

The Role of Medication Adherence and Digital Health in the Shift Towards Value-Based Health Care

Marina Krygin
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Table of Contents

I.	Introduction	03
II.	Importance of Medication Adherence in Value-Based Care	07
III.	Improving Medication Adherence Using Behavioral Economics	09
IV.	Policy Implications	11
V.	Conclusion	13

Introduction

Per capita health care spending in the U.S. exceeds twice the average of other developed countries, yet the U.S. continues to rank poorly with respect to many population health outcomes. In 2016, national health expenditures in the U.S. accounted for 17.9% of GDP. Under current law, this is projected to increase to 19.7% by 2026.¹ With many metrics, the U.S. consistently ranks below average compared to other developed countries.² In recent years, this disconnect between health care spending and outcomes has been the catalyst for a paradigm shift in health care reimbursement.

Rather than conventional fee-for-service models in which providers are reimbursed based on quantity of services delivered, in the past few decades there has been a new focus on models that emphasize value, or quality of outcomes per dollar spent. An approach towards reimbursement reform that aligns with this shifting trend is called Value-Based Insurance Design (V-BID). The goal of V-BID is to generate health benefit designs that promote better consumer decision-making, and it is gaining support across private and public sectors. The premise of V-BID is to align patients' out-of-pocket costs with the value of health care they receive. The higher the value, the lower the patient cost-sharing (in the form of co-pays or co-insurance, for instance). Previous attempts to lower healthcare costs focused on increasing patient cost-sharing, since the extensive third-party coverage in the health sector insulates patients from the true costs of care and affects their decision-making as consumers. However, research has shown

¹ <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/national-health-expend-data/nhe-fact-sheet.html>

² https://www.pgpf.org/chart-archive/0011_health-outcomes

that while increased patient cost-sharing decreases health care consumption, it reduces the use of both appropriate and inappropriate care.³ This results in individuals getting less care than what they need to be healthy.

The primary flaw with this approach is not aligning costs with value—which V-BID accomplishes by implementing a concept known as clinical nuance. Clinical nuance is composed of two key components:

1. Clinical services differ in the benefits they produce.
2. Clinical benefit depends on who is receiving the care, who is administering it, and where that care is being given.⁴

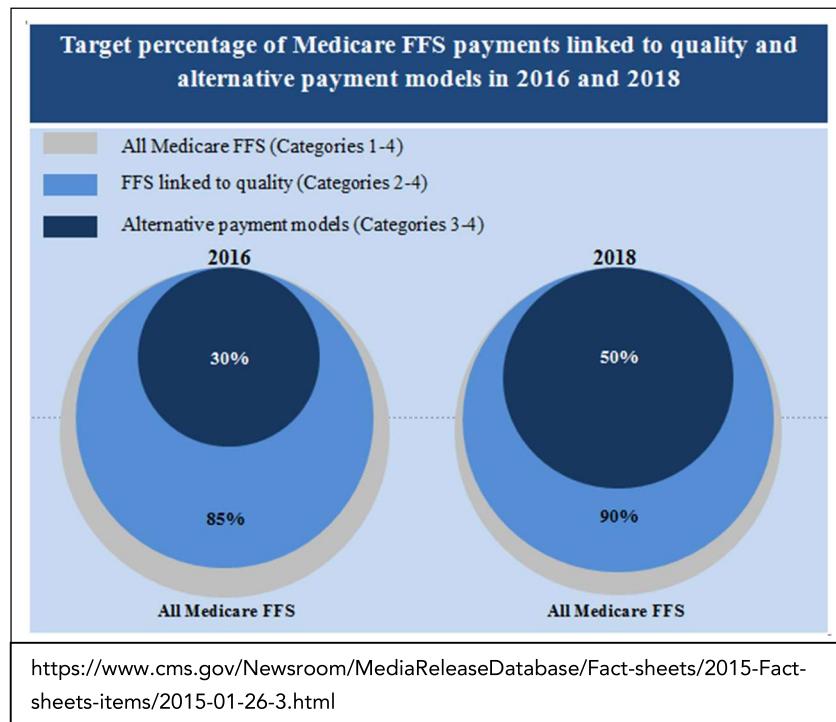
On the federal level, programs such as the Hospital Readmissions Reduction Program (HRRP) have been created which follow value-based arrangements. Established under the Affordable Care Act (ACA), HRRP mandates Centers for Medicare and Medicaid Services (CMS) to reduce payments to Inpatient Provider Payment System hospitals with excess readmissions.⁵ Overall within CMS there is a movement towards all contracts being associated with value of care provided. In 2016, the US Health and Human Services Department publicized their goal of

³ Newhouse JP, Manning WG, Morris CN, Orr LL, Duan N, Keeler EB et al. Some interim results from a controlled trial of cost sharing in health insurance. *N Engl J Med.* 1981;305(25):1501–7

⁴ <https://www.ajmc.com/contributor/vbid-center/2016/10/understanding-clinical-nuance>

⁵ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html>

having 90% of Medicare payments tied to value-based arrangements, as depicted by the graphic below:⁶



On the state level, there has been a rise in programs such as New York's Delivery System Reform Incentive Payment Program (DSRIP). DSRIP incentivizes community-level collaborations focused on system reform—with the main goal of achieving a 25% reduction in avoidable hospital use over the course of 5 years. This program is part of New York State's Value Based Payment Reform effort, the existence of which is an indicator that state governments are also contributing to this reimbursement redesign.⁷

⁶ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html>

⁷ https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/vbp_alignment_paper_final.htm

In the private sector, major insurance companies have amended their provider-payer contract agreements to align with the V-BID model. For example, Cigna published a white paper in early 2016 describing their efforts to shift towards value-based models. V-BID demonstrations are also being expanded as a part of Medicare Advantage. Part of the ACA, the Medicare Advantage V-BID Model allows Medicare Advantage plans to offer reduced cost sharing or additional benefits to enrollees with any of the 19 CMS-specific chronic conditions.

While these initiatives involve a variety of quality metrics, a common thread among them is measuring medication adherence. Lack of medication adherence is a highly prevalent issue in the U.S. and one that has serious, widespread consequences. Medication adherence is defined as the process by which patients take their medication as prescribed. This includes initiating a medication regimen when instructed, adhering to the dosing instructions after initiating that medication regimen, and continuing to take medication for the duration of a prescription.⁸ According to the WHO, approximately 50% of patients with chronic conditions do not adhere to treatment, such as taking their medications as prescribed.⁹ Not only does this lead to adverse health outcomes for patients who are subject to it, but it results in excess costs within the health care sector. The full health benefits of taking medications cannot be realized if medications are not taken properly.

⁸ Vrijens B, De Geest S, Hughes DA, et al. A new taxonomy for describing and defining adherence to medications. *British Journal of Clinical Pharmacology*. 2012;73(5):691-705. doi:10.1111/j.1365-2125.2012.04167x.

⁹ Sabaté E, editor., ed. *Adherence to Long-Term Therapies: Evidence for Action*. Geneva, Switzerland: World Health Organization; 2003.

Importance of Medication Adherence in Value-Based Care

There are a variety of factors which influence medication adherence, making it a complex issue to address. Socioeconomic disparities in income, social status, and education are known to affect health outcomes and low socioeconomic status has been linked with low medication adherence. The quality of care given by a provider or hospital system can impact medication adherence (for instance, how much follow-up a hospital does following a patient's discharge). Many of those struggling with medication adherence face chronic conditions, and according to literature are more likely to have comorbidities as a result. In turn, comorbidities can increase the chance of low medication adherence. This is because having multiple diagnoses often requires taking more medications, complicating care plans and hindering medication adherence.¹⁰ This network of contributing factors present a challenge to developing effective medication adherence interventions.

Providers involved in programs such as DSRIP, HRRP, and the others mentioned above have attempted a variety of interventions to improve their medication adherence scores to align with new value-based standards. These efforts have ranged from nurse care managers following up with patients to make sure they are refilling their prescriptions to more digital-based interventions. Past digital health interventions have addressed adherence by providing pill reminders and enabling patient-provider communication but haven't inspired patient

¹⁰ Ferdinand KC, Senatore FF, Clayton-Jeter H, et al. Improving Medication Adherence in Cardiometabolic Disease: Practical and Regulatory Implications. J Am Coll Cardiol. 2017 Jan 31;69(4):437-451

motivation: most studies report low patient engagement.¹¹ Yet interventions addressing economic barriers, such as with V-BID, have been shown to dramatically increase medication adherence.

In July of 2018, Health Affairs published a systematic review of 21 studies that investigated the impact of V-BID on medication adherence. In the review, all but two studies showed a statistically significant improvement in medication adherence with V-BID. The exceptions found no difference in adherence with a V-BID model compared to without. These improvements were evaluated by looking at Medication Possession Ratio (MPR) or Proportion of Days Covered (PDC), two commonly used metrics for medication adherence. Using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system, the authors found evidence of improvement in medication adherence from 0.1-14.3% with V-BID.¹²

These results are promising, but there is still room for improvement. Medication adherence rates in the U.S. are currently around 50% in chronic disease populations, so even on the far end of the spectrum seen in the review, average medication adherence with V-BID would only amount to approximately 64.3%.¹³ For medication adherence rates to be closer to 100%, this complex problem needs to be approached from various angles and not just from the standpoint of health care payment redesign. There is a critical need to combine financial

¹¹ Holtz B, Lauckner C. (2012). Diabetes Management via Mobile Phones: A Systematic Review. *Telemedicine and E-Health*, 18(3): 175-184. doi:10.1089/tmj.2011.0119 (PMID: 22356525).

¹² <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.1633>

¹³ Sabaté E, editor., ed. Adherence to Long-Term Therapies: Evidence for Action. Geneva, Switzerland: World Health Organization; 2003.

incentives with digital health technologies of proven clinical benefit to continue improving medication adherence.

Improving Medication Adherence Using Behavioral Economics

Behavioral economics is the study of why individuals perform the behaviors they do. Recent research in the field has offered a deeper understanding of human behavior and motivation. Wellth, a digital health company that helps patients achieve better adherence and engagement, has incorporated behavioral economics into its mobile solutions to better improve patient outcomes. For instance, the concept of present bias helps explain why patients often don't adhere to their care plans. Present bias is when people weigh present-day rewards greater than future rewards, and even though many patients want to get healthier, they don't always do the right things necessary to get there (such as taking daily medications). This cognitive bias can also be harnessed for good; by understanding this bias, it's possible to create more effective behavioral health interventions. Wellth tackles present bias by providing a tangible, immediate motive in the form of financial incentives to reinforce healthy behaviors. By doing so, more present value is generated for behaviors such as taking daily medications.

Wellth uses the behavioral economics concept known as loss aversion to further improve medication adherence and create habit formation. Loss aversion is the tendency of individuals to be more motivated by avoiding potential losses than by receiving equivalent gains. Research has supported this concept: in a 2016 study it was found that loss aversion was 29% more effective at inducing high BMI patients to track over 7,000 steps per day compared to gain

incentives and lotteries.¹⁴ Wellth employs both concepts in the incentive structure of its programs to maximize patient adherence. When an individual is enrolled into the Wellth program, they start out with a set balance in a virtual account that cannot be accessed until the end of the program, contingent on their adherence to their daily tasks. For each day they miss, they lose up to \$2 of their rewards.

The results from Wellth's approach have been significant. Wellth partnered with a long-term care arm of an New York City (NYC) based insurance company to help its Type 2 Diabetes population improve medication adherence. Eligibility criteria included having a baseline A1c level above 8.0 within the past six months, which served as a proxy for low medication adherence. Over the course of 12 months, there was a 90% level of adherence in this previously non-adherent population. This high level of adherence was accompanied by an average decrease in A1c levels by 1.03 in this population, which supports the claim that medication adherence can improve health outcomes. When working with a high risk ambulatory care clinic in NYC, the Wellth program resulted in an average adherence rate of 88% among that population. Additionally, the Net Promoter Score across all Wellth populations is 92%, showing that members enjoyed the Wellth program and would strongly recommend it to others who might benefit.¹⁵

¹⁴ Patel et al. (2016) "Framing Financial Incentives to Increase Physical Activity Among Overweight and Obese Adults." Ann Intern Med. 164: 385–394.

¹⁵ Based off most recent Wellth data as of August 2018.

Policy Implications

Under the traditional fee-for-service model of reimbursement, laws were established to protect patients and federal healthcare providers and programs. For example, provisions under the Civil Money Penalties (CMP) Law and the federal Anti-Kickback Statute (AKS) prohibit inducements to beneficiaries of federal health care, known as Beneficiary Inducement Prohibitions. Written decades ago, these laws were created prior to mass personalization now possible in health care due to digital health. While these policies were intended to protect patients and providers while improving health outcomes, with the shift towards value-based care and with the rise in digital health, they sometimes hinder progress.

Over the years, there have been exceptions made to this statute to accommodate changes in the industry. The BBA (1993), MMA (2003), and ACA (2010) all included exceptions as to what would be considered a remuneration in the AKS, and just recently in 2016, the Office of the Inspector General issued a Final Rule in which new safe harbors were added under the AKS and revisions were made under the CMP in which the definition of remuneration was modified. Exceptions to the remunerations include:

1. Certain remuneration that poses a low risk of harm and promotes access to care.
2. Coupons, rebates, or other retailer reward programs that meet specified requirements.
3. Certain remuneration to financially needy individuals.¹⁶

¹⁶ Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 42 CFR § 1003.2016.

A major concern with the above-defined exceptions is that they are vague; it quickly becomes unclear what applies to digital health and what does not. Even if a digital health company has an innovative solution to a health care problem, policies such as these Beneficiary Inducement Prohibitions may deter providers, payers, and other healthcare organizations from adopting them out of risk aversion. These exceptions still do not clearly lay out what would be considered "beneficiary inducement." For instance, "certain remuneration that poses a low risk of harm and promotes access to care" is so all-encompassing that it becomes confusing what would be considered an acceptable financial incentive to provide to individuals to improve their access to care. Without clarity on what is acceptable, new innovations face difficulty with implementation out of concern that they might somehow fall under what is not acceptable.

These are hurdles for digital health and for value-based care due to how inextricably linked the two are. Value-based care places an emphasis on quality, and digital health makes it easier for health providers to achieve quality. This is because quality is a complicated thing to measure, but digital health allows providers to monitor patient health outcomes and quality of care in a real time fashion and at a finer level of data granularity than conventional mechanisms. Defined as the use of technology in providing and managing health care, digital health generates the data that is then used to inform measures of quality. In turn, these policies that make it difficult to implement digital health interventions also have a negative impact on value-based care.

Since these regulatory hurdles are not likely to be modified in the near term, in order to succeed as a digital health startup currently, significant amount of regulatory review needs to be done internally. For example, Wellth has hired extensive legal resources to review the CMP and AKS in order to draft a memo summarizing the company's compliance with these

regulations. This upfront investment in terms of time and financial resources is necessary in the current digital health and value-based care landscape, but the ideal in the future is a landscape where regulations are adapted to better align with value-base care initiatives and the adoption of innovative digital health interventions.

Conclusion

As a response to poor health outcomes and rising costs in the U.S., the health care industry is undergoing a shift towards value-based care. With this, there has been growth in digital health as well as changes to health policy. As illustrated by the example of medication adherence, improving outcomes in health care requires multi-faceted and innovative approaches. This kind of innovation is best when it involves perspectives and collaboration from a variety of stakeholders. For instance, one solution to the issue with the Beneficiary Inducement Prohibitions could be to clarify those exceptions in more detail, referencing specifically what would be considered exceptions in digital health and value-based care interventions. Regardless of what the optimal solutions to current and future hurdles may be, in the continued effort towards improving health care value, there is a need for continued communication and partnership between these various sectors.