Point-of-Care Diagnostics as a Tool to Map and Manage Chronic Diseases

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GHIC 2019
DISCLOSURES

- Employee of Jana Care Inc. whose products are discussed
- Jana Care diagnostic devices (Aina, Aina Station) are not yet approved for use in the United States as medical devices
Diabetes

Notable Infectious Diseases

Low- & Middle-Income Countries

Estimated Prevalence (millions)

- Malaria
- HIV
- TB
- Ebola

Diabetes

Notable Infectious Diseases
NCDs (non-communicable diseases) accounted for 38 million (68%) of deaths worldwide in 2012. NCD deaths is projected to reach 52 million by 2030.

WHO recommends cost-effective interventions to reduce mortality rate caused by NCDs.

Integrated NCD programs should be implemented at primary care level.

Source: World Health Organization
DECENTRALIZING CARE

Hospital

Clinic

Home Monitoring
ACCESSIBLE MOBILE SCREENING SOLUTION

AINA — *The first smartphone-based diagnostics platform*

Performs various assay types: immunoassay, enzymatic or chemical-affinity

HABITS — *Behavior coaching app*

Enables personalized disease management improving outcomes
MOBILIZING CHRONIC CARE: FROM HEALTH SCREENING TO PRIMARY CARE TO HOME

COMMUNITY

SCREEN

Real-time tests for: HbA1c, Lipid panel, Hb, Glucose

Aina Mobile
Mobile health screening, GP clinics
User: screening operator, HCP staff

Aina Station
GP clinics, Diabetologists, Outreach clinics
User: HCP staff

STRATIFY

High Risk
- HbA1c > 8.5%
- High lipid readings
- Other risk factors

Medium Risk
- HbA1c 6.0 to 8.5%
- Medium high lipid readings
- Other risk factors

Low Risk
- HbA1c < 6.0%
- Healthy lipid readings
- Low risk factors

TREAT & MONITOR

Intensive treatment then lower risk to primary care

Regular follow ups at primary care & home monitoring

Aina Mini + Habits
SMBG+ Behavioral changing Apps:
- T2D
- GDM
- Prediabetes
User: Patients

Habits Clinic Dashboard
Lab data, SMBG, lifestyle records, population-wide analytics, communication with patients.
Collects data from Aina and Habits.
User: Physicians, HCP Staff
HABITS: EVIDENCE BASED BEHAVIORAL CHANGING APPS

HABITS DIABETES COACH

Based on the landmark study, Diabetes Prevention Program (DPP), Habits Diabetes Coach is designed for pre-diabetes, type 2 diabetes patients to improve health outcomes.

Collaborators: Global Obesity Centre, Madras Diabetes Research Foundation, Published at JMIR

HABITS GESTATIONAL DIABETES COACH

Personalized and localized gestational diabetes management content, localized lifestyle advices, wireless weight tracking and connected glucose meter.

Collaborators: National University Hospital, Singapore
Clinicaltrials.gov ID: NCT03249896

HABITS HEART

Habits Heart is designed to aid patients with congestive heart failure to self-manage their condition at home. It comes with wireless weighing scales and symptoms guided surveys.

Collaborators: Massachusetts General Hospital
Clinicaltrials.gov ID: NCT03238729
20,000 food items available. Food databases for Western (US) diet, South Asian, Singapore/Malaysia.

Lifestyle content adjusted for specific diet and region through collaboration with KOL.s

Languages available: English, Chinese, Malay, and Hindi.

Translation and food database can be implemented.
Macro-level overview of population health status in real-time: Demographic, glycemic control, medication, lab work, diet, activities and other lifestyle controls.

Review individual level details to prescribe specific treatment plan and review progress.

Onboard patient directly to health screening program through dashboard.

Communicate directly with patients for follow-up.
MONITOR PATIENT PROGRESS, REVIEW LAB DATA HISTORY, AND COMMUNICATE ALL IN ONE PLACE

REMOTE MONITORING
Real-time self-monitoring blood glucose, diet, exercise, weight, and medication tracking of patients through Habit app.

LAB REVIEW
Lab data history for review to access and adjust treatment plan.

2-WAY COMMUNICATION
Communicate with patients on non-critical questions to manage workload and in-person visits.
Understand field operations through an administrative dashboard. Review progress of each health screen site and operator.

- View each test performed annotated with time and date, GPS coordinates, device serial number, and operator name.
- Data is de-identified to maintain patient confidentiality.
- Administrator can create multiple accounts with appropriate levels of access for all staff.
- Remotely monitor Quality Check (QC) schedules.
- Map view representation of data.
FROM BLOOD TO BYTES

Jana Care collects structured longitudinal biomarker and health data.

Aina obtains anonymized data through clinical use—300k+ patients thus far.

Biomarker data is paired with location, time, and combines with the Habits App to add diet and steps.

Context-rich data provides insights for both individuals and populations.

We can begin asking **bigger questions** than what is the level of one biomarker.
RESULTS IN INDIA: TACKLING THE DIAGNOSTIC GAP AT KUMBH MELA
RESULTS IN INDIA: TACKLING THE MANAGEMENT GAP WITH GENERAL PRACTITIONERS
MAPPING DIABETES IN BANGALORE

Average HbA1c
Green: 6-7%
Yellow: 7-8.5%
Red: >8.5%

Higher HbA1c correlates with:
• Less parks and open spaces
• Higher income
• Newer migrant areas
• Areas with low density of clinics
Over 1,000 clinics using Aina

75,000 Habits users

500,000+ Aina tests shipped

Presence in over 20 states

Expanding nationally with distribution partners (Siemens Healthineers)

Expanding into Southeast Asia and Latin America
Provide Aina Devices and basic training to assay developers

Enable end-point and kinetic measurements in ready-to-use platform

Two-way respect for IP

Faster path to manufacturing, commercialization, and launch

Potential for distribution partnership

Pilot program is 1+ years in with half a dozen partners from industry and academia

Interested in Open Aina?
Email: contact@janacare.com
Care to the People ➔ जन ➔ Jana Care
Access to all user accounts is controlled via authentication.
- All APIs use token key based authentication.
- Strong password policy in place for all user roles.
- Strict mapping of HCP and patients to prevent unauthorized data access.

Data encryption at rest on both clients and server.
- Data encryption during transit using HTTPS.
- 24/7 monitoring and logs for all activities are maintained at a secured location.
- Passed 3rd party penetration test.

Hosting server provider is Amazon Web Services (AWS).
- AWS ensures ISO 27001 and FISMA certified data centers managed by Amazon.
- Server database is backed up at regular intervals.
- Region restrictions to prevent data outflow.

- Clear segregation of data classes and access.
- Secure Software Development Lifecycle in place for all development activities.
## HIGH PERFORMANCE TESTS

<table>
<thead>
<tr>
<th></th>
<th>HbA1c</th>
<th>Blood Glucose</th>
<th>Total Cholesterol</th>
<th>HDL</th>
<th>Triglycerides</th>
<th>Hemoglobin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measuring range</td>
<td>4 - 15%</td>
<td>10 - 500 mg/dl</td>
<td>100 - 400 mg/dl</td>
<td>25 - 85 mg/dl</td>
<td>50 - 450 mg/dl</td>
<td>7 - 23 g/dl</td>
</tr>
<tr>
<td>Test time</td>
<td>3 minutes</td>
<td>5 seconds</td>
<td>1 minute</td>
<td>1 minute</td>
<td>2 minutes</td>
<td>30 seconds</td>
</tr>
<tr>
<td>Reference</td>
<td>Variant II Turbo (Bio-Rad)</td>
<td>2300D STAT Plus (YSI)</td>
<td>Dimension RxL Max (Siemens)</td>
<td>Dimension RxL Max (Siemens)</td>
<td>Dimension RxL Max (Siemens)</td>
<td>LH750 (Beckman Coulter)</td>
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<tr>
<td>R²</td>
<td>0.972</td>
<td>0.994</td>
<td>0.973</td>
<td>0.969</td>
<td>0.970</td>
<td>0.970</td>
</tr>
<tr>
<td>Clinical accuracy</td>
<td>97.6% samples within 10% bias</td>
<td>95.7% samples within 15% bias</td>
<td>100% samples within 20% bias</td>
<td>99% samples within 15% bias</td>
<td>95% samples within 15% bias</td>
<td>97.2% samples Within 15% bias</td>
</tr>
<tr>
<td>Blood sample</td>
<td>5µL Capillary and venous whole blood</td>
<td>2µL Capillary whole blood</td>
<td>15µL Capillary and venous whole blood</td>
<td>15µL Capillary and venous whole blood</td>
<td>15µL Capillary and venous whole blood</td>
<td>10µL Capillary and venous whole blood</td>
</tr>
</tbody>
</table>

* More clinical data available at Jana Care’s Analytical Performance Summary Report
THE SMARTPHONE AS A POINT OF ACCESS

Smartphone ownership

<table>
<thead>
<tr>
<th></th>
<th>Developed</th>
<th>Developing</th>
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</thead>
<tbody>
<tr>
<td>Any mobile phone</td>
<td>91%</td>
<td>90%</td>
</tr>
<tr>
<td>Smartphone</td>
<td>80%</td>
<td>82%</td>
</tr>
</tbody>
</table>

Deloitte report 2017

Smartphone penetration in India estimated at ~25% in 2018 by Pew Research Trust

Based on our experience, believe it’s somewhere between 25 – 82%

www.gapminder.org