

Implementing MedViewer for Daily Adherence Feedback: How feasible and acceptable is use of a novel hair-based antiretroviral monitoring tool in busy clinical encounters?

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Background

- Patient-provider interactions influence antiretroviral (ART) adherence.
- Objective adherence feedback enhances patients' ART adherence, particularly when coupled with counseling.
- Improving providers' knowledge of patients' ART adherence can enrich their ability to provide tailored adherence counseling.
- The ability to accurately monitor ART adherence in clinical settings has the potential to augment existing ART adherence programs.
- New tools to monitor ART adherence must be feasible and acceptable to patients and providers.



Study Objective

To investigate the feasibility and acceptability of using a novel intervention, named MedViewer (MV), to provide patients and their providers feedback on longitudinal patterns of ART adherence during a clinic visit.

MedViewer (MV) Assay: #ADHERENCE2022 From Patient to Mass Spectrometry Imaging (MSI) to Adherence Reporting







Adherence Reporting





MedViewer (MV) Intervention

Provider training/ communication aids



Establishing Novel antiretroviraL ImaginG for Hair To Elucidate Non-adherence



Informational video for patients



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26	27	28	29	30	31	

KEY

Dive calendar days: The MedViewer Test indicated no missed doses on these days.

Gray calendar days: The Medvlewer Test indicated that you may have missed doses of your ARV medicine on these days.

White calendar days: The MedViewer Test was not performed on these days.

IRB# 18-3360 FOR INVESTIGATIONAL USE ONLY

MedViewer Provider Report for

Date of test (Day 0): 31-Jan-2020 Date 30 days prior to sampling: 00-Jan-2020 Days with optimal concentration: 2/30 (6.7%) Estimated period of evaluation: 30 days

MedViewer testing and reports

Drug evaluated: Emtricitable Test threshold: 500 Test sensitivity: 91% Test specificity: 89%

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Average consecutive days under threshold: 14.0 days



Pilot Study Overview

- Design: One-arm pre-post feasibility study
- Patient Eligibility: Age ≥18 years, HIV+, in care at UNC ID clinic, >1 HIV viral load in last 2 years, ≥1 clinic visit in last year, scheduled with enrolled provider, On dolutegravir or emtricitabine ≥90 days, ≥1 cm hair NOT chemically treated in past 4 weeks
- Patient Assessment: Baseline, post clinic visit, 30-day follow-up
- Provider Assessment: Pre-training baseline, post clinic visit after each patient visit, study end

Outcomes



	Primary	Secondary
Feasibility	Proportion patients receiving MedViewer as planned	Duration of time for assay
		Duration of MV discussion
Acceptability	Proportion patients agreeing to participate	Provider perception of effect on clinic flow
		Perceived Understandability
		Patient likelihood of future use
		Provider likelihood of recommending in future



Patient Participant Characteristics N = 36

- Median Age was 51.5 years (IQR: 37.5-57.5).
- 61% identified as male, the rest as female.
- 56% identified as Black, 26% White, 8% another race.
- 6% identified as Latinx/Hispanic.
- 61% had annual income < \$20K , 21% \$20-50K.
- 43% had federal insurance, 23% uninsured.



Results: Feasibility

Among 37 clinic visits:

- At 35 (95%), the MV report was discussed,
 - 3 patients were referred to pharmacist or another provider
 - o 66% spent 2-5 minutes discussing MV.
 - 34% spent 5-10 minutes discussing MV.
- At 30 (81%), the assay was completed within 2 hours of initiation; mean duration was 1.8 hours (SD 0.414).
- At 28 (76%), both the assay was completed within 2 hours AND the report was discussed.



Results: Acceptability

- Of the 68 eligible, 58 (85%) agreed to participate.
- Of 58 scheduled for an initial visit, 36 (53% of total eligible) enrolled.
- Patients and providers described the calendar reports as "straightforward", "practical," and "easy-to-understand."
- About half of providers shared the bar graphs with patients because it

"I guess [I thought] if all of my patients had another sheet of paper that I had to go through, it could be disruptive, but, someone handed me a folder at the beginning of my clinic session... and it was not disruptive."

Acceptability #ADHERENCE2022 Overall Usefulness of MedViewer

How likely would you be in the future to

now intery would you be, in the luttile to						
	Patients	Providers				
	Use it?	Recommend it?				
	(N=36)	(N = 15)				
Definitely would NOT	0%	0%				
Likely would NOT	3%	0%				
Likely would	19%	47%				
Definitely would	78%	53%				



Limitations

- Self-reported data are subject to social desirability bias.
- 7% of screened patients were ineligible due to short or treated hair.
- Mid-course shift to remote sample collection due to COVID hindered day of visit collection.
- Missed appointments hindered ability to deliver the planned intervention



Conclusions

- MV use was feasible and well-regarded by patients and providers to facilitate ART adherence discussions.
- Integrating telemedicine and remote sample collection may enhance feasibility.
- Studies to understand the effects of integrating MV into routine practice on ART adherence are needed.

Acknowledgements

Study Participants

Clinical-Behavioral Team

- Ella Ferguson, MPH
- Rose Perry, MPH
- Amanda Poliseno, BS, CCRP
- Claire Farel, MD, MPH
- Lauren Hill, MSPH, PhD
- Allie Munson, MPH
- Allison Pack, MPH, PhD
- Heather Prince, MPA, CCRP
- Cheryl Hendrickson, BS
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Data and Statistical Team

- Michael Hudgens, PhD
- Katie Mollan, MS
- Jessica Keys, PhD

Pharmacology Team

- Elias Rosen, PhD, Co-PI
- Nicole White
- Katherine Barley, BA
- Angela Kashuba, PharmD, Pl
- Monica Gandhi, MD, MPH (UCSF)



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Back up Slides

Patie	ent Participant Characteristics (co	Ont.) #ADHERENCE20	22			
	Highest Education Level (%)		-2			
	Some High School	20%				
	High School Graduate/GED	25%				
	Some College (4-Year)	25%				
	<u>></u> College Graduate (4-Year)	30%				
	Yearly Income (Past Year) (%)					
	<u><</u> \$10,000	32%				
	>\$10,000-\$20,000	29%				
	>\$20,000-\$50,000	21%				
	>\$50,000	18%				
Health Insurance (%)						
	Medicare &/or Medicaid	43%				
	Private Insurance	34%				
	None	23%				



Among the 10 assays conducted before the COVID-19 modifications, 5 (50%) reports were delivered within 2 hours of hair collection; the mean combined duration was 2.1 hours (SD 0.223, median 2.0, range 1.8-2.6).

MedViewer Patient Report for

November							
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3	4	5	6	7	8	9	
10	11	12	13	14	15	16	
17	18	19	20	21	22	23	
24	25	26	27	28	29	30	

December SMTWTFS						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

KEY

Blue calendar days:

The MedViewer Test indicated no missed doses on these days.

Gray calendar days:

The MedViewer Test indicated that you may have missed doses of your ARV medicine on these days.

White calendar days:

The MedViewer Test was not performed on these days.

Calendar report:

- Recommended for use by patients
- Days with likely missed doses indicated





Date of test (Day 0): 12-Dec-2019 Date 30 days prior to sampling: 13-Nov-2019 Days with optimal concentration: 21/30 (70.0%) Estimated period of evaluation: 30 days Average consecutive days under threshold: 9.0 days

Drug evaluated:EmtricitabineTest threshold:500Test sensitivity:91%Test specificity:89%

Bar-chart report:

- Recommended for use by providers
- Shows daily ART drug levels
- Contains information about specificity and sensitivity of test to detect missed doses of ART





PATIENT PARTICIPANT ACTIVITIES



ARVs in Hair: A long-term record of

drug exposure Timeframes Examined by Pharmacologic Measures of Adherence



Hair is:

- Slow growing and provides a record of daily changes in adherence.
- Easy to collect.
- Easy to store/ship.
- Not subject to white-coat adherence.

Spinelli et al. Current HIV/AIDS Reports, 2020.

MedViewer Benchmarking: UNC022 **ENLIGHTEN Study**

Establishing Novel Antiretroviral Imaging for Hair To End Nonadherence





FTC Signal Abundance Cutpoint



Key benefits of real-time adherence feedback

Suggested by patients and providers, illustrated as corresponding to constructs of the Information-Motivation-Behavioral Skills Model of Adherence to ART

ADHERENCE INFORMATION

- Reinforcement of importance of ART adherence for viral suppression
- Accurate knowledge of personal adherence history

ADHERENCE BEHAVIORAL SKILLS

- Identification of periods/patterns of missed doses for problem solving
- Discovery of adherence barriers associated with each period/pattern
- Development of strategies and skills to address these barriers

ADHERENCE BEHAVIOR

ADHERENCE MOTIVATION

- Comparison of patient results to ideal adherence, goal setting
- Positive reinforcement of good adherence

#ADUEDENCE2022



Patients not meeting pre-screen eligibility

Patient taking emtricitabine or dolutegravir	Seen for HIV care within 1 year of scheduled clinic visit	Documentation of viral load? (1/year, for past 2 years)	Fail to meet 2 or more criteria
98%	84%	71%	11%