



Telehealth Diabetes Screening Utility of a Wireless Handheld iAssay Blood Analyzer: A Cost Benefit Analysis

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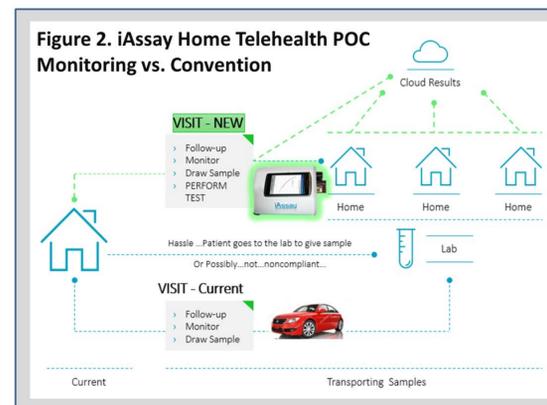
National University Nurse-Managed Clinic – Interprofessional Collaborative Practice (NUNMC-IPCP)

- **NUNMC-IPCP:** A nurse-managed person-centered interprofessional (IP) healthcare ambulatory clinic centrally located in the Watts-Willowbrook community, offers direct inexpensive on-site and home point of care (POC) health services to its underserved residents.
- **NUNMC-IPCP Model:** An 8-week student-centered **practicum**; engages cohorts of faculty-mentored nursing and health professional students (undergrad/grad; Capstone/Internship) in collaboration with the IP healthcare team; **students gain IPCP skills and competencies.**
- IP teams comprising the NUNMC assess health outcomes associated with project initiatives in collaboration with community-based organizations as well as clinical affiliates of National University.
- The NUNMC-IPCP **telehealth POC model** supports rapid diagnosis in remote non-clinical settings versus traditional approaches; can potentiate **medical-cost savings**; and bridge access disparity and inequity gaps in underserved communities like Watts-Willowbrook.

Background

Mobile telehealth devices have:

- Transformed the practice of health care by significantly impacting and extending service to underserved areas, and improving health outcomes and medical system efficiency (West, 2012);
- Assisted community health workers in improving the quality of care provided, efficiency of services, and capacity for program monitoring (Braun, Catalani, Wimbush, Israelski, 2013); and
- With increased attention in prevention and management of chronic diseases such as diabetes, handheld blood glucose monitoring devices have evolved to offer real time electronic results, reduced pain, and increased accuracy (Clarke & Foster, 2012; Scholtes-Timmerman, et al., 2014; NIH Factsheet, 2013).



NUNMC-IPCP was asked to serve as the first beta-test site to evaluate by clinical trial the feasibility of POC testing by the wireless handheld mobile iAssay System (a Class I, 510(k) candidate); to test its ability to remotely collect, analyze and HIPAA compliantly submit (via a Smartphone platform) to The Cloud diabetic patients' blood glucose and cholesterol data, and compare functionality of the iAssay device to a similar FDA-approved device in current use at the clinic.

Objectives

- To perform a preliminary cost benefit analysis (CBA) of utilizing the iAssay System blood glucose- and cholesterol-testing device that frames its POC serviceability for home health providers versus conventional testing at medical facilities (labs and clinics).
- To develop a clinical research **feasibility study** protocol, based on CBA results, that can assess the **efficiency** of the iAssay device in POC screening home health diabetic patients by *in vitro* diagnostics and determine its **efficacy** at monitoring **blood glucose and cholesterol** versus a device in current use.

Methods

We developed a CBA to determine the monetary value associated with structuring a feasibility study of the iAssay System at POC testing of 200 adult diabetic patients' finger-prick blood samples in non-clinical settings compared to conventional methods of testing in commercial lab or clinical settings, through a literature review and interviews with the NUNMC Program Director (A. Finney) and an iAssay inventor/executive about mobile blood analysis technology and health care practices, as well as discussions regarding program budget costs in clinical versus underserved settings. Factors considered in developing the CBA included measuring NUNMC staffing and program costs, direct and indirect costs associated with hospital and clinical lab visits and testing, and related costs associated with using handheld devices. Benefits, defined as cost savings in contrast to cost expenditures, were estimated and the ratio of benefits to costs were calculated.

Results and Discussion

The CBA estimated costs associated with assessing the feasibility of implementing the wireless handheld iAssay System for rapid POC testing and diagnosis of blood glucose and cholesterol from finger-prick blood samples of 200 adults in the non-clinical setting of the Watts-Willowbrook community. Its proposed impact on reduced costs for lab tests, clinical visits, and treatment was also considered. The **total costs** for staffing, direct, indirect and overhead amounted to \$302,486 (Table 1). The potential medical dollars saved (**total benefits**) associated with utilization of the iAssay device due to avoiding emergency room (ER) use/visits, reduced return visits and lab fees amount to a savings of \$367,894 for one of 30 sites projected (Table 2). The net benefit for 30 testing sites is estimated to be \$10,734,334 (\$11,036,820 – 302,486) (Table 3); and thus the **benefit/costs ratio** is \$11,036,820/302,486 or **36:1**.

Table 2. Estimated cost benefits of proposed iAssay POC utility.

BENEFITS (If iAssay technology is adopted)	
Reduced ER Utilization	
• ER Cost Avoided \$1,719,295 x 15% for applicable health issues	\$257,894 (NUNMC; Washington, Andrews, & Mutter, 2013; Hornberger, 1998)
Reduced Return Visits	
• Cost per visit \$117 x 2 visits x 400 patients (2/3 of practice)	\$93,600 (NUNMC)
Reduced Lab Fees	
• Lipid Panel \$41 x 400 patients	\$16,400 (NUNMC)
TOTAL BENEFITS	\$367,894

Table 1. Estimated costs of proposed iAssay POC utility research study.

COSTS		
Staffing		
• Principal Investigator	\$300/hr	\$144,000 (Fautsch & Klous, 2011)
• Study Coordinator	\$60/hr	\$28,800 (Fautsch & Klous, 2011)
• Nurse Practitioner x 4	\$75/hr	\$14,400 @ 10% (NUNMC)
Total		\$187,200
Direct Program Costs		
• iAssay X 4	\$4,000	\$16,000 (mean estimated price)
• Accutrend Plus x 4	\$200	\$800
• Testing Supplies x 2	\$500	\$1,000
• Cost per visit x 200	\$117	\$23,400 (NUNMC)
• Study Incentives x 200	\$25	\$5,000
Total		\$46,200
Overhead (20% of Direct Costs and Staffing)		
• Rent, utilities, supplies, fees, etc.		\$46,680 (Fautsch & Klous, 2011)
Indirect Costs (8% of Previous Totals)		
• Admin Fees, legal fees, translation		\$22,406 (Fautsch & Klous, 2011; Emergo Group, 2016)
• Services, etc.		
TOTAL COSTS		\$302,486

Table 3. Estimated benefits-to-costs and benefits/costs ratio.

NET BENEFITS (30 sites)	
• Benefits - Cost	\$10,734,334
RATIO OF BENEFITS TO COST	
• Benefits/Cost	\$11,036,820/\$302,486 = 36:1

The CBA estimated home telehealth POC testing to be cost-effective, saving \$36.00 for every \$1.00 spent.

Conclusions

Potential utility of the iAssay for non-clinical POC telehealth testing in remote underserved home telehealth settings may offer health care benefits including avoiding costs of routine clinical lab testing and reduced ER and clinic (re)visits, at a fraction of the cost. This CBA supports the pending NUNMC-iAssay feasibility study.

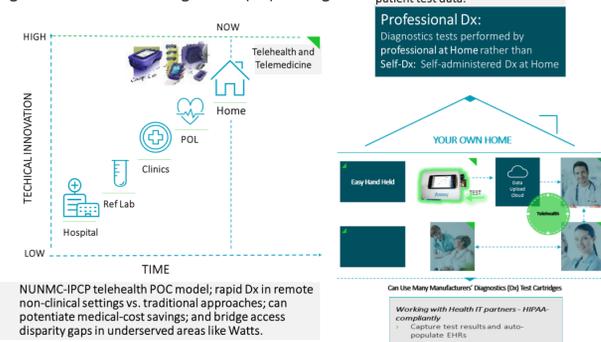
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References available upon request.ssti

Figure 1. Evolution of Diagnostics (Dx) Testing



A significant proportion of adults within the Watts-Willowbrook population variably seeks medical or healthcare services located far outside their local community, and suffers with high rates of preventable acute and chronic health problems, along with markedly poor health outcomes (Health Facts for Service Planning Area 6, n.d.).