ValidationInstitute

2022 Validation Report

Review for: One Drop

Validation Achieved: Level 2 - Outcomes

Valid through: September 2022

Company Profile

ONE DROP®

Category:	Disease Management
Website:	https://onedrop.today
Year Established:	2015
Public or Private:	Private
CEO:	Jeffrey Dachis
Company contact:	results@onedrop.today

Description:

One Drop (Informed Data Systems Inc.) is a precision health company at the nexus of personal diagnostics, artificial intelligence, and telehealth. Powered by machine learning algorithms and a wealth of real-time data, the digital platform combines predictive insights, a behavior change program, and the human touch of coaching, filling in the gaps between doctor's visits and simplifying daily decision-making. The goal: empower everyone to take proactive action for better health outcomes, peak performance, and a more fulfilling life. **One Drop** products and services are available for purchase in the award-winning **One Drop** app (iOS and Android) and at onedrop.today, Walmart, Amazon, BestBuy, the Apple Store, and CVS.

For information on how **One Drop** can help your organization lower its cost of care, contact results@onedrop.today, or visitjoinonedrop.com/employer.

Claim Assertion for Validation

One Drop's multi -condition program was associated with statistically significant reduction of blood glucose and blood pressure for people who had one or more lessons or interactions with a health coach over 30 to 180 days.

Improvements in blood glucose are associated with lower medical costs. In blood glucose, a 1% reduction in HbA1c levels has been shown to link to a two percent decrease in annual total medical costs and a 13% decrease in annual diabetes-related medical costs; this equates to a $429 in total medical costs, and $736 in diabetes medical costs per year. (Lage and Boye, 2020) Using a digital therapy program in addition to usual care for hypertension is associated with $840 in medical costs in year one. (Nordyke et al.). Extrapolating One Drop's clinical outcomes with estimates from these studies and accounting for inflation, One Drop has the potential to yield $1,239 and $1,892 in per-person annual cost savings for diabetes and hypertension, respectively.

*Note: The program also tracked weight measures. Early data showed positive results; however, Validation Institute standards require at least 12 months of weight tracking. One Drop plans to have this data validated when it is available.

Method / Calculation / Examples

All methods and results have been previously presented and published.[1,2,3] Employees and spouses were invited to enroll in the program; people identified themselves as having prediabetes, diabetes, and/or hypertension. The analysis included all of those who enrolled and completed at least one lesson and/or sent one message to a coach. Only participants who had two clinical measures more than 30 days apart could be included.

Blood glucose levels were recorded by the One Drop app by manual entry, synced One Drop meter or synced continuous glucose monitor (CGM). Blood pressure readings were recorded by manual entry or Bluetooth blood pressure monitor in the One Drop app.

For each participant, the measure taken at his/her last entry was compared to his/her first (or baseline) entry. The average change was calculated for each measure. Separate calculations were done for people whose first entry was higher than the goal and those who were already at the goal. The goal for blood pressure was systolic level less than 130; and for blood glucose, the goal was an average weekly level of less than 154.

Because the multi-condition program includes all people with qualifying conditions, not just those with higher clinical values, separate analyses are conducted for people starting the program at target clinical levels, where we expect the program to help them maintain their target levels, versus people starting the program above target clinical levels, where we expect the program to help them reduce their clinical values. For people with diabetes,

Method / Calculation / Examples

average weekly BG less than 154 mg/dL (estimated A1c less than 7%) was considered at target, and 154 mg/dL and above was considered above target. For people with hypertension, SBP of less than 130 mmHg was considered at target, and Stage 1 or higher hypertension (SBP>130 mmHg) was considered above target.

For people at target, the analysis evaluated the percentage of people who remain at target. For people who were above target at baseline, Wilcoxon signed rank and t-tests evaluated change in outcomes between first and most recent measurement.

Participants were also grouped by the number and type of conditions they had, such as hypertension with diabetes. While prediabetes weight loss outcomes were outside of the scope of validation, these people were also considered in analysis of the multi-condition program.

Findings & Validation

Table 1 summarizes program engagement by condition.

Program Engagement	Analysis Cohort		
	Prediabetes	**Diabetes**	**Hypertension**
Duration	4-20 weeks	6-32 weeks	4-21 weeks
Completed 1+ Lesson	90%	94%	95%
Avg (SD) Lessons Completed	7 (6)	9 (10)	9 (8)
Sent 1+ Coach Message	78%	73%	80%
Avg (SD) Messages to Coach	19 (24)	26 (50)	22 (28)
Completed 1+ Lesson and Sent 1+ Coach Message	69%	67%	76%

Table 1

Findings & Validation

Table 2 shows the summary of average outcome change for members starting the program above target, split by condition and comorbidities. All of these changes were statistically significant (p < .05) with the exception of DBP change for members with hypertension and diabetes, which was marginally significant (p = .09).

Cohort	Estimated A1c Change	Blood Pressure Change (Systolic/Diastolic)
All Prediabetes		
All Diabetes	-0.9%	
All Hypertension		-16.5/-9.3 mmHg
Prediabetes-only		
Diabetes-only	-0.8%	
Hypertension-only		-16.5/-10.3 mmHg
Prediabetes + Hypertension		-19.4/-9.9 mmHg
Diabetes + Hypertension	-0.9%	-12.5/-6.3 mmHg

Table 2: Change in participants' measures

Findings & Validation

For diabetes, 81.0% of those who began the program at the goal level were still at the goal level at their last data entry. For hypertension, a similar percentage (81.6%) started the program at the goal level and were still at the goal level at their last data entry.

From the first to the latest data entry, people who had diabetes and hypertension improved their blood pressure on average by 12.5 mm Hg systolic and 6.3 diastolic; in addition, they reduced their estimated blood glucose (HbA1c) by an average of 0.9%. People who had prediabetes and hypertension reduced their blood pressure by an average of 19.4 mm Hg systolic and 9.4 mm Hg diastolic. These improvements were significant for the person's health status and were statistically significant.

Limitations

Several limitations associated with retrospective, pre-post real-world evaluation should be noted. First, participants self-identified as having the illnesses, which may have put people into the program who do not clinically qualify as having the illnesses and leave out some who do, but don't know it (these individuals could also be at higher risk of deterioration). Moreover, the groups were not randomly selected.

Second, participants enrolled voluntarily and may have had personal motivation to improve their health, though no incentives were given for joining. Personal motivation would increase the amount of positive change and may not be representative of other people who have these illnesses. A randomized controlled design will be needed to confirm causal effects of the program.

Lastly, changes over 4 to 32 weeks may reflect normal fluctuations in clinical measures rather than lasting improvement. Without a control or comparison group, we don't know how many participants would improve in the absence of the One Drop intervention; this natural phenomenon is called "regression to the mean".

While these limitations are inherent to real-world, pre-post study designs, the present findings are reflective of real-world engagement and outcomes.

Work Cited

Lage, Maureen J., and Kristina S. Boye. "The relationship between HbA1c reduction and healthcare costs among patients with type 2 diabetes: evidence from a U.S. claims database." Curr Med Res Opin, vol. 36, no. 9, 2020, pp. 1441 - 1447. PubMed, https://pubmed.ncbi.nlm.nih.gov/32643451/. Accessed 4 12 2021.

Nordyke, Robert J., et al. "Estimating the Impact of Novel Digital Therapeutics in Type 2 Diabetes and Hypertension: Health Economic Analysis." Journal of Medical Internet Research, vol. 21, no. 10, 2019. Journal of Medical Internet Research, https://www.jmir.org/2019/10/e15814/. Accessed 6 12 21.

Validation and Credibility Guarantee

One Drop Multi-condition Program achieved Level 2 validation for Outcomes. Validation Institute is willing to provide up to a $25,000 guarantee as part of their Credibility Guarantee Program. To learn more, visit https://validationinstitute.com/credibility-guarantee/.

Level 1 – Savings
Can reduce health care spending per case/participant or for the plan/purchaser overall.

Level 2 – Outcomes
Product/solution has measurably moved the needle on an outcome (risk, hba1c, events, employee retention, etc.) of importance.

Level 3 – Metrics
Credible sources and valid assumptions create a reasonable estimate of a program's impact.

Level 4 - Contractual Integrity
Vendor is willing to put a part of their fees "at risk" as a guarantee.

VALIDATION INSTITUTE
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Woburn, MA 01801

Validation Expiration: September 2022

CERTIFICATE OF VALIDATION

Applicant: **One Drop**

166 Mercer St, New York, 10012, US

Product: One Drop Multi-condition Program

Claim: Users of One Drop's multi-condition program improved their blood glucose and/or blood pressure with at least 30 days participation along with one lesson or interaction with a health coach. The conditions were prediabetes, diabetes, and hypertension.

Validation Achieved: **Level 2 – Validated for Outcomes**

Validation Award Date: January 2022

Linda Riddell
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Validation Institute

Benny DiCecca
Chief Executive Officer
Validation Institute

About Validation Institute

Validation Institute is a professional community that advocates for organizations and approaches that deliver better health value - stronger health outcomes at lower cost. We connect, train, and certify health care purchasers, and we validate and connect providers delivering superior results. Founded in 2014, the mission of the organization has consistently been to help provide transparency to buyers of health care.