons for strengths or weaknesses in one set of indicators compared to the other, and these reasons must be understood in order for improvement interventions to be successful. Sites with weaknesses in DQ for patient demographics and visit dates may need training for data clerks and data managers, new standard operating procedures for routine data audits, or simple interventions like the posting of wall calendars as reminders of current dates. In contrast, sites showing weakness in clinical DQ indicators might require more complex interventions targeting clinical practice and health systems issues.

Theme 4: Investments in the IT platform for iSanté should be carefully evaluated. We hypothesized that DQ would be higher among sites using a local network and server, reflecting the greater investment of resources in the IT platform at these sites. While using a local network was favorably associated with three DQ indicators, it was surprising that it was not more strongly and favorably associated with the remaining DQ indicators, especially timeliness of data entry. Local networks were still vulnerable to interruptions in power supply. During the Delphi process, local stakeholders heavily emphasized the frequency of power interruptions and their negative effects on system use. Further assessment of the costs and benefits of different investments in the IT platform for iSanté, with recognition that optimal choices may differ by facility size and complexity, is needed. Such cost-benefit assessment should include exploration of upgraded power sources and IT platforms with low-power draws. It should not be assumed that having a local network and server is a panacea for all sites, particularly in the absence of a stable power supply.

Theme 5: Technical assistance to raise motivation and capacity for DQ oversight should focus on specific departments and the mixed sector. The relative weakness of several outlying departments was consistent with our hypothesis that data quality would be strongest in the West Department, due to the proximity of centralized Ministry of Health and iSanté technical assistance resources within Port-au-Prince. The observation that facilities with mixed site governance also performed relatively poorly after controlling for other site and system factors was also important. As a cross-cutting "building block" for health systems strengthening, a clinical information system like iSanté depends upon strong leadership to motivate personnel to use the system in the expected manner and to assure the inputs required to keep the system running (WHO 2007). In mixed sites, where both public and private sectors are involved in

governance, there may have been ambiguity about who carried responsibility for oversight of the health information system. Targeting departmental authorities in selected departments and in sites with mixed governance with additional technical assistance toward enhanced leadership and oversight of the iSanté system could be productive.

Theme 6: Increasing the number of users of iSanté must be accompanied by efforts to increase their capacity. Our finding of no consistent and prominent associations between the number of iSanté system users and DQ indicators, after controlling for patient volume and other factors, suggests that there may be a trade-off in sharing the burden of capturing data in the system and widening use of the system to less knowledgeable users. A prior survey of the characteristics of electronic data systems in 15 low-resource countries, found that more hours of data clerk time per 100 patients and more training for data clerks were significantly associated with both less missing data and with lower levels of loss-to-follow-up among ART patients (Forster et al. 2008). We were not able to measure the profile of users (data clerks vs. clinicians), the amount of time they interacted with the system, or their level of training on the system. Further investigation is warranted on how the number, type, and competency of users affect iSanté DQ. As the number of users is expanded, it will be important to provide adequate training to assure new users have strong competency in using the system.

Theme 7: Increased experience and maturity of the system generally helped, but did not necessarily guarantee, strong DQ. We hypothesized that both greater site-level experience and greater system-level maturity would be associated with favorable DQ, as sites gained familiarity and comfort with the data fields and as DQ-related features and functions within iSanté improved in successive software releases. However, it should be recognized that the associations observed with greater system maturity could reflect external temporal trends not

related to the features and functions of the system. The fact that these temporal factors helped in some areas of DQ but not others, suggests that experience should be reinforced with training and technical assistance, so that unfavorable practices, interpretations, or work-arounds do not become entrenched with experience. Iterative improvements to the software to reinforce DQ, via point-of-entry validation flags and other features, should be guided by DQ needs.

Theme 8: Mixed methods of qualitative and quantitative research are valuable in informing DQA and interventions to improve DQ. Our study demonstrated the value of combining qualitative work on stakeholder information priorities with quantitative DQA. As a third step, it would be valuable to undertake additional qualitative assessment to further examine reasons for strong vs. weak DQ and to inform the design of interventions to improve DQ.

Strengths and Limitations

A key strength of this study is its focus upon DQ indicators that were identified as relevant by local stakeholders. The diversity of the DQ indicators—spanning patient demographic, clinical, laboratory, pharmacy, and encounter data—was also a strength. Sites strong in some areas were not necessarily strong in others, and the wide scope supports the notion that DQ improvement is of universal concern.

A limitation of the study is that it did not apply a "gold standard" for validating patient data. However, the study demonstrates the efficiency of using automated queries to uncover DQ problems for resolution and improvement. Another limitation of the study is that our measurement of site and system-level factors affecting data quality was incomplete and subject to measurement error. We lacked provider lists for each facility and were therefore unable to assess penetration of use amongst relevant clinical and data management staff at each facility.

We were unable to measure staff turnover or level of training of system users. We also lacked data on system "uptime" and of availability of local resources for system maintenance. Information in all of these areas would have been beneficial in terms of suggesting areas of intervention to strengthen the iSanté data system. Despite these limitations, the study was useful in illuminating strengths and weaknesses of the iSanté data system and potential areas for intervention to improve data quality. While the particular DQ indicators presented in this study may be specific to iSanté or the Haitian context, the study methodology is highly relevant for other large-scale clinical information systems in resource-limited settings.

Conclusion

Strong DQ is a precursor to strong data use. According to the DQ priorities expressed by local stakeholders, the iSanté data system exhibited both strengths and weaknesses. The heterogeneity in DQ performance across sites indicates that excellent DQ is achievable in Haiti, but that many sites have much work to be done to improve data quality for a few or many DQ indicators. A dynamic, interactive "DQ dashboard" within iSanté would bring transparency and motivate improvement. Recommendations also include greater assurance of the stability of the IT infrastructure for the system, and targeted training and TA to particular geographic areas and types of facilities according to the strengths and weaknesses observed in our study.

Table 4.1: Rule Sets for Data Quality Indicators

Data element	Rule set for data flag	Data quality priority to which the indicator is related
Incomplete data flag		
Age	• Pediatric patients with missing day, month or year of birth; OR • Adult patients with missing month or year of birth.	• ART eligibility (adult vs. pediatric criteria) • Weight curve
Height	• Clinical visit held but height not recorded (at any visits for pediatric, and at least once for adult patient); OR • Height data recorded but not machine readable.	• BMI
Weight	• Clinical visit held but weight not recorded; • Weight data recorded but not machine readable; OR • Weight data recorded but no unit of measure.	• Weight curve/BMI
Pregnancy status	• Clinical visit held but no data recorded for pregnancy status question (women aged 15-49 or of unknown age).	• Number of HIV+ pregnant women newly placed on ART / PMTCT follow up / HIVQUAL: prophylaxis PMTCT to pregnant women / testing and ART during pregnancy
ART eligibility	• Clinical visit held but no ART eligibility or reason for eligibility recorded for patients prior to initiation of a life-long ART regimen	• ART eligibility (yes or no) / Number of patients medically eligible for ART
TB screening	• Clinical visit held but no data recorded in either "Statut TB" or "Evaluation TB" section.	• TB screening / TB status
Discontinuation form	• No discontinuation form completed following last clinical visit, where last clinical visit recorded >180 days before study close.	• Retention of patients on ART / Patients not active on ART / Number of patients LTFU
Inaccurate data flag		
Age	• Invalid DD, MM or YY value for DOB (DD>31; MM>12; YY<1904 or >2013); • Difference in >730 days in comparison of “age in years” and “date of birth” fields; • Difference in DOB values from MM or YY components of national ID; • Patient registration type (adult vs. pediatric) conflicts with recorded age; OR • Pediatric patient with marital status of married, widowed, separated/divorced, or living together	• Reporting indicators where adult/pediatric distinction is relevant (ART eligibility) • Weight curve/BMI
Male sex	• Obstetric history, pregnancy, or last menstrual period is recorded for a male patient; • Female-only diagnosis recorded for male patient (conditions of ovaries, cervix, or uterus, vaginal candidiasis, conditions of pregnancy); OR • Female-only lab test recorded for male patient (Pap test, pregnancy test, vaginal smear)	• Sex

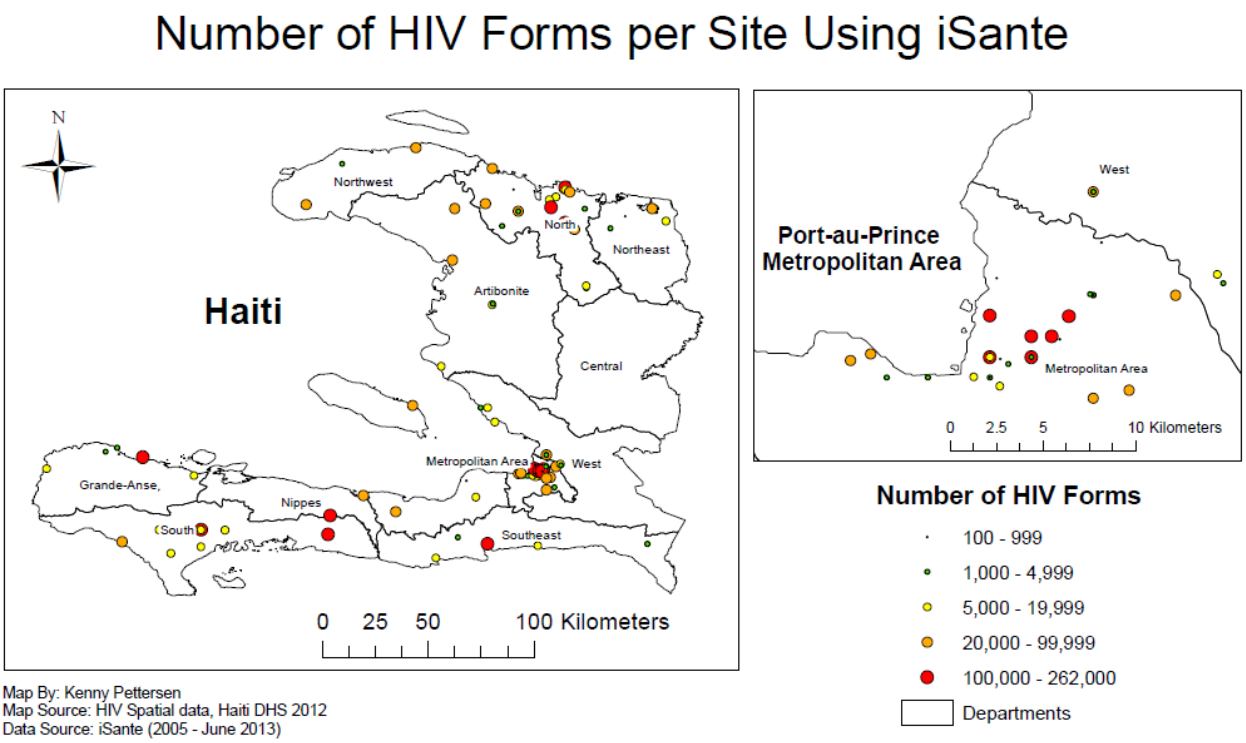
ART medications dispensed	• Dispense date on any individual medication within a regimen is before the visit date; • Dispense date on any individual medication within a regimen >30 days later than visit date; • Dispense date or dose days for any individual medication within a regimen is different from that of any other individual medication within the regimen; OR • Dispense indicated but no dispense date or number of pills recorded.	• ART regimen • ART adherence • ART enrollment/ On ART or not
Visit dates	• Visit date is prior to January 1, 2004; • Visit date is after the create date for the form; • Visit date for any type of encounter falls before patient registration date; • Visit date for pharmacy, lab, counseling, or discontinuation falls before first clinical visit date; • Dispense date on any individual medication within a regimen is either before or >30 days after the visit date; OR • Result date on any laboratory test is either before or > 30 days after the visit date.	• Visit dates • Retention of patients on ART / Patients not active on ART / Number of patients LTFU
CD4 level	• CD4 has invalid values (<0 or >2500) or implausible values (0 or >2000); • CD4% has invalid values (<0 or >100) or implausible values (>68); OR • CD4 or CD4% value recorded but not machine readable	• CD4 at enrollment / CD4 level
Late data entry flag		
Create date	• Form entered 3 or more days after the visit date	• Late data entry

Table 4.2: Characteristics of Sites Using the iSanté Data System

	Sites		HIV patients		C_TB	A_CD4	T_Late
	n	%	n	%	%	%	%
Facility type							
University hospital	3	3.2	10,169	9.8	56.9	0.6	22.7
Hospital	26	27.4	53,258	51.4	25.4	1.4	30.5
Health center	61	64.2	37,856	36.6	34.0	1.0	44.9
Dispensary	5	5.3	2,283	2.2	17.7	13.1	53.6
Sector							
Public	27	28.4	45,143	43.6	29.2	1.3	30.2
Private	38	40.0	34,428	33.2	29.3	2.0	31.9
Mixed	30	31.6	23,995	23.2	37.8	1.1	46.2
Department							
Artibonite	5	5.3	5,399	5.2	8.6	2.4	32.7
Grand-anse	7	7.4	3,908	3.8	27.0	2.3	34.8
Nippes	2	2.1	5,022	4.9	37.9	1.4	32.1
North	15	15.8	19,147	18.5	46.5	1.0	45.0
North-east	6	6.3	3,610	3.5	37.0	2.1	69.9
North-west	4	4.2	8,151	7.9	21.6	1.0	30.6
West	41	43.2	44,177	42.7	31.1	1.7	31.3
South	10	10.5	10,697	10.3	27.4	0.7	32.8
South-east	5	5.3	3,455	3.3	28.1	1.0	31.5
Location							
Rural	42	44.2	24,579	23.7	28.9	1.2	46.2
Urban	53	55.8	78,987	76.3	32.4	1.5	31.3
Date of system adoption							
3/05-6/07	25	26.3	66,916	64.6	35.5	1.1	29.0
7/07-6/09	31	32.6	27,112	26.2	25.3	2.7	48.1
7/09-6/11	14	14.7	6,100	5.9	4.4	1.0	59.4
7/11-6/13	25	26.3	3,438	3.3	2.4	1.6	75.8
Maximum number of users per month							
1-3 users	39	41.1	7,324	7.1	48.6	2.2	80.4
4-10 users	23	24.2	16,356	15.8	19.0	2.8	60.2
11-25 users	20	21.1	39,536	38.2	30.1	1.2	31.2
26-50 users	13	13.7	40,350	39.0	34.5	1.3	29.2
Total number of forms							
100-5,000	37	39.0	5,370	5.2	17.9	1.0	73.6
5,001-20,000	23	24.2	13,264	12.8	23.8	2.1	62.9
20,001-100,000	21	22.1	30,410	29.4	22.8	2.2	44.5
100,001-262,000	14	14.7	54,522	52.6	37.1	1.0	24.2

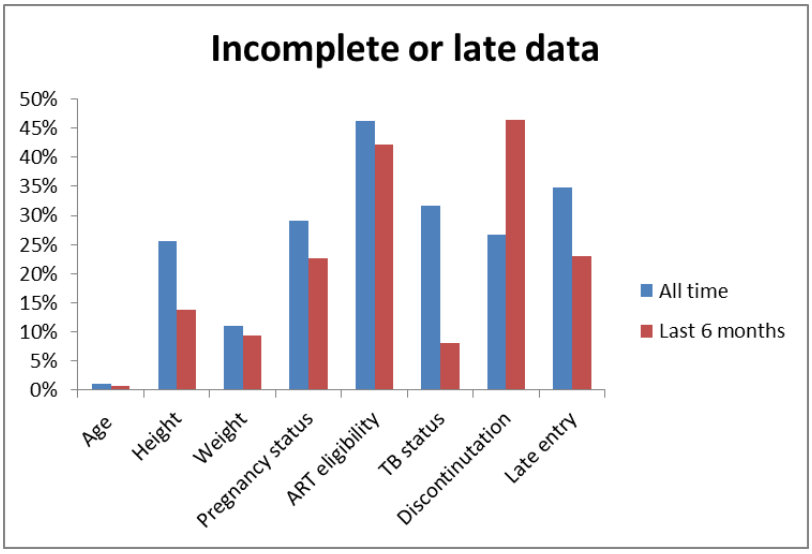
Key: C_TB=incomplete TB status; A_CD4= inaccurate/suspicious CD4 result; T_late=late data entry

Figure 4.1: Number of HIV Forms per Site Using the iSanté Data System



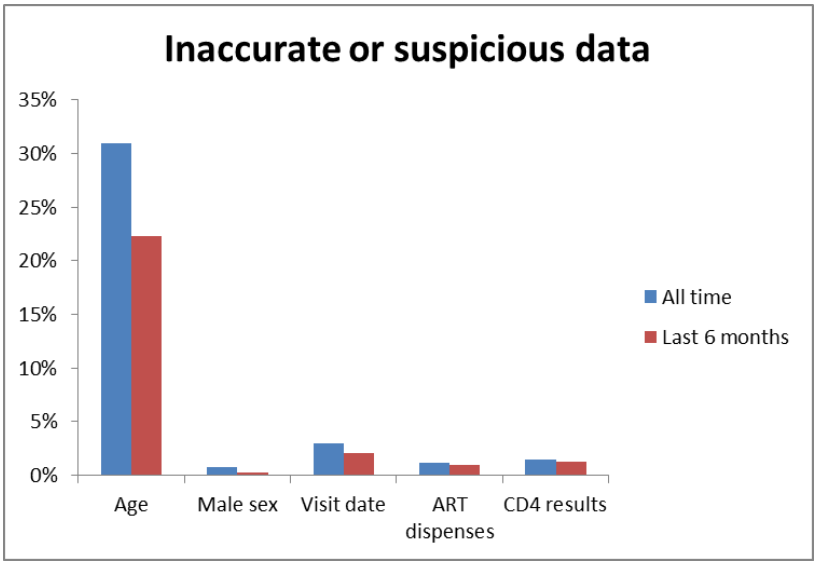
Map By: Kenny Pettersen
Map Source: HIV Spatial data, Haiti DHS 2012
Data Source: iSante (2005 - June 2013)

Figure 4.2: Average System-Wide Data Quality within the iSanté Data System



Number of sites and number of forms for each indicator

Age: 95 sites, 103 566 forms (all time); 89 sites, 10 689 forms (last 6 months)
Height: 95 sites, 1 128 574 forms (all time); 90 sites, 136 743 forms (last 6 months)
Weight: 95 sites, 1 128 574 forms (all time); 90 sites, 136 743 forms (last 6 months)
Pregnancy status: 95 sites, 571 659 forms (all time); 90 sites, 67 711forms (last 6 months)
ART eligibility: 95 sites, 533 351 forms (all time); 90 sites, 47 193 forms (last 6 months)
TB status: 95 sites, 1 128 574 forms (all time); 90 sites, 136 743 forms (last 6 months)
Discontinuation: 94 sites, 56 724 forms (all time); 89 sites, 6 918 forms (last 6 months)
Late entry: 95 sites, 3 558 387 forms (all time); 90 sites, 532 619 forms (last 6 months)



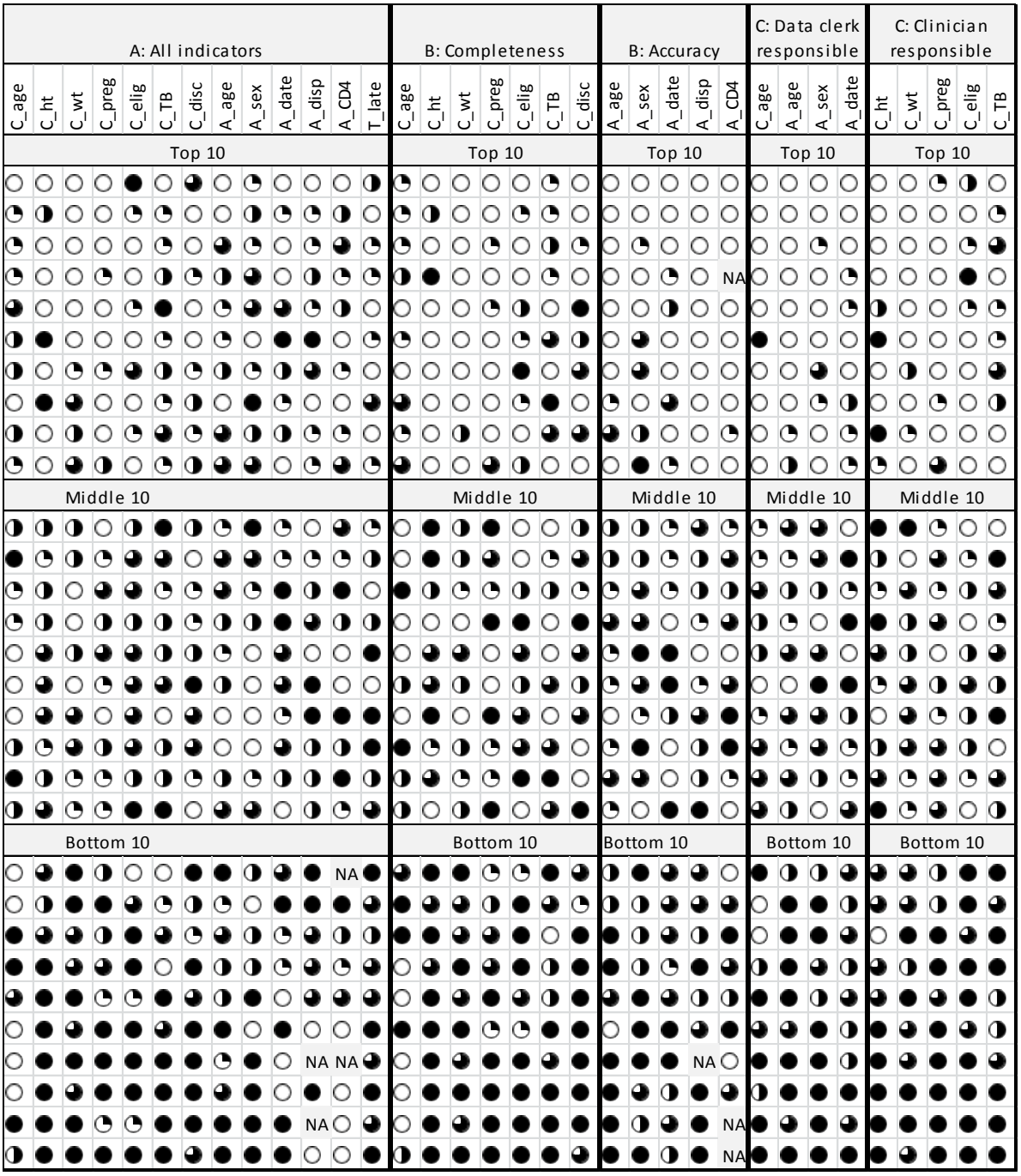
Number of sites and number of forms for each indicator

Age: 95 sites, 103 560 forms (all time); 89 sites, 10 684 forms (last 6 months)
Male sex: 95 sites, 444 587 forms (all time); 89 sites, 17 750 forms (last 6 months)
Visit date: 95 sites, 3 487 383 forms (all time); 90 sites, 471 784 forms (last 6 months)
ART dispenses: 93 sites, 734 216 forms (all time); 88 sites, 108 618 forms (last 6 months)
CD4 results: 89 sites, 209 910 forms (all time); 82 sites, 31 648 forms (last 6 months)

Table 4.3: Variability in Site-by-Site Performance on DQ Indicators within the iSanté Data System

		# sites	Typical site (median)	IQR	DQ threshold (% flags)	# sites meeting threshold
Incomplete data						
Age	All time	95	0.3%	(0.0, 0.9)	<1%	72
	Last 6 months	89	0.0%	(0.0, 0.6)		75
Height	All time	95	29.6%	(14.3, 51.3)	<10%	19
	Last 6 months	90	12.3%	(5.4, 38.5)		40
Weight	All time	95	8.0%	(4.5, 12.9)	<10%	66
	Last 6 months	90	6.6%	(2.9, 12.3)		58
Pregnancy status	All time	95	30.2%	(20.4, 47.5)	<10%	6
	Last 6 months	90	24.1%	(14.5, 42.9)		14
ART eligibility	All time	95	33.2%	(14.7, 62.0)	<10%	12
	Last 6 months	90	30.0%	(10.5, 68.8)		19
TB status	All time	95	13.8%	(1.7, 37.1)	<10%	45
	Last 6 months	90	0.7%	(0.1, 3.8)		78
Discontinuation	All time	94	42.3%	(15.4, 81.8)	<20%	27
	Last 6 months	89	49.1%	(25.0, 89.5)		17
Late data						
Data entry >2 days	All time	95	66.6%	(37.9, 88.8)	<20%	4
	Last 6 months	90	44.5%	(13.5, 89.3)		13
Inaccurate or suspicious data						
Age	All time	95	24.4%	(13.2, 39.2)	<10%	16
	Last 6 months	89	15.8%	(8.6, 26.3)		28
Sex	All time	95	0.4%	(0.0, 0.9)	<1%	74
	Last 6 months	89	0.0%	(0.0, 0.3)		83
Visit date	All time	95	2.6%	(1.6, 3.6)	<1%	5
	Last 6 months	90	1.8%	(1.0, 3.3)		24
ART dispense	All time	93	1.2%	(0.7, 2.3)	<1%	39
	Last 6 months	88	0.8%	(0.2, 1.8)		50
CD4	All time	89	0.6%	(0.0, 1.4)	<1%	56
	Last 6 months	82	0.4%	(0.0, 1.6)		52

Figure 4.3: Heat Tables for Site Rankings on iSanté DQ Indicators



Top 20%
Second 20%
Third 20%
Fourth 20%
Bottom 20%

Key: C_age=incomplete age; C_ht=incomplete height; C_wt=incomplete weight; C_preg=incomplete pregnancy; C_elig=incomplete ART eligibility; C_TB=incomplete TB status; C_disc=incomplete discontinuation; A_age=inaccurate/suspicious age; A_sex=inaccurate/suspicious male sex; A_date= inaccurate/suspicious visit date; A_disp= inaccurate/suspicious ART dispense; A_CD4= inaccurate/suspicious CD4 result; T_late=late data entry

Table 4.4: Association between iSanté DQ Indicators and Site and System Factors

	A	B	C	D	E	F	G	H	I	J	K	L	M
Level of facility (hospital=reference)													
University hospital	0.3	0.4	0.4	2.0	1.0	5.8	0.2	0.9	1.0	1.1	1.6	0.2	0.8
Health center	1.1	1.1	0.8	1.0	1.6	1.6	1.0	0.8	1.9	0.8	1.2	0.7	1.2
Dispensary	1.5	0.3	1.0	2.6	2.7	1.8	0.4	0.7	0.9	0.9	2.1	9.4	1.4
Sector (public=reference)													
Private	1.3	1.5	0.6	0.7	0.8	0.8	1.1	1.1	1.5	0.8	0.6	1.6	0.7
Mixed	0.9	2.1	0.8	2.2	1.0	2.2	1.5	1.1	0.6	0.8	0.8	0.9	1.0
Location (rural=reference)													
Urban	0.9	0.8	1.3	1.2	0.6	1.0	2.4	1.2	0.7	1.1	1.0	0.1	0.8
IT platform (internet=reference)													
Local server	0.6	0.7	0.9	1.3	1.6	0.4	0.5	0.9	0.7	1.5	0.8	0.9	0.7
Temporal variables													
Site exp'ce (+12 mos)	1.3	0.7	1.2	0.7	1.0	1.1	0.8	1.0	1.1	0.9	0.9	0.8	0.8
System age (+12 mos)	0.8	1.0	0.8	1.0	0.9	0.5	1.7	0.8	0.7	0.9	0.9	1.2	0.9
Facility size variables													
Volume (+100 HIV pat's)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
User login	1.1	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0

Key: A=incomplete age; B=incomplete height; C=incomplete weight; D=incomplete pregnancy; E=incomplete ART eligibility; F=incomplete TB status; G=incomplete discontinuation; H=inaccurate/suspicious age; I=inaccurate/suspicious male sex; J= inaccurate/suspicious visit date; K= inaccurate/suspicious ART dispense; L= inaccurate/suspicious CD4 result; M=late data entry

	OR < 1.0, p<0.05
	OR < 1.0, p<0.10
	OR>1.0, p<0.05
	OR>1.0, p<0.10
	p≥0.10

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Chapter 5: Conclusion

Together, these papers demonstrate uses of data from the iSanté EMR system in Haiti at the individual, group, and population levels, toward improvements in care delivery and patient health outcomes within Haiti's HIV care and treatment program. Our first paper on developing and validating an alert for risk of ART failure identified pharmacy-based adherence measures along with data on sex, baseline immunologic status, and duration of enrollment in care prior to ART initiation as key elements in predicting risk. A simple prediction model grouping patients into high, medium, and low risk categories could help health care providers optimally target patients with ART adherence support interventions, when program resources are limited. This paper underscores the value of leveraging routinely collected data to provide timely, actionable information back to clinicians. In this way, the paper contributes to a growing literature on development, validation, and application of clinical decision support tools within electronic data systems in low-resource settings (Oluoch et al. 2012).

Our second paper identified a 12-month attrition rate from the ART program of 26.6% (95% CI: 24.6-28.7%) at two large, public-sector hospitals. Distant location of patient residence, spending less time enrolled in HIV care prior to ART initiation, receiving a non-standard ART regimen, and lacking counseling prior to ART initiation were all associated with elevated risk of attrition. These findings suggest quality improvement interventions which could be tested at the two hospitals, such as: rapid follow-up to trace patients who are late in returning to pick up ART refills; counseling for all patients prior to ART initiation; targeting patients at risk of attrition

with enhanced retention support, including transportation subsidies; and medical case review for patients placed on non-standard ART regimens.

Our third paper identified stakeholder perspectives on data elements with high priority for completeness and accuracy in order to serve purposes of clinical management of HIV patients and HIV program reporting, and then conducted a quantitative data quality assessment of these elements. Across 95 facilities using the iSanté data system, data quality varied widely by specific indicator and by site. The strong performance of some sites on every data quality indicator considered indicated that excellent data quality is achievable in Haiti; however the wide heterogeneity in performance indicates that many sites have much work to be done to improve data quality. Key themes relevant to improving iSanté data quality were that: 1) each site has a unique pattern of data quality issues to work on; 2) interventions should attend to the reasons behind poor data quality and the relevant responsible entities which can effect change; 3) assuring a stable power supply is a critical part of the IT infrastructure and must be considered along with other potential investments in the IT platform for the EMR; 4) facilities within the "mixed" sector and within several specific departments struggled with data quality and may benefit from further technical assistance; 5) greater maturity of the system over time was important for better data quality; 6) greater site experience and greater uptake of use did not guarantee strong data quality; and 7) mixed methods of qualitative and quantitative research are valuable in informing data quality assessment and interventions to improve data quality. A recommendation of the study is to implement an interactive data quality "dashboard" within iSanté containing the indicators used in the study, to bring transparency to site-level performance and to motivate sites to improve data quality over time.

Future research stemming from our work falls into two categories: 1) further knowledge generation to better inform interventions and investments; and 2) intervention research. In the first category, qualitative research focusing on provider perceptions of the alert for risk of ART failure would be valuable in designing the presentation of the alert, how it should be integrated into clinical workflow, as well as what type of training would be necessary to optimize use of the alert. Other future research could replicate the present study methodology in other EMR systems or in other clinical areas in iSanté where patient adherence to medication is important, such as in prophylaxis for tuberculosis. Our work on ART attrition using iSanté data could inspire similar research at a national level. The scope of the iSanté data system offers a rare opportunity to assess facility factors associated with strong or weak patient health outcomes. It would be possible to study of ART attrition amongst the full set of sites using the iSanté system, and thereby study patient-level as well as facility-level factors associated with successful health outcomes. This would provide a unique contribution in a field of study where data sources often are only limited to single institution or a small network of sites. In another example, it would be possible to evaluate ART attrition under the newly-adoption Option B+ policy in Haiti, whereby all HIV positive pregnant women are offered life-long ART rather than short-course therapy, regardless of their immunologic status (WHO 2013; IATT 2013). The policy promises to reduce barriers to prevention of mother-to-child HIV transmission, but also carries risk of elevated loss-to-follow-up among patients enrolled on ART when still healthy (Tenthani et al. 2014). Haiti is one of only a handful of low-income countries which has officially adopted the Option B+ policy, so analysis of patient retention under the policy will provide valuable insight to policy makers throughout the world on the implications of Option B+ in the Haitian setting.

Future research in the area of data quality could follow the results of our quantitative assessment with additional qualitative work to identify barriers and strategies for data quality improvement. Further understanding in these areas is especially important in the area of completeness of clinical data, since reasons for poor completeness could include lack of provider time for documentation, use of alternative methods ("work arounds") for documentation, inadequate training, lack of supply of paper forms for recording data, system downtime due to technology issues, or other factors. Additional research could also explore the development and application of other rule sets for accuracy of clinical EMR data, in other modules of iSanté such as the primary care module, or in other EMR systems (Kahn et al. 2012). Cost and cost-effectiveness analysis could also be applied to Haiti's EMR system, including comparative cost analysis of different IT platforms including costs of equipment, supplies, and patient and provider time costs.

There are also multiple possibilities for interventional research inspired by our three studies. First, it would be valuable to study implementation of the alert for risk of ART failure within the iSanté EMR. An experimental or quasi-experimental study design could be used to examine the effects of the alert on provider behavior (including how and to whom providers offer adherence counseling and supportive services, and whether they target communication messages by risk group), as well as on the patient health outcome of ART failure. It would also be possible to compare the effects of the alert under different intervention designs, including use of a passive alert, combining a passive alert with training and mentoring, or use of an active alert where providers receive proactive cues to specific clinical actions. Other interventional research could be done to test one or more of the quality improvement interventions suggested by the results of the ART attrition study. This could be done within a rapid-cycle small scale quality

improvement framework (Plan-Do-Study-Act cycle) or as a larger-scale experimental or quasi-experimental framework. The presence of the iSanté EMR means ready availability of data to measure the ART attrition outcome before and after the intervention.

Implementation of a data quality "dashboard" within iSanté would also provide fertile ground for interventional research. Literature on audit and feedback has shown that providing information to health care workers on their performance against standards can motivate improvements in provider adherence to care guidelines and even in patient clinical outcomes (Ivers et al. 2012; van der Veer et al. 2010). An intervention presenting feedback on data quality to health care workers extends the principles of audit and feedback to another area of performance within the health care system. It would be possible to measures effects of a "dashboard" by studying performance on data quality indicators before and after implementation of the "dashboard." As with the iSanté alert for risk of ART adherence, it would be possible to compare the effects of different implementation models (passive feedback alone, passive feedback combined with training and mentoring, or feedback with cues to action) (Hysong, Best, and Pugh 2006).

Our research described in this dissertation, as well as the future research possibilities described above, fit squarely within the tradition of health services research, and its examination of access, quality, and efficiency issues in health care. By using iSanté data to identify improvements in individual patient follow-up, organization of services, and quality of information used in clinical care, our studies all relate intimately to quality of care concerns. The study on the alert for risk of ART failure touches on the issue of access to in-depth ART adherence support and counseling services, and how to allocate constrained resources most efficiently in order to optimize access. The evidence about the importance of distance of patient

residence to retention on ART has bearing on the question of the right level of decentralization of ART services to balance patient access, quality and cost concerns. Finally, our data quality assessment offers strategies for focusing data quality improvement efforts in ways that are most likely to pay off; in this way, this study begins to address efficient allocation of system-wide resources for the iSanté EMR system.

Together, these studies demonstrate the value of using iSanté data to inform and guide decision-making at the individual, group, and population levels. There are tremendous on-going pressures to expand access to HIV care and treatment, to assure quality of services, and to optimize efficiency in Haiti and other low-resource settings. Our analyses of iSanté EMR data represent three examples of data use which address these pressures. Building upon the momentum of the present analyses by translating the findings into on-ground program improvements, and by exploring other data uses which answer timely health services research questions is of great importance.

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