“Give me the Kit”:
Choice of Self-Collected Testing in TelePrEP

Christopher Hall, MD, MS

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Dr. Hall serves as Clinical Medical Director of Molecular Testing Labs. He also provides clinical care for QCarePlus (where he is Chief Medical Officer), is an STI consultant for RubiconMD, and is provides biomedical HIV prevention capacity building with the UCSF STI Prevention Training Center (NNPTC).
DEDICATION

Dr. Dawn K. Smith
(MD, MS, MPH)
1949-2022
## HOW SPECIMEN SELF-COLLECTION WORKS

### Lab Order Created
- Provider licensed in patient’s state approves patient for self-collection and orders necessary assays.

### Collection Kit Sent
- Collection Kit is delivered (via USPS or other carrier) to patient’s preferred address in 1-5 days.

### Specimens Collected
- Patient collects required samples, and ships back to the lab with pre-addressed return label.

### Specimens Analyzed and Resulted
- Lab processes samples and notifies the provider of results. Most results available within three days.

### Provider Discloses, Treats, and Links
- Ordering provider releases results to patient, if needed providing counseling and linkage to treatment/care.
IMPROVING ACCESS

In order to allow more healthcare providers to take advantage of our validations for non-clinical self-collected specimens, standardized Collection Kits have been developed that include all the materials to successfully collect and return specimens.

These kits are simple, cost effective, and can be used in a variety of non-clinical settings, including the home.
Regulatory requirements surrounding devices developed to support self-collected specimen collection (e.g., dried blood spot cards, microtainers) vary globally.

### Summary Regulatory Requirements for Global Medical Device Registration in the Primary Target Markets

<table>
<thead>
<tr>
<th>Primary Target Markets</th>
<th>United States (US)</th>
<th>European Union (EU) and EU Member States</th>
<th>Canada</th>
<th>Japan</th>
<th>China</th>
<th>Australia</th>
<th>Brazil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governing Regulatory Authority</td>
<td>U.S. Food and Drug Administration (FDA)</td>
<td>European Commission and EU Member States</td>
<td>Health Canada (HC)</td>
<td>Pharmaceutics and Medical Devices Agency (PMDA) and Ministry of Health, Labor, and Welfare (MHLW)</td>
<td>China Food and Drug Administration (CFDA)</td>
<td>Australian Therapeutic Goods Administration (TGA)</td>
<td>Agencia Nacional de Vigilancia Sanitaria (ANVISA)</td>
</tr>
<tr>
<td>Governing Regulations</td>
<td>21 CFR Part 820</td>
<td>European Medical Device Regulations (MDD) and In Vitro Diagnostic Regulations (IVDR)</td>
<td>Canadian Medical Device Regulations (CMR 580/98–282)</td>
<td>Pharmaceticals and Medical Devices Act (PMD Act)</td>
<td>China Medical Device Regulations</td>
<td>Therapeutic Goods Medical Device Regulations of 2002</td>
<td>Resolution RDC 185/2001</td>
</tr>
<tr>
<td>Device Classification based on Risk Level</td>
<td>• Class I</td>
<td>• Non-Sterile, Class I, Non-Measuring</td>
<td>Class I</td>
<td>General Class I</td>
<td>• Non-Sterile, Class I, Non-Measuring</td>
<td>Class I</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Class II</td>
<td>• Sterile, Class I, Measuring</td>
<td>Class II</td>
<td>Specified Controlled Class I</td>
<td>• Sterile, Class I, Measuring</td>
<td>Class II (Cadastro)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Class III</td>
<td>Class II</td>
<td>Class II</td>
<td>Controlled Class II</td>
<td>Class II (Cadastro)</td>
<td>Class II (Register)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Class IV</td>
<td>Class III</td>
<td>Highly Controlled Class IV</td>
<td>Class II</td>
<td>Class III</td>
<td>Class IV (Register)</td>
<td></td>
</tr>
</tbody>
</table>
By lowering the barriers to testing, infections identified that might otherwise have gone undetected and untreated.

*Shown are all self-collected specimen Kits from respective states.*

As a CLIA-certified lab, all positive results reported to appropriate local health jurisdictions.

<table>
<thead>
<tr>
<th>State</th>
<th># of Assays</th>
<th>Detected Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York</td>
<td>5,391</td>
<td>3.52%</td>
</tr>
<tr>
<td>Mississippi</td>
<td>5,864</td>
<td>3.10%</td>
</tr>
<tr>
<td>Georgia</td>
<td>56,748</td>
<td>2.93%</td>
</tr>
<tr>
<td>Texas</td>
<td>128,372</td>
<td>2.82%</td>
</tr>
<tr>
<td>Alabama</td>
<td>17,379</td>
<td>2.76%</td>
</tr>
<tr>
<td>Florida</td>
<td>115,874</td>
<td>2.74%</td>
</tr>
<tr>
<td>South Carolina</td>
<td>17,718</td>
<td>2.68%</td>
</tr>
<tr>
<td>Kansas</td>
<td>4,248</td>
<td>2.61%</td>
</tr>
</tbody>
</table>

*All specimens, 9/2018 - 9/2021*
RESULTS: TelePrEP and Self-Collect Testing, 2018-2021

With Emory & Oregon Health & Sciences University, the impact of self-collect testing on PrEP initiation and persistence was analyzed.

Since 2018, Molecular has supported >43,000 U.S. PrEP users with self-collect testing.
- Of these, 1.2% were found HIV-positive (typically at initiation)
- Note: significantly higher positivity in the South (1.5%) and in rural (non-core) zip codes (1.3%; both results p<0.05 by chi-square test).

In 2021*, Molecular’s self-collect supported approx. 13% of U.S. PrEP users at some point
- Among persons <35 years, approx. 20% were supported
- Among persons <25 years, approx. 30% were supported

Diagnosing Sentinel STIs in PrEP Users
- Among the ~43K U.S. PrEP users tested by Molecular’s healthcare partners, 30.1% had positive rectal gonorrhea or chlamydia tests, and 8.3% had reactive syphilis tests

* 2021 proportions are based on 2020 AIDSVu denominator data
**RESULTS: TelePrEP and Self-Collect Testing, 2018-2021**

In 2021, the percentage of PrEP users supported by telePrEP was substantially higher than the percentage of clinic-based PrEP users in the following groups (

*(AIDSVu data denominator)*

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**Proportion of TelePrEP patients vs. Clinic-based Patients**

- <24 Years Old
- 25-34 Years Old
- South

- **TelePrEP**
- **Clinic-based**
Further analysis conducted to understand the demographics and preferences of these patients utilizing HIV PrEP at one of Molecular’s partners, Q Care Plus.

In 2021, Q Care Plus served 5,090 unique PrEP patients who completed the enrollment process and an initial clinician visit.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Male</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>97.8</td>
<td>2.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sexual Orientation</th>
<th>Gay</th>
<th>Bisexual</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>18.7</td>
<td>10.3</td>
<td>71</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Black</th>
<th>Hispanic</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>53.4</td>
<td>31.1</td>
<td>15.5</td>
</tr>
</tbody>
</table>
**SUB-ANALYSIS: Q CARE PLUS TelePrEP Users**

### Insurance Status
- **Insured:** 46.2%
- **Uninsured:** 53.8%

### Urban/Rural
- **Urban:** 50.1%
- **Suburban/Rural:** 49.9%

### Region
- **South:** 62.6%
- **West:** 26.6%
- **Northeast/Midwest:** 10.8%

### Previous Partners*
- **0-1:** 36.9%
- **2-3:** 38.4%
- **4+:** 24.7%

### Previous PrEP Exp.
- **Oral PrEP:** 23.3%
- **No Exp.:** 72%
Among 2021 QCP patients, **four-fifths elected a self-collect option**

QCP patients selecting self-collect testing were slightly more likely to have a PrEP follow-up in the ensuing 6 months, with self-collect testers **1.14 times more likely** to have at least one follow-up compared to those choosing blood draw (Prevalence ratio 1.144; 95% CI: 0.995, 1.316)
LOWERING BARRIERS TO TESTING

A Pilot of Mail-Out HIV and Sexually Transmitted Infection Testing in Washington, District of Columbia During the COVID-19 Pandemic


Introduction: In 2019, the District of Columbia recorded a 20-year low rate in new HIV infections but also had near-record numbers of gonorrhea and chlamydia infections. District of Columbia Department of Health has supported numerous forms of community-based in-person screening but not direct at-home testing.

Methods: In summer 2020, the District of Columbia Department of Health launched GetCheckedDC.org for District of Columbia residents to order home-based oral HIV antibody test and urogenital, pharyngeal, and rectal chlamydia and gonorrhea tests. Initial and follow-up surveys were completed by individuals for both test modalities.

Results: A retrospective analysis was conducted for the first 5 months of the program. During that period, 1,089 HIV and 1,262 gonorrhea and chlamydia tests (535 urogenital, 520 pharyngeal, 207 rectal) were ordered by 1,245 District of Columbia residents. The average age was 33.1 (median=31, range=14–78) years; 51.6% of requesters identified as Black; 39.3% identified as men who have sex with men; 16.2% reported no form of insurance; and 8.1% and 10.4% reported never being testing for HIV and sexually transmitted infections, respectively. More than half of people requesting tests reported convenience and COVID-19 as the reasons. In total, 39.5% of sexually transmitted infection tests were returned; 7.2% of people testing for sexually transmitted infections received a posi
LOWERING BARRIERS TO TESTING

The Binx everywhere STI Collection Program & Alabama DPH in collaboration with Binx Health, reviewed 4-12/2021

49% had never been HIV tested >2 yrs ago / never / uncertain

1,866 kits requested, 41% of which were returned (92.5% received within 30 days), with 5.2% CT+, 3.2% NG+. Alabama has 8th highest CT rate, 3rd highest NG rate, and 15th highest primary / secondary syphilis rate in U.S.
LOWERING BARRIERS TO TESTING

The Binx everywhere STI Collection Program & Alabama DPH in collaboration with Binx Health, reviewed 4-12/2021

Significant stigma and practical/financial barriers to HIV testing

1,866 kits requested, 41% of which were returned (92.5% received within 30 days), with 5.2% CT+, 3.2% NG+. Alabama has 8th highest CT rate, 3rd highest NG rate, and 15th highest primary / secondary syphilis rate in U.S.
CONCLUSIONS

- Self-collect testing served **one in 7 US PrEP users in 2021** and **was used disproportionately among those** at high risk of HIV infection: **young people, men, and people in the US South.**

- Those seeking telePrEP in the South and rural areas were **more likely to be HIV-positive.**

- TelePrEP **addresses barriers to PrEP access**, including **limited accessibility, stigma, and safety concerns** during the COVID-19 pandemic.

- TelePrEP **contributes to supporting PrEP use and persistence** in the most vulnerable US PrEP users.
CONCLUSIONS FOR AN INTERNATIONAL AUDIENCE

- Remote care and collection addresses **stigma, safety, and privacy issues** that may facilitate access to care in vulnerable populations.
- Experience with and openness to **remote self-collected and guided specimen collection** internationally, though regulatory requirements vary globally.
- Digital resources required for continuous remote care may not be consistently available and may be **exacerbated by economic inequities** that need to be solved for.
- In varied settings, **specimen stability validation** may be required.

*Dr. Hall wishes to thank co-authors Drs. Eric Hall & Patrick Sullivan for their assistance with data analysis.*