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: From Patient to Mass Spectrometry Imaging (MSI) to Adherence Reporting

MSI Analysis

Longitudinal Profile

Adherence Reporting

FTC
MedViewer (MV) Intervention

Provider training/communication aids

MedViewer testing and reports

Informational video for patients
Pilot Study Overview

• **Design:** One-arm pre-post feasibility study

• **Patient Eligibility:** Age $\geq 18$ 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

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<thead>
<tr>
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<th>Primary</th>
<th>Secondary</th>
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<tr>
<td><strong>Feasibility</strong></td>
<td>Proportion patients receiving MedViewer as planned</td>
<td>Duration of time for assay</td>
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<tr>
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<td></td>
<td>Duration of MV discussion</td>
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<tr>
<td><strong>Acceptability</strong></td>
<td>Proportion patients agreeing to participate</td>
<td>Provider perception of effect on clinic flow</td>
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<tr>
<td></td>
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<td>Perceived Understandability</td>
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<tr>
<td></td>
<td></td>
<td>Patient likelihood of future use</td>
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<tr>
<td></td>
<td></td>
<td>Provider likelihood of recommending in future</td>
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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
  - 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 Overall Usefulness of MedViewer

<table>
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<tr>
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<th>Patients Use it? (N=36)</th>
<th>Providers Recommend it? (N = 15)</th>
</tr>
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<tbody>
<tr>
<td>Definitely would NOT</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Likely would NOT</td>
<td>3%</td>
<td>0%</td>
</tr>
<tr>
<td>Likely would</td>
<td>19%</td>
<td>47%</td>
</tr>
<tr>
<td>Definitely would</td>
<td>78%</td>
<td>53%</td>
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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
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• Jessica Keys, PhD

Pharmacology Team
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• Nicole White
• Katherine Barley, BA
• Angela Kashuba, PharmD, PI
• Monica Gandhi, MD, MPH (UCSF)

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Thank you!
(The Hair Study)
Back up Slides
## Patient Participant Characteristics (cont.)

<table>
<thead>
<tr>
<th>Highest Education Level (%)</th>
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<tr>
<td>≤ Some High School</td>
<td>20%</td>
</tr>
<tr>
<td>High School Graduate/GED</td>
<td>25%</td>
</tr>
<tr>
<td>Some College (4-Year)</td>
<td>25%</td>
</tr>
<tr>
<td>≥ College Graduate (4-Year)</td>
<td>30%</td>
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<table>
<thead>
<tr>
<th>Yearly Income (Past Year) (%)</th>
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<tbody>
<tr>
<td>≤$10,000</td>
<td>32%</td>
</tr>
<tr>
<td>&gt;$10,000-$20,000</td>
<td>29%</td>
</tr>
<tr>
<td>&gt;$20,000-$50,000</td>
<td>21%</td>
</tr>
<tr>
<td>&gt;$50,000</td>
<td>18%</td>
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<th>Health Insurance (%)</th>
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<tbody>
<tr>
<td>Medicare &amp;/or Medicaid</td>
<td>43%</td>
</tr>
<tr>
<td>Private Insurance</td>
<td>34%</td>
</tr>
<tr>
<td>None</td>
<td>23%</td>
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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).
Calendar report:

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

**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.
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

-6 months to Day 1
- Pre-Screening

Day 1/Visit 1
- Informed Consent, MedViewer Video, In-Person Screening
- Baseline Data Collection
  - Sample collection
  - Demographics
  - Baseline Questionnaire
- Clinic Visit with Provider (including MedViewer Report Review)
- Post-Visit Data Collection
  - Post-Visit Questionnaire

Day 28/Visit 2 (+/- 60 days)
- Follow-up Data Collection (subsample)
  - Follow-up Sample Collection
  - In-Depth Interview
  - Endline Questionnaire

Sequence of events for patient participant study 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.

Establishing Novel Antiretroviral Imaging for Hair To End Nonadherence

Single-center, open-label, directly observed therapy, triple phase study (NCT03218592)

- **Phase 1:** 28 days, Single Dose on Day 0
- **Phase 2:** 28 days, Daily Dosing
- **Phase 3:** 28 days, Dose Proportionality

Tenofovir/emtricitabine or Dolutegravir or Maraviroc (n=12)

Hair Samples Collected on Days 3, 7, 14, 21, 28

Graph showing Sensitivity or Selectivity vs. 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 MOTIVATION**
- Comparison of patient results to ideal adherence, goal setting
- Positive reinforcement of good adherence
Patients not meeting pre-screen eligibility

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