OUTCOME MEASUREMENT IN
DIRECT PRIMARY CARE

by

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ABSTRACT

The cost of healthcare in the United States compared to the quality of outcomes achieved is disproportionately high. Limitations in access to primary care result in poorer population health, increase in frequency and severity of exacerbations of chronic conditions, higher numbers of emergency room visits, surgical interventions and specialty consultations which increase healthcare expense. A novel model of primary care delivery, Direct Primary Care (DPC), claims anecdotal improvement in cost, access, satisfaction, and clinical outcomes but the results have not been validated in the literature. This project aimed to gain insight to the degree of improvement in access and care outcomes achieved at a direct primary care clinic in Montana. A valid and reliable, patient-reported outcome measure (the Person-Centered Primary Care Measure) was implemented to identify the extent to which this DPC clinic achieved improvements in these areas. The results of this project indicated that efforts in DPC have the capacity to advance population health, improve clinical outcomes and reduce cost through increased access to care. Further evaluation is recommended including repetition of this project in other geographic locales. Others wishing to continue the work may desire to include demographic information such as age, gender and length of practice membership.

Keywords: Direct Primary Care, DPC, primary care access, healthcare cost

CHAPTER ONE

BACKGROUND AND SIGNIFICANCE

Problem Identification

The cost of healthcare in the United States leads the world but does not boast quality outcomes to justify such an investment. Consistent access to quality primary care and preventative services have been demonstrated to decrease health care expenses by reducing emergency room visits, hospitalizations, and specialist referrals, while also improving individual and population health (Ghany et al., 2018). Many Americans remain uninsured or underinsured, having either no insurance or high deductibles and copays. With the expiration of the Affordable Care Act's Individual Mandate in 2019, citizens are now less likely to purchase health insurance and more likely to face bearing sole responsibility for high out-of-pocket costs associated with the traditional medical model, as well as to delay preventative care or routine care for chronic conditions (Eibner, 2018).

An innovative care model gaining traction across the nation proposes a solution. Direct primary care (DPC) clinics tout improved access to preventative and primary care and improved outcomes and population health while simultaneously reducing costs. Direct contracting between patient and provider dramatically reduces expense by eliminating third-party billing and other administrative costs. An individual month-to-month contract between patient and provider is established for a monthly fee between $25-125 (Busch et al., 2020). This membership fee allows for unlimited access to the provider 24 hours/day, 365 days/year and includes basic annual labs and minor office procedures. Other care such as urgent-care services or procedures are billed to the patient at a rate much lower than the industry standard. Because DPC providers negotiate wholesale prices with local lab and radiology providers, patients receive services at deeply discounted prices of up to 95% off retail, for example paying $300 for workups that would otherwise cost nearly $20,000 (Gross, 2018). The care model has demonstrated value to consumers and is gaining popularity nationwide (Rowe et al., 2017) with the number of DPC clinics rising to 1,306 across 48 states and Washington DC, with eight in Montana (DPC Frontier, 2020).

The precedent of quality measurement in healthcare is long-standing, but the rapid growth of the DPC market has not been accompanied by the adoption of consistent objective measures of care quality. Implementation of a standard primary care metric is needed for evaluation of DPC clinic outcomes. Such a metric will aid in quantifying and demonstrating the value to consumers and other stakeholders, as well as determining whether the stated objectives of high-quality, cost-effective, and accessible care are being met.

Background and Significance

The DPC clinic model finds its roots in the traditional medical model pre-dating third-party payment systems but was re-invigorated by the Affordable Care Act (ACA) of 2010 (Affordable Care Act, 2010) and further defined in 2011. Additional legislative attempts have been made to delineate DPC arrangements from insurance products at the state level, and finally, with a federal definition allowing for expansion of services nationwide. Most recently, bipartisan federal legislation has been proposed to allow health savings account (HSA) funds to be used to pay membership fees associated with DPC care, further increasing consumer access and affordability.

S. 128 was re-introduced in the United States Senate in January 2021 (previously introduced in 2017 and 2019) and currently stands under referral to the Committee on Finance. The clarification sought is that under the IRS standards, HSA funds are used in combination with a high-deductible health plan (HDHP). Although many pieces of state and federal legislation clarify that DPC is separate from insurance, the IRS does not view the distinction as such and limits HSA funds to use in one health plan only. S. 128 would seek to clarify the 1986 IRS rule to formally establish DPC as separate from insurance, allowing the use of HSA funds for beneficiary use for services received under the HDHP coverage and DPC membership fees (U.S. Government Publishing Office, n.d.).

The DPC model has gained considerable favor with consumers and providers and has anecdotally demonstrated the ability to reduce cost while improving access and quality (Gross, 2018; Eskew & Klink, 2015; McCorry, 2014; Meyers et al., 2019; Busch et al., 2020). Given the existent positive correlation between access to primary care visits and increased individual and population health (Jerant, 2012), the claims of DPC to enhance access to care warrant validation. Included in the monthly membership fee, patients are entitled to virtually unlimited access to their provider. They may receive as many appointments as necessary to care for their needs, have access to same-day appointments, and can take advantage of alternative methods of care delivery such as telephone and video visits, email, and text messaging, including enhanced after-hours access to their provider. Increased time and access strengthen the patient-provider relationship and is correlated with heightened satisfaction and comprehensiveness in care, which further improve outcomes (Carlasare, 2018).

Such rapid success and effective improvements in care delivery are motivating more providers to turn to the DPC model and open freestanding clinics. As stated previously, there are currently just over 1,300 practices in 48 states and Washington, DC (DPCFrontier, 2020). Of these, 72% have been in operation less than three years, less than 10% have been open four or more years, and 91% of DPC providers would promote the model to others. The average patient panel is 345 patients, and 54% of the clinics started from scratch. Of providers not currently operating DPC practices, 41% would be interested in adopting the model (Martin, 2018)

Despite such healthcare victories, a paucity of evidence in published literature supports these significant DPC outcomes. Limitations include small practice size, short operational duration, and limited electronic medical record (EMR) data reporting capacity (Eskew & Klink, 2015) as well as a lack of comprehensive standardized, valid, and reliable metrics accommodating reduced administrative overhead implicit in the DPC model (Edwards, 2019).

While DPC has been gaining traction in the last decade, regular and standardized outcome evaluations have long been normative in the healthcare industry. Organizations such as the Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare and Medicaid Services (CMS), and the American Association for Family Physicians (AAFP) have developed standardized tools for measuring primary care outcomes. Several measures have been proposed as markers of value and payment in traditional clinic models, but it has been observed that quality measurement remains poorly standardized despite tremendous expense (Burstin et al., 2016) and fails to produce data that accurately captures the quality of primary care. For example, the American Board of Family Medicine's response to CMS's suspension of quality reporting during the COVID-19 pandemic asked, "If current clinical quality measures are not valuable in a pandemic, what does that tell us about what we are measuring?" (Shuemaker, 2020, p. 381). The author further concludes that quality measurement should align tightly with the quadruple aim: to improve health outcomes, patient experience, reduce clinician burnout, and lower costs—metrics that maintain value in all circumstances.

A newly developed, highly reliable, and valid instrument aligning with the quadruple aim has been collaboratively developed by researchers from Virginia Commonwealth University, Case Western Reserve University, and the Larry A. Green Center. Designated the "Person-Centered Primary Care Measure" (PCPCM), this instrument contains 11 items endorsed by CMS and the AAFP as a standardized measure for primary care (Etz et al., 2019). The PCPCM was further endorsed and recommended at the Direct Primary Care Summit by Dr. Angela Edwards in 2019 for use in DPC clinics.

Scope of Problem at Project Site

The project site was a DPC clinic established in 2018, which had grown to employ three staff members, two full-time providers, and one part-time RN. In line with its niche, there was no existing quality improvement program and no data to quantify measures of healthcare access, cost, clinical outcomes, or patient satisfaction. Since opening, informal anecdotal feedback from patients had supported claims for improved performance over traditional models but the data was unverified. There was an EMR in use that did not contain robust reporting features, so a separate method for distributing the PCPCM to respondents was needed. The EMR did support messaging between patients and providers and was routinely used for patient to provider communication such as text messages, email, and weekly newsletter distribution, but the data contained were neither standardized nor easily tracked.

Purpose Statement

The purpose of this project was to initiate a quality reporting program at a DPC clinic by selecting and implementing a validated and standardized quality measure, while utilizing a method that would not add administrative burden to the practice or create additional cost. As a result of implementing an initial quality metric, the practice would gain insight into the extent to which it was achieving its mission and goals and reflecting components of the quadruple aim. An additional anticipated result was the ability to review objective measurements gained by implementing the quality measure to develop improvement plans to guide future practice, continuously monitoring achievement of the clinic's mission.

Congruence with Mission, Goals, Strategic Plan

By implementing its inaugural quality measure, the practice would achieve a meaningful understanding of the degree to which the mission of "High quality, affordable health care for all ages," and vision to "provide care that is individualized, collaborative and high-quality" (Flex Family Health, 2020) have been achieved.

By enacting this change, the practice would adopt a performance evaluation standard consistent with recommendations for primary care clinics nationwide, allowing for benchmarking and comparison with other care models. The ability to compare common outcome measures would allow for adaptation or further evaluation of care delivery and strategic goals. In doing so, the practice would formally demonstrate the achievement of its mission and successful embodiment of the quadruple aim. Such efficacy of care delivery could encourage widespread use of the DPC model on a national level to reduce the cost of healthcare while improving quality and patient and provider satisfaction. This project aimed to enhance the growing body of evidence evaluating the extent to which the DPC model provides answers to the American health care system's cost, quality, and access problems.

CHAPTER TWO

REVIEW OF LITERATURE

This literature review will discuss the growth and current state of DPC practices across the United States, as well as current evidence from the literature regarding the impact of DPC services on population health and the quadruple aim of healthcare. Thus, this project will contribute to the advancement of healthcare quality, value, and safety by proposing standardized quality reporting metrics for DPC clinics. It will provide evidence for the value and efficacy of such clinics in improving population health. The rapid growth of the DPC industry is driven by consumer demand and provider innovation, without routine monitoring of outcomes that is standard in other healthcare settings. To advance practice and demonstrate safety and efficacy, it is essential for DPC practices to routinely evaluate care outcomes.

The number of DPC clinics is increasing exponentially, fueled by consumer demand. In the United States in 2010, fewer than 20 DPC clinics existed. By 2015, that number had increased to 300 clinics, in 2016 to roughly 400 clinics (Luthra, 2016), and in 2020 over 1,300.

The primary limitation in the literature is that very few studies have been conducted demonstrating the outcomes of care delivered by implementing a DPC model. A comprehensive search of peer-reviewed literature using PubMed, CINAHL, and EBSCO revealed fewer than 15 articles addressing DPC outcomes. A librarian-assisted extension of the search including additional terms such as “concierge” and “membership medicine” increased the number of results to 60, although there are notable distinctions between DPC and concierge medicine. The literature will continue to grow as DPC becomes a topic of increasing interest to varied stakeholders.

Drivers of Cost in Healthcare

The majority of literature available addresses cost comparisons between DPC and traditional models and demonstrates that primary drivers of cost in healthcare include emergency department (ED) utilization and hospitalization rates as well as delayed care and exacerbations of chronic conditions (Branning, 2016). Increased access to primary care services reduce cost and improve population health outcomes (Collins et al., 2013; Glass et al., 2017; Lee et al., 2007) by preventing these (unnecessary) costs. Busch et al. (2020) evaluated cost savings of DPC over traditional primary care models on influencing costs for inpatient (-5%), outpatient (-6.3%), emergency department (ED) (+5.6%), physician (-6.8%), overall medical (-12.6%), prescription drug (-15.8%), and total overall healthcare expense (-12.64%). The reduction in cost for primary care services was -35.31%, and DPC clinics boasted a reduction in emergency room utilization of -40.51% in this study. Patients with chronic illnesses demonstrated lower rates of inpatient hospitalization, outpatient hospital use, as well as ED and ambulatory care rates compared to patients not enrolled in an enhanced-access, personalized model such as DPC (Busch et al., 2020).

Gross (2018) provided data demonstrating the DPC cost savings possibilities for three cases without health insurance: the first requiring treatment for thyroid cancer, the second requiring an ER workup for abdominal pain, and the third receiving bloodwork for rheumatoid arthritis. The patient with thyroid cancer was quoted a treatment plan of $100,000 via the traditional model, but instead received full treatment (including surgery, staging, specialty consult, imaging, medications, and six months of full medical care) for just over $10,000 through the DPC. The second patient was billed $19,723.27 of itemized charges in the emergency room for an abdominal pain workup that could have been provided in an equally timely manner for $301.29 from the DPC. The patient with rheumatoid arthritis was quoted $1800 for bloodwork, which she received for less than $100 from the DPC, with the savings from one of the tests alone paying her clinic membership for nearly two and one-half years (Gross, 2018). MRIs that are traditionally billed at $10,000 cost this DPC provider's patient $225, and CT scans were available to the DPC patients for $175 through his contracts with local radiology departments. At the family level, Gross projects a ten-year potential savings of $241,700 over an average employer-sponsored PPO plan based on the Milliman Medical Index (Gross, 2018), with the DPC model providing primary care services for ten years accompanied by an appropriate catastrophic-event wraparound insurance policy at a cost of $39,960 compared to the traditional PPO at $281,660. While the majority of DPC practices are young and small, and therefore lack the data tracking for such outcome measures, simply adopting a payment model such as DPC that does not involve third-party payers is estimated to reduce over 40% of overhead costs.

Further examples of reduction in overhead and administrative costs yielding tremendous savings for DPC patients were noted by another provider. Through his DPC clinic's directly negotiated laboratory and diagnostic rates, he is able to provide prostate cancer screening for $5 compared to $175 from the same lab for typical provider billing arrangements. Additionally, a mammogram costs $80 rather than the typical $350, and colonoscopies are $400 rather than the typical $2000 (Brekke, 2016). The savings obtained by reducing administrative overhead and third-party billing services in DPC are passed along to the healthcare consumer.

Improved Clinical Access, Outcomes, and Satisfaction

Few studies have been conducted to demonstrate improvement in access to care with the DPC model, though one did demonstrate a reduction in racial disparities in care among Hispanics with hypertension, hyperlipidemia, and diabetes (Busch et al., 2020) after implementing the DPC model. The model incorporates 24-hour, 7 days per week access for enrolled practice members as a standard benefit, which is beyond the experience of patients in traditional primary care practices (Gross, 2019; Rowe et al., 2017). Increased access to primary care services has been demonstrated to reduce mortality rates (Jerant et al., 2012), use of emergency services, hospitalizations, hospital readmissions, surgeries, and specialist visits (Brekke, 2016), all of which are significant drivers of cost in healthcare. Access to after-hours primary care services has been associated with reduced cost of care and non-emergent use of the ED (Villani & Mortensen, 2013). The DPC model is unique from other primary care models in its standard provision of 24/7 access directly to the patient's provider at no additional cost, as part of the practice membership fee, and would therefore be expected to increase access to primary care services. The model also provides for each clinician to carry a smaller panel size, 600 versus the 2,500 in traditional clinic models, which allows scheduling flexibility and near-constant availability of same and next-day appointments (Brekke, 2016). DPC-associated improvements in access and frequency of primary care utilization reduce the need for higher-cost services such as ED visits, hospitalizations, specialists, surgical procedures, and other tests by over 50% (Eskew & Klink, 2015).

In one evaluation of pilot programs by the Harvard Interfaculty Program for Health Systems Improvement, Harvard Medical School, DPC quality indicator outcomes were improved over care received with the traditional model, and patients reported increased satisfaction as well as reduced cost of care (Fernandopulle, 2013, as cited in Carlson, 2015). Patients with poorly controlled blood pressure (SBP > 160) improved by an average of 42 points over six months, and poorly controlled blood glucose (A1C > 9) improved by 2.38 points. There were reduced health disparities by race, with Hispanic patients entering the practice with more poorly controlled SBP, LDL, and A1C values than controls, which were fully reversed within six months. Physical and mental function scores on a standardized measure improved 14.8 and 16.1% compared to baseline after six months at the clinic (Fernandopulle, 2013). Patients reported over 55% fewer missed workdays due to illness compared to before entering the practice, and net medical spending was reduced by 20%, commensurate with a 41% drop in inpatient admissions and 48% decrease in ER visits (Fernandopulle, 2013). These quantifiable improvements in patient outcomes can be attributed to the patient and provider rapport and ease of accessibility to care.

Summary

To demonstrate the effectiveness of the DPC model and ensure transparency and accountability within the existing system, DPC clinics are obligated to align with the existing standard of reporting outcome data. Claims that the DPC model serves as an improved form of healthcare delivery require demonstration of objective data over time and in different geographical regions throughout the nation. The DPC model has been demonstrated as effective and financially sustainable (Wu et al., 2010; Spangler, 2020) and found to offer improved clinical outcomes (Fernandopulle, 2013; Carlson, 2015; AHRQ, 2012; McCorry, 2014), improved patient and clinician satisfaction (McCorry, 2014; Huff, 2015), improved access to care over traditional models (Busch et al., 2020; Gross, 2019), and significant cost savings

(Gross, 2018; Eskew & Klink, 2015; McCorry, 2014; Meyers et al., 2019; Busch et al., 2020). Evidence and practice demonstrate the industry standard surrounding quality reporting and improvement efforts in healthcare, especially related to clinical outcome quality, access, cost, and patient satisfaction (AHRQ 2020; IHI, 2020). Though public reporting data is currently unavailable, and a paucity of peer-reviewed studies have been conducted to objectively demonstrate the value of DPC, the literature provides initial evidence to support further development of quality improvement programs in the DPC setting.

A standardized system for outcome reporting in DPC clinics does not yet exist; however, a standardized measure has been recommended. This measure will allow outcome reporting to demonstrate the value of care and also help address the needs of the project site. The outcome information will contribute objective and standardized data to further evidence the health system improvements delivered by DPC clinics.

CHAPTER THREE

SETTING AND METHODS

QI Framework: Model for Improvement

The Model for Improvement (Langley et al., 2009) with cycles of Plan, Do, Study, Act (PDSA) was selected as the best fit for this project. PDSA was designed by Edward Deming for use in complex and rapidly changing systems, is recognized and widely used in healthcare, and provides for multiple iterations. The model is an excellent fit for the project site because it is convenient, simple, and implementation requires minimal additional cost or administrative overhead. PDSA cycles are ideal for small-scale tests of change, which may expand to additional clinic sites or locations. At the end of Cycle 1, the change may be implemented or adopted, dropped or abandoned, modified or adapted, increased in scope or expanded, or tested under new conditions (Langley et al., 2009). After the initial test of change, if the evaluation determines the intervention was a successful improvement, the PDSA cycle may be repeated at additional DPC clinics while a second PDSA cycle and small-scale test of change is run sequentially at the original site to initiate further improvements based on results from Cycle 1. In this manner, improvements spread efficiently and without the risk associated with sweeping changes. It has been demonstrated that small changes increase the success of sustained improvement over time (Langley, 2009). Keeping risk, cost, and administrative burdens low aligns well with the DPC model and will yield data that is necessary industry-wide to substantiate the anecdotal improvements these clinics yield.

Agency Description

The project was implemented at a DPC clinic in Montana that has been operational for 18 months and is staffed by one nurse practitioner, one physician, and one registered nurse. The target population for the project was DPC clinic members over age 18 years with at least one month of care and one provider visit.

Stakeholders

This project yielded data supporting the transformation of healthcare, and as such, potentially affecting a broad swath of society. Stakeholders include the clinic and providers/staff; patients in the community; community members who are not yet patients; uninsured individuals; other clinics in the community; other DPC clinics within the state and nationwide; policymakers and legislators; state, local, and national governments; insurance companies; the centers for Medicare and Medicaid (CMS); and DPC advocacy groups.

Facilitators and Barriers to Implementation

A SWOT analysis diagram has been included for reference (Appendix B) detailing facilitators and barriers to implementation. The clinical site was fortunate to have been founded by a doctoral-prepared nurse practitioner who was experienced and highly capable of designing and implementing QI projects and provided strong support and participation. Lack of leadership support and engagement are two of the top four reasons projects fail (Donnelly, 2017), making such buy-in and enthusiasm a great benefit. Further strengths included the presence of specific and well-defined aims, the use of Specific, Measurable, Attainable, Relevant, Time-bound

(SMART) goals to avoid scope creep or loss of focus, the use of a defined timeframe for measurement, and simplicity of intervention to add little administrative or cost burden to the clinic's workflow or bottom line. The clinical site embodied a culture of learning, support, and quality; was passionate about quality outcomes and satisfied patients; and eager to have validated metrics inform care. Patients at the clinic were dedicated, passionate about direct primary care, and desired to broaden their understanding of the value DPC offers to all healthcare consumers.

Barriers to successful implementation included lack of available administrative time at the clinical site for project implementation, minimal funding, and potential for patient-level impedances resulting in low response rate. To mitigate these barriers, the design process incorporated interventions that would ameliorate the need for supplemental time, funding, or complexity.

Project Design

The purpose of this quality improvement project was to address the gap in the literature and demonstrate objective achievement of improved outcomes of access, comprehensiveness, and patient satisfaction in the DPC population using a standardized, reliable, and valid nationally recognized measure (see implementation table in Appendix C). Within the overarching purpose, this project had several aims. The primary and short-term objective was to use automation to deliver results of a nationally recognized patient-level quality outcomes survey, which then served as initial data for the clinic's internal quality evaluation. SMART objectives are identified for each aim. For Aim I, DPC clinic patients (S) would achieve a response rate greater than 15% (M), a goal that was possible with available resources (A), based on similar methodologies used in other practice settings (R) over 12 weeks (T). Of note, the originally designed timeline was subsequently adjusted to accommodate the requirements of the graduate school and shortened to three weeks.

A secondary aim of this project was to provide access to information (survey data) that would allow the DPC clinic to measure the extent to which the services aligned with their mission, vision, and values. Eleven outcome measures represented in Appendix D (S) from the PCPCM were scored (M) on a Likert scale. Measurement was achieved (A) with a nationally utilized, valid, and reliable third-party instrument endorsed by the AAFP, DPC providers, and CMS. Collation of such data aligned with national standards for quality reporting in healthcare (R) and could be completed within the original 12 or modified three-week implementation timeframe.

The final aim of this project was to substantiate the DPC model as an efficacious and preferred care delivery model by demonstrating improvements in cost, outcomes, access, and patient satisfaction. The results of this project intended to provide the practice an opportunity to listen to customers, further tailor primary care to meet the needs of the consumer, and prepare future healthcare consumers to use the DPC model. This differentiation of the DPC model proposed to help attract consumers of other primary care models to achieve desired health outcomes while receiving a higher-value service at a lower cost. Following the implementation of the survey at the local DPC clinic, the project would be disseminated and expanded as a proposed method of standardization for quality metric reporting in other DPC clinics throughout the state and/or nation by open-access availability of to-be-published results as well as presentations at DPC meetings and conferences.

Project Methods

As a new model of autonomous care delivery designed to connect consumers directly to providers, DPC clinics have not yet adopted standardized reporting measures for quality in clinical outcomes, affordability, access, or patient/provider satisfaction (Eskew & Klink, 2015; Edwards, 2019; Burstin et al., 2016), but the PCPCM (Etz, 2019) does address several of these factors. Thus, this DNP project uses the PCPCM for assessment/evaluation.

The PCPCM, developed by the Virginia Commonwealth University's Larry A. Green Center (Etz et al., 2019), addresses eleven quality domains including access and satisfaction. The PCPCM's eleven outcome measures (each representing a quality domain of primary care) were scored by a four-point Likert scale within the three-week survey period. The eleven quality domains were accessibility, continuity, integration, coordination, comprehensiveness, relationship, advocacy, family context, community context, goal-oriented care, and health promotion. The four-point Likert scale measurements were "definitely," "mostly," "somewhat," and "not at all."

Its simplicity, scope, and accuracy have been attested to by CMS, the AAFP, and DPC advocates (Edwards, 2019). The measure boasts a factor analysis of >0.6, Cronbach's alpha of 0.95, and a Rasch item fit score of 0.62-1.44, consists of 11 measures and takes less than 5 minutes to complete, all evidencing its value and fit for the task of quality measurement in DPC clinics. The PCPCM was uniquely developed by a diverse group of stakeholders with competing interests who collectively answered the question, "What defines good care?" Areas of overlap and agreement were used to develop the 11 items comprising the measure. Representatives who developed the tool were patients, practicing nurses, social workers, family medicine providers, insurers, policy makers, family medicine and pediatric providers, occupational therapists, employers, international primary care leaders, actuaries, and employers (Etz et al, 2019).

During the original reliability and validity testing for the PCPCM, the SurveyMonkey (SM) platform was utilized for the delivery of the survey to primary care patients. SM has demonstrated equitable results to data retrieved from major market research tools with additional benefits of a much faster turnaround time, zero cost, and inbuilt analytics (Bentley et al., 2019). Keeping overhead costs low and minimizing administrative burden are core tenants of the DPC movement, so this method was likewise selected for delivery of the PCPCM to DPC patients in this project. SM is ISO27001 certified, does not use information collected from the survey in any way, and responses are sent over a secure, encrypted connection (SurveyMonkey, 2020).

The Institute for Health Care Improvement (IHI)'s planning form was utilized to document the project's progress and modified to represent the adjusted timelines (Appendix C). In the initial PDSA cycle represented by this project, to achieve the first aim, 11 items from the PCPCM were programmed into SM format and distributed electronically to the full panel of approximately 400 adult patients at the DPC clinic. After 7 days, a second email with the survey was sent to maximize the response rate, and a final attempt was delivered to all intended respondents the following week. Results of the survey were automated and graphed for analysis by the SM software. At the end of each week, the implementation team (project site staff and this author) met to evaluate the response rate and results of quality data and determined to adopt and continue rather than augment or abandon the survey method. The DPC clinic staff used the survey results to evaluate the attainment of their mission to the community and to plan desired improvements. The two lowest-scoring items from the PCPCM were identified for further improvement efforts, which were beyond the scope of this project but may be continued at the clinical site's discretion during future projects. Repeated iterations may be conducted on an ongoing, monthly basis as new members join the practice to yield additional quality data and inform priorities for ongoing improvement efforts.

Human Subjects Protection

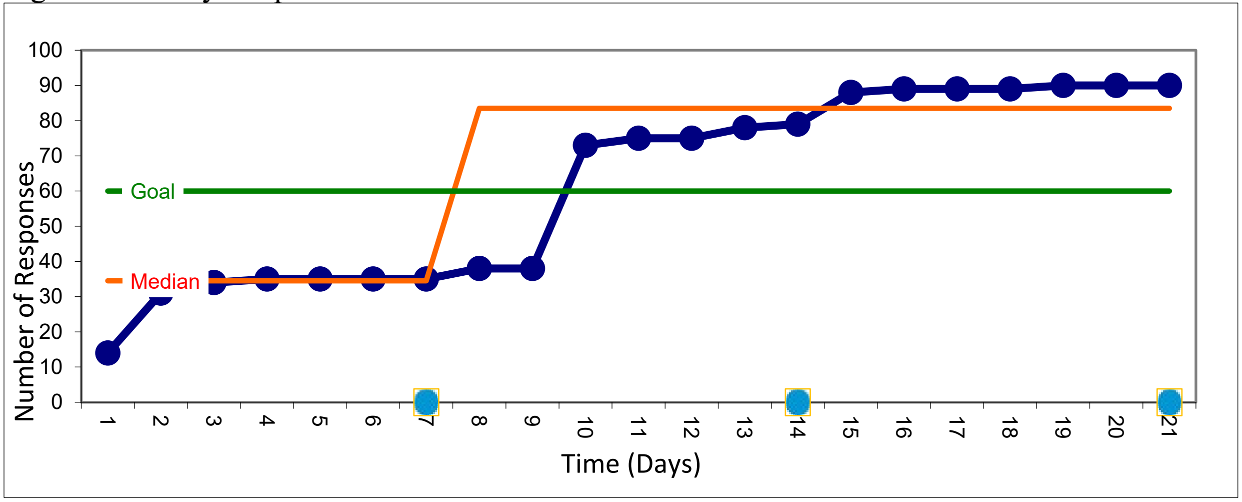
This project received the designation of exempt status for IRB review under the standards of research at Montana State University (Appendix E). The survey procedures used for this project collected no identifiable information from respondents; disclosure of results outside of the project would not place subjects at risk of criminal or civil liability, be damaging to financial standing, employability, or reputation. The project included the collection and study of existing data and records, which were recorded in a manner in which the subjects could not be identified. The project was approved by the DNP committee to study the public benefit of DPC services.

CHAPTER FOUR

RESULTS

This project was developed to demonstrate quality outcomes in a direct primary care setting using a professionally recognized, valid, and reliable standardized metric. The first aim was to use automation to deliver results of a professionally recognized patient-level quality outcomes survey, the PCPCM, to collect outcome quality data for the clinic. SurveyMonkey (SM) was used to deliver an electronic link to the PCPCM to 400 enrolled DPC members (patients) of the clinic. Figure 1 demonstrates the overall survey response rate of 22.5% (n = 90) achieved over three weeks.

Figure 1. Survey Response Rate



The second aim of this project was to provide access to information (survey-reported outcome measures), which allowed the clinic to evaluate the degree to which services provided aligned with its values of delivering high-quality, individualized care.

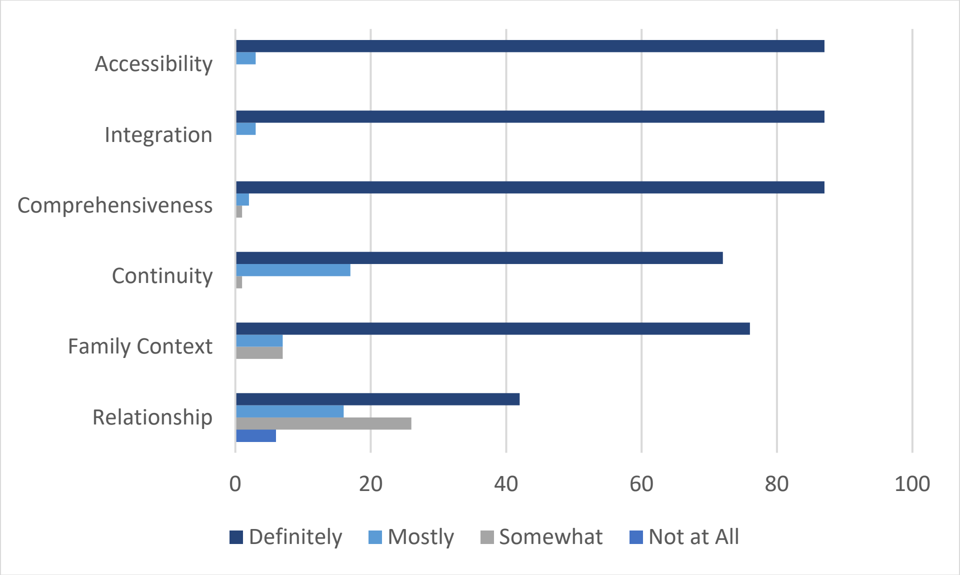
Table 1. Survey Results by Measure and Quality Domain

Q	Domain	Question	Definitely		Mostly		Somewhat		Not at all	
			%	n	%	n	%	n	%	n
1	Accessibility	The practice makes it easy for me to get care	96.67	87	3.33	3	0	0	0	0
2	Continuity	This practice is able to provide most of my care	80	72	18.89	17	1.11	1	0	0
3	Integration	In caring for me, my doctor considers all factors that affect my health	96.67	87	3.33	3	0	0	0	0
4	Coordination	My practice coordinates the care I get from multiple places	80	72	18.89	17	1.11	1	0	0
5	Comprehensiveness	The doctor or practice knows me as a person	96.67	87	2.22	2	1.11	1	0	0
6	Relationship	My doctor and I have gone through a lot together	46.67	42	17.78	16	28.89	26	6.67	6
7	Advocacy	My doctor or practice stands up for me	91.11	82	5.56	5	3.33	3	0	0
8	Family Context	The care I get takes into account knowledge of my family	84.44	76	7.78	7	7.78	7	0	0
9	Community Context	The care I get in this practice is informed by knowledge of my community	84.44	76	11.11	10	4.44	4	0	0
10	Goal-oriented care	Over time, this practice helps me to meet my goals	87.78	79	11.11	10	1.11	1	0	0
11	Health Promotion	Over time, my practice helps me stay healthy	94.44	85	5.56	5	0	0	0	0

Survey results for each assessed measure and quality domain are provided in Tables 1 and 2, with results for the three highest- and lowest-scoring categories summarized in the following section and represented in Figure 2. The three highest performing categories were accessibility, integration, and comprehensiveness. The domain of accessibility was measured by the statement "The practice makes it easy for me to get care," and was the strongest-performing category. 96.67% (n = 87) of patients answered "definitely," 3.33% (n = 3) answered "mostly," zero answered "somewhat" and "not at all." The domain of integration was the second-highest performing, measured by the statement, "In caring for me, my doctor considers all factors that affect my health." 96.67% (n = 87) of patients answered "definitely," 3.33% (n = 3) answered "mostly," zero answered "somewhat" and "not at all." The domain of comprehensiveness, the third-highest scoring domain, was measured by the statement, "The doctor or practice knows me as a person." 96.67% (n = 87) of patients answered "definitely," 2.22% (n = 2) answered "mostly," 1.11% (n = 1) answered "somewhat," and zero answered "not at all."

The three lowest-performing categories were continuity, family context, and relationship. The domain of continuity was measured by the statement, "This practice is able to provide most of my care." 80% (n = 72) of patients answered "definitely," 18.89% (n = 17) answered "mostly," 1.11% (n = 1) answered "somewhat," and zero answered "not at all. "The domain of family context was measured by the statement, "The care I get takes into account knowledge of my family." 84.44% (n = 76) of patients answered "definitely," 7.78% (n = 7) answered "mostly," 7.78% (n = 7) answered "somewhat," and zero answered "not at all." The domain of relationship was measured by the statement "My doctor and I have gone through a lot together." 46.67% (n = 42) of patients answered "definitely," 17.78% (n = 16) answered "mostly," 28.89% (n = 26) answered "somewhat," and 6.67% (n = 6) answered "not at all."

Figure 2. Highest vs. Lowest Scoring PCPCM Items



Areas of strength and weakness were further categorized and ordered by calculating composite scores for each domain within the survey scale (see Table 2). The calculation for the composite score was a mean value of the total number of responses for each Likert tier, multiplied by an assigned factor for a maximum possible of 360 per domain. Each “definitely” score was multiplied by a factor of 4, each “mostly” score by a factor of 3, each “somewhat” score by a factor of 2, and each “not at all” by a factor of 1, and the sum total provided the composite score. Two domains were identified as areas of greatest strength: accessibility (“The practice makes it easy for me to get care,” composite score of 357) and integration (“In caring for me, my doctor considers all factors that affect my health,” composite score of 357). Two domains were identified as areas of greatest weakness: family context (“The care I get takes into account knowledge of my family,” composite score of 339) and relationship (“My doctor and I have gone through a lot together,” composite score of 234).

Table 2. Survey Results by Highest Scoring Domain

Item Average Score	**Domain**	**Measure**	**Q**
357	Accessibility	The practice makes it easy for me to get care	1
357	Integration	In caring for me, my doctor considers all factors that affect my health	3
356	Comprehensiveness	The doctor or practice knows me as a person	5
355	Health promotion	Over time, my practice helps me stay healthy	11
349	Advocacy	My doctor or practice stands up for me	7
348	Goal-oriented care	Over time, this practice helps me to meet my goals	10
342	Community context	The care I get in this practice is informed by knowledge of my community	9
341	Coordination	My practice coordinates the care I get from multiple places	4
341	Continuity	This practice is able to provide most of my care	2
339	Family context	The care I get takes into account knowledge of my family	8
234	Relationship	My doctor and I have gone through a lot together	6

The final aim of this project was to validate claims of the DPC model as a preferred delivery method for primary care services by demonstrating the achievement of high-quality patient care outcomes. To this end, the summary of Likert scale results for all items are as follows: 85.4% (n = 845) of responses indicated quality measures were “definitely met,” at the clinical site. 9.6% (n = 95) of responses indicated quality measures were “mostly met,” 4.4% (n = 44) were “somewhat met,” and less than one percent (0.6%; n = 6) of responses indicated an unmet quality measure at the clinical site.

In summary, automated delivery of the PCPCM using SM software effectively achieved an above-average response rate of 22.5% (n = 90) compared to the goal of 15% set forth in the first project aim. Use of the PCPCM further identified excellent patient-level outcomes at the direct primary care clinic, with 95% of assessed measures and quality domains scoring “mostly” or “definitely” met. The survey results were used by the clinic to confirm care provided aligned with its values of delivering high-quality, individualized care. The findings supported the second project aim to provide quantifiable data measuring the extent the DPC services aligned with their mission, vision, and values. The results further confirm and differentiate the DPC model as an effective delivery system for high-quality primary care and provide a contribution of such to peer-reviewed literature.

CHAPTER FIVE

DISCUSSION

Direct primary care is a rapidly expanding segment of healthcare that intends to provide high-quality, accessible care at significant cost savings to the consumer and healthcare system. The number of independent direct primary care clinics is increasing; however, peer-reviewed literature demonstrates a paucity of data related to quality outcomes, and no standardized method of quality reporting was found to be utilized across DPC clinics. This project employed a simple, cost-effective, valid and reliable measure to evaluate quality outcomes at a local DPC clinic.

Discussion of Results

The results of this project, particularly the highest two outcome measures (accessibility and integration), add evidence to support the findings of Carlasare (2018), who demonstrated that increased access correlates with comprehensiveness and improves health outcomes. These results also continue to elucidate the reasons behind the growing DPC trend, with enhanced-access and quality outcomes, validating claims previously made by Gross (2018), Eskew & Klink (2015), McCorry (2014), Meyers et al., (2019) and Busch et al. (2020). The project was well-aligned with the current recommendation from Shuemaker (2020) to maintain value in quality measurement by focusing on measurables that carry meaning relative to the quadruple aim: those which improve health outcomes, patient experience, reduce clinician burnout, and lower costs--metrics that maintain value in all circumstances.

Accessibility to primary care bears tremendous effects on population health outcomes (Jerant, 2012 and Ghany, 2018). Accessibility was measured in this project by the statement

“The practice makes it easy for me to get care” and was the strongest-performing category on the PCPCM, with a mean score of 357 from a total possible 360. 96.67% (n = 87) of patients answered “definitely,” 3.33% (n = 3) answered “mostly.” One benefit unique to DPC that may have resulted in this strong response includes direct access to the provider 24 hours/day, 365 days/week via phone, email, telehealth, in-office, or home visit. Because DPC practices limit panel size to around 600 patients per provider, same-day appointments are available. The design of a DPC practice is to prioritize accessibility, thereby improving satisfaction and outcomes, so the high item score was anticipated. Notably, the DPC model from its inception included telehealth access, with standard memberships including 24/7 video, email, phone, or text access to providers. When the COVID-19 pandemic began, this feature of DPC allowed patient access to care to continue uninterrupted, while traditional clinics had to shift technology to adopt and implement these less traditional methods of care delivery.

The domain of integration achieved the same mean score of 357, measured by the statement, “In caring for me, my doctor considers all factors that affect my health.” 96.67% (n = 87) of patients answered “definitely,” and 3.33% (n = 3) answered “mostly.” This strong result may be due to another favorable consequence of limited panel size in DPC: longer per-patient visits, which allow for thorough health and social histories, and deeper discussion of factors contributing to health and disease.

The two lowest-performing categories were family context and relationship. The domain of family context was measured by the statement, “The care I get takes into account knowledge of my family.” 84.44% (n = 76) of patients answered “definitely,” 7.78% (n = 7) answered “mostly,” and 7.78% (n = 7) answered “somewhat.” Although it was a lower-scoring item on the survey, the mean score for this domain was still exceptionally high at 339 of a possible 360. Because the design of DPC lends itself to knowing the patient in the context of his or her personal milieu, the lower score was surprising, and this item can be included in future quality improvement efforts at the practice for targeted improvement.

Patient-provider relationship is central to the DPC design, so the low number would come as a surprise without consideration of patient and practice-specific underlying factors. The mean score of 234 may reflect characteristics such as short operational duration of the practice (24 months), a recent increase in new memberships, and the hiring of a new provider to the practice within 6 months of the survey. As such, patients may have been less likely to agree that “my doctor and I have been through a lot together.” Within the modified timeframe for the project, the methods were also adjusted to send the survey to the entire patient panel rather than those who had been with the clinic for a longer period, and some may not have had a clinic visit. Relationship was the lowest-scoring item; 46.67% (n = 42) of patients answered “definitely,” 17.78% (n = 16) answered “mostly,” 28.89% (n = 26) answered “somewhat,” and 6.67% (n = 6) answered “not at all.” Future surveys could include data collection regarding how long the respondent had been a member of the DPC practice, to determine if the short duration of the relationship indeed factored into the lower-than-expected score.

Challenges to Implementation

Reduced implementation time was a significant challenge to the project. Rather than the initial 12-week data collection period with PDSA cycles, the project was condensed into a three-week data collection period. The adjustment made to accommodate the time constraint was to survey all DPC patients, rather than limiting the panel to patients with memberships longer than one month, and as mentioned above, may have had some impact on responses, particularly the domain of relationship.

Limitations, Strengths, and Contributions

Limitations include the small total population of 400 and sample size of 90, which is limited to only one DPC practice and yielded a 22.5% survey response rate. However, the average survey response rate is 10-15% (PeoplePulse, 2018), and while small in number, the dedicated sample did achieve a higher-than-expected rate of return and participation. The potential for non-response bias is a concern for surveys, and the current project is not an exception. Individuals who did not respond may have feedback that differs from what was reported by those who did respond. Considerations to improve response rate may be including additional time for future projects or expanding methods of survey collection to include options for completion in-office at time of service via a dedicated tablet or laptop, staff training to ask patients to complete surveys at the time of appointment, or sharing the survey via members-only social media. An additional limitation is that the PCPCM does not include criteria for capturing cost savings, which is a crucial element of the quadruple aim as well as a factor affecting access to care. However, cost data for comparison is recorded by the practice and available for inclusion in future studies. Demographic data were not collected as part of the survey but could be included in future studies to determine the effects of age or sex on survey response.

Strengths of this project were many. The project site's providers are extremely experienced, knowledgeable, and highly committed to their patients. The clinic's leadership was extremely supportive of the project, with the owner also holding a DNP degree with previous QI project experience; the RN at the clinic also had previous QI experience. (The project received guidance and support from an extremely committed and experienced, interprofessional group of research and academic advisors from Montana State University's DNP program, and the project committee was chaired by a PhD-RN.) A low-cost, reliable survey response tool used to develop the original PCPCM was available for use in this project, allowing for a similar methodology as used in the existing literature. The automated survey software did not add administrative burden or cost. As detailed in the feasibility section, this method created cost savings compared to traditional survey mailing methods and reduced administrative time necessary for manually collating results. The results successfully allowed the practice to determine that their care and services aligned with their mission statement. DPC clinics had boasted anecdotal success in areas measured by the PCPCM, so although no survey results from previous use of this measure in DPC were available, there was an anticipation of favorable results and feasibility. The clinic boasts a dedicated panel of patients, which contributed to the survey response rate (22.5%) surpassing the average external survey response rate (15%).

Recommendations for Future Work

The PCPCM is validated for use in primary care settings and would be applicable and valuable in traditional as well as direct primary care settings due to its simplicity, affordability, ease of use, and wide range of meaningful outcomes evaluated. To further demonstrate and quantify the value of DPC, the PCPCM could be applied similarly in a future comparison study. As demonstrated in the review of literature, significant cost savings have been achieved when the DPC model is used for primary care, and the frequency of high-cost services such as emergency room visits and hospitalizations are inversely related to the amount of access an individual has to their primary care provider (Ghany et al., 2018). Because the DPC model increases access to primary care, ongoing cost reduction can be anticipated. Continuous evaluation of cost savings with comparative studies (which could be done via retrospective chart review) between DPC monthly charges vs. comparison groups in traditional studies would also be beneficial to demonstrate cost savings and could be an area of future study interest.

Doctor of Nursing Practice (DNP) Essentials

DNP essentials encompassed by this project include I. scientific underpinnings for practice, II. systems thinking/healthcare organizations, III. clinical scholarship and evidence-based practice, IV. information systems/technology, V. healthcare policy for advocacy in healthcare, VI. interprofessional collaboration, and VII. clinical prevention and population health.

Essential I, scientific underpinnings of practice, comprises the elements of analytical knowledge and organizational knowledge. Analytical knowledge involves collecting and evaluating evidence and data to make judgments, "using thought processes to make connections and derive meaning" (Zaccagnini & White, 2017). Organizational knowledge involves understanding any one organization as part of an entire system in motion; with dynamic relationships among many moving parts; in this project the relationships between DPC, traditional clinics, collaborative healthcare services (lab, x-ray, ultrasound, pharmacy services); and the larger healthcare system are examples. Organizational knowledge emerged regarding gaps and disparities in the health system, and the project further validated a novel care delivery system with potential opportunities for future outcome improvements, access improvements, and cost savings in healthcare.

Essential II, systems thinking, “emphasizes ongoing improvement of health outcomes,” and indicates that “nurses should be prepared with sophisticated expertise in assessing organizations, identifying systems issues, and facilitating organization-wide changes in practice delivery,” (Zaccagnini & White, 2017), which were objectives completed in this project. The project also utilized clinical scholarship and evidence-based practice (DNP Essential III) in utilizing current peer-reviewed literature to develop, plan, design, and complete the project as well as drew conclusions and recommendations for further advancements. DNP Essential IV, information systems and technology, was implemented when introducing the SM software with utilization in delivery of the patient survey and analysis of results.

The project also serves to inform healthcare policy and advocacy, as issues related to DPC are being discussed during the 2021 legislature session. Montana Senate Bill 101 was brought forth in January 2021 (Trevellyan, 2021) to expand access to affordable healthcare by differentiating DPC from insurance in state law and offering DPC clinics additional legal protections, although DPC has less formally been set apart from insurance by state advisory memo since 2017. The perspective and outcome data achieved during this project help further clarify the value of DPC services to the consumer and inform such policy decisions.

Finally, interprofessional collaboration (Essential VI) for improving patient and population health were employed; thanks to committee members from diverse nursing backgrounds as well as a variety of stakeholders, this project was successful in demonstrating implementation of a quality improvement program at a local DPC clinic and obtaining measurable results to demonstrate the value of services provided. Carlasare (2018) demonstrated that increased healthcare access led to improved health outcomes, and this quality improvement project revealed that the greatest strength of DPC is increased access to primary care services in southeastern Montana for patients from a surrounding three-state area. It is reasonable to suggest that additional, further studies may reveal a beneficial association between DPC and preventative efforts leading to improved national/population health. The project was an early indication that efforts toward demonstrating that prevention and population health are achievable in this clinic setting (DNP essential VII)

Feasibility and Sustainability

This project was conducted in a sustainable manner utilizing automated survey delivery and results-analyzing software. The cost of software subscription for one year was $276, paid by the student. By comparison, if paper mailings had been used, 400 surveys x $0.55 = $220, x2 (letter and return envelope) = $440, x 3 rounds of surveys = $1320. Administrative time was zero, and the team collaborated over a one-hour, previously existing lunch-and-learn slot to evaluate results once weekly for the three weeks. The same survey link can be reused for the entire 365-day subscription period without further cost, and results can be sorted and further analyzed and compared within that timeframe. The survey may be distributed via email, any other electronic media, in-office at point of contact within the year or renewed indefinitely, so long as the practice/clinic? desires to do so.

Summary of Project Outcomes

Aims of this project were to use automation to deliver results of a standardized and validated quality outcome measurement tool to provide data to use in creating a quality improvement program at a DPC clinic. A secondary aim was to provide access to survey data allowing the DPC clinic to measure the extent to which the services provided align with the clinic's mission, vision, and values. The final aim of the project was to demonstrate value substantiating direct primary care as a preferred model among other primary care services by observing outcomes including access and satisfaction.

In conclusion, the administration of the PCPCM in this project demonstrated that the novel delivery system of direct primary care effectively achieves quality outcomes. Measurement of the first aim, using automation to deliver survey results, was to achieve a response rate of greater than 15%, which was surpassed when the response rate of 22.5% was achieved. Measurement of the second aim was achieved by receiving Likert scale responses to each of 11 questions representing quality outcome domains. The clinic's values are the provision of high-quality, affordable health care for all ages that is collaborative and individualized. Survey responses indicated areas of strength and needed improvement for these goals. The final aim combined the previous two by listening to healthcare consumers and demonstrating the value of DPC in achieving a high degree of accessibility, satisfaction, and quality outcomes at an affordable cost.

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APPENDICES

APPENDIX A

EVIDENCE REVIEW TABLE

Citation: (i.e., author(s), date of publication, & title)	Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses])
Carlasare, L. E. (2018). Defining the Place of Direct Primary Care in a Value-Based Care System [; Review]. *WMJ : official publication of the State Medical Society of Wisconsin, 117*(3), 106-110. <Go to ISI>://MEDLINE:30193018	None	Literature Review	Does not reveal number of articles reviewed	Prevalence of practices Average fees Contributors to physician burnout leading to DPC model Ethical and policy considerations associated with direct primary care	No explicit mention of inclusion/exclusion criteria Information about various retainer models for medical care, focusing on "direct primary care" "concierge" Literature on effects of administrative and regulatory burdens on physicians	Report; no structure or flow diagram provided	82% physicians report some degree of burnout Practice model is still relatively rare DPC practices reduce administrative burden, provide more time with patients, There is a need for further research on the DPC model	Does not include key information as to how literature was selected for review, specify search terms or inclusion/exclusion criteria
Cole, E. S. (2018, 2018). Direct Primary Care: Applying Theory to Potential Changes in Delivery and Outcomes. *Journal of the American Board of Family Medicine : JABFM, 31*(4), 605-611. https://doi.org/10.3122/jabfm.2018.04.170214	Donabedian's "Structure-Process-Outcome)	Descriptive Study	The model of 723 Direct primary care (DPC) practices	IV: Care Setting (DPC or Traditional Primary Care Clinc Model) DV: Structure, process, outcome	Variables were not directly measured, as a "Dirth of data" currently exists IV: nominal = Care setting DV: Projected by existing studies correlating outcomes related to each variable (Ex: frequency of contact, etc)	None	Based on existing literature, expectations of the DPC's impact include increased continuity and accessibility, improved care processes, first contact care and longitudinality as well as patient satisfaction, lower hospitalization rates and cost.	Level VI (Descriptive Study) No definitions were given to clarify dependent variables inclusion criteria, leaving wide interpretive space.
Eskew, P. M., & Klink, K. (2015). Direct Primary Care: Practice Distribution and Cost Across the Nation. *Journal of the American Board of Family Medicine : JABFM, 28*(6), 793-801.	n/a	Literature review	N = 141 practices; 273 locations; 39 states	Number of physicians Number of non-physicians Fees Whether practice was pure or hybrid DPC model Did practice opt out of Medicare	Nominal: Medicare status, pure or hybrid DPC Model Interval: number of physicians, non-physicians, fees	None (reported directly)	DPC patients have fewer ER visits, radiology testing, specialty visits, and surgical services vs. traditional practice Costs of care are reduced when access to quality primary care is improved	Review of literature Variety of practice types and sizes; lack of standardized objective quality data

https://doi.org/10.3122/jabfm.2015.06.140337								
Fernandopulle, R. (2013). Learning to fly: building de novo medical home practices to improve experience, outcomes, and affordability. *J Ambul Care Manage, 36*(2), 121-125. https://doi.org/10.1097/JAC.0b013e3182871fac	n/a	Pre-post Case Report of program in use at Harvard Medical School	N = 9 practices across the country Boeing Company Virginia Mason Everett Clinic Valley Medical System Seattle AtlantiCare UniteHere Fund Las Vegas Culinary Trust Dartmouth College Freelancers Insurance Company Brooklyn NY	Clinical outcomes: SBP and A1C control Racial disparities in quality markers of SBP and A1C Functional Status Absenteeism Cost of total healthcare spending	Functional status: 12-item Short Form Health Survey	None (reported directly)	Pilot programs demonstrate Improved patient satisfaction Rate doctor avg of 9.62/10 compared to 7.75 for prior physician Improved Clinical outcomes Pts with SBP in poor control (>160) dropped average of 42 points after 6 months Poor blood sugar control (A1C >9) dropped average of 2.38 points over first 6 months Reduced racial disparities Hispanic averaged 2.8 points higher SBP, 9.8 points higher LDL, 0.13 points higher A1C. After 6 months all disparities were reversed. Better functional status 12-item Short form health survey physical function scores improved 14.8% and mental functions scores improved 16.1% compared with baseline Reduction in absenteeism Patients reported 56.5% fewer missed work days in last 6 months because of illness compared with before entering the practice Independent analysis demonstrated outcome improvements were consistent with significant reductions in total healthcare spending: Net medical spending 20% lower Case control study 12.3% net lower spending driven	Cofounder and CEO of Iora Health Fernadopulle MD executive director of Harvard Interfaculty Program for Health Systems Improvement from 2001 to 2004, current faculty at Harvard Medical School

							by 41% drop in inpatient admissions and 48% drop in ER visits (AHRQ Health Care Innovations Exchange 2012)	
Gross, L. (2018). *Reducing health care costs: Improving affordability through innovation* (Testimony for November 28, 2018 U.S. Senate Committee on Health, Education, Labor and Pensions)	None	Quasi-experimental Single-subject design embedded in a Government report	N = 3 patients	Cost of care comparison -Thyroid cancer treatment -Abdominal pain workup -Labs for rheumatoid arthritis	(USD)	Direct comparison	Significant difference in cost of care for traditional method vs. DPC model Thyroid cancer treatment $100,000 in traditional model vs. $10,000 DPC. Abdominal pain workup $19,723.27 vs. $301.29 at DPC RA Labs $1800 in traditional model vs $100 in DPC	Weak design (single subject), single clinic sample
Palumbo, R. (2017, May). Keeping candles lit: The role of concierge medicine in the future of primary care. *Health Serv Manage Res, 30*(2), 121-128. https://doi.org/10.1177/0951484816682397	n/a	Systematic Review	N = 29 articles	Research questions: What are distinguishing attributes of concierge medicine? What are the effects of concierge medicine on universal coverage and on the sustainability of the healthcare service system?	Search of Scopus, Web of Science and PubMed Search terms: “concierge care” “concierge medicine” “concierge practice” in ALL FIELDS Inclusion criteria: Published before 2015 English language Exclusion criteria: None 93 peer reviewed articles	Graphical synthesis of research process in flow diagram	Concierge model contributes to improved population health outcomes via enhanced access to services Concierge model is a sustainable method for providing quality primary care Climate of current US health system design prevents maximizing use of this model	Systematic Review (strongest) Small number of articles; initially n = 274 but 29 met inclusion criteria
Rowe, K., Rowe, W., Umbehr, J., Dong, F., & Ablah, E. (2017, Feb). Direct Primary Care in 2015: A Survey with Selected Comparisons to 2005 Survey Data. *Kans J Med, 10*(1), 3-6. https://www.ncbi.nlm.nih.gov/pubmed/29472957 https://www.ncbi.nlm.nih.gov/pmc/articles/PM	None	Survey	65 DPC practices Response rate of 38 DPC practices (59%)	Location, membership fee, patient panel size, insurance billing status, training, demographic	Nominal measurement of location, billing status, training, demographic Ordinal: Membership fee Interval: Panel size	n/a	Cost has gone down since 2005. In 2005 annual membership fee was > $1500. In 2015 88% of practices offer annual rates between $500-1499 Majority of practices are family medicine (87%) compared to 62-77% in 2005. 84% use EMR 82% allow email to physician 76% have 24-hour access	Convenience sample Small sample size

C5733409/pdf/kjm-10-1-3.pdf							92% offer same day appointments 74% offer wholesale labs 11% will bill insurance	
Saultz, Brown, Stenberg, Tdesinski, Tillotson, Eigner, and DeVoe (2010).	None stated	Cohort Study	600 patients enrolled in Oregon Health Science University (OHSU)'s "Access Assured" program	Demographics: gender, age, clinic site, and income level as well as utilization patterns (number of followup visits)	IV: Group (gender, age, clinic site, income level) DV: number of followup visits Independent t tests and Wilcoxon rank sum tests for continuous variables (where approp) and	Multivariable Poisson regression analysis	Age is significant determinant of return visit rate; 0.7% increase in return rate for each additional year of age (p = .006) Women had 26% higher return visit rate than men (p = .001); After accounting for age, sex, and clinic site, fee discount level was not a significant independent determinant of return visit rate (p = .118)	Cohort study limited to enrolled patients at one university health clinic (two sites)
Ko, J., Rodriguez, H., Fairchild, D., Rodday, A., & Safran, D. (2009). Paying for enhanced service: Comparing patients' experiences in a concierge and general medicine practice. *Adis Data Information BV.*	None Stated	Quasi-Experimental, stratified random sampling within subgroups (concierge vs. general medicine practice)	Academic Medical Center with two primary care clinics: general medicine and concierge.	IV: Group (Concierge vs. GP) DVs: care coordination Access to care Staff Interactions Staff helpfulness Staff respectfulness Availability of urgent appointments Availability of non-urgent appointments Wait Time Returned Calls during office hours Quality of provider interactions Enough time during encounter Willingness to recommend Overall provider rating Specialist referral	IV: Nominal (Group) DV: AHRQ's CAHPS survey and ACES survey The reliability and validity measures for these tools is not mentioned in the article, and not promninent on the developer's website.	One-way ANOVA comparing groups on categorical variables; Two sample t tests to compare continuous variables	Patient experiences with care coordination (p<0.01), access to care (p < 0.001), and interactions with office staff (p< 0,001) favor concierge model over general medicine practice. On specific DVs: **<u>Statistically significant difference favoring CM > GP:</u>** care coordination (p = 0.005) Access to care p < 0.001 Staff Interactions p < 0.001 Provider f/u on test results p< 0.01 Staff helpfulness p < 0.001 Staff respectfulness p < 0.001 Availability of urgent appointments p < 0.001 Availability of non-urgent appointments p < 0.001 Wait Time p < 0.001 Returned Calls during office hours p < 0.001 Enough time during encounter P = 0.003	Level 2: Randomized study Did use convenience sample of two clinics available at the academic center.

							<u>No significant difference:</u> Likely to recommend p = 0.06 General rating p = 0.09 Quality of provider interactions p = 0.20 Specialist referral p = 0.86	
Saultz, J., Heineman, J., Selzer, R., Bunce, A., Spires, L., DeVoe, J. (2011). Uninsured patient opinions about a reduced0fee retainer program at academic health center clinics. *Jounal of the American Board of Family Medicine.*	None	Qualitative study: semistructured phone interviews	Patients from OHSU's Access Assured program. Two groups: Those who chose to re-enroll and those who did not choose to do so after initial enrollment period. From each subgroup, numerically sorted by telephone number and called in sequence until 20 patients from each group were successfully interviewed.	None	None	Transcript analysis using Borkin's technique of immersion/crystallization Areas of disagreement resolved by discussion Researcher analyses were replicated with NVivo8 software which further reviewed data to determine no themes were missed	Common themes identified from immersion/crystallization: No need when healthy: didn't understand why they should remain enrolled when they were not sick Personal Agency: People didn't know how to re-enroll, or when their terms were coming up No Choice: Patients wanted more options Continuity: Valued being able to see the doctor they chose Resepct: Felt treated with respect even though they were uninsured Appreciation: Appreicated the program, especially access to providers without a visit (Via email or telephone) Quality of Care:Various comments both positive and negative Confusion and Transparency: Patients didn't understand the benefits or terms of the program Economic Stress: Patients enrolled in program were under economic pressures.	Strengths: Same interviewer conducted all linterviews, asked questions in same sequence, all interviews were audio recorded and transcribed verbatim by two members of the team, who proofread transcripts total of 3 times to ensure accuracy. Transcripts were de-identified before being read and analyzed by the rest of the research team. IRB approval noted.
Miller, R., Weir, C. & Gulati, S. (2018). Transforming primary care: Scoping review of research and practice. *Journal of Integrated Care.*	Literature Review	Scoping review of primary care transformation	36 reviews of literature on primary care transformation Inclusion criteria: published	Features common to practices that have successfully transformed primary care delivery	No measurement; identification of emerging themes (practice transformation elements): External facilitation	nVivo software analysis with discussion and clarificatio	Successful primary care practice transformation includes the following elements: external facilitation of change; developing clinical and non-clinical leaders;	Strength: combined review of literature with stakeholder interviews and case studies to

		literature synthesized with 10 international case studies	between 2007 and 2017; English language; based on primary research; peer reviewed Exclusion criteria: commentary rather than research based; not in English; not focused on primary care transformation		Leadership support Ongoing learning Stakeholder engagement Trnasitional funding Robust evaluation	n of emerging themes	learning through training and reflection; engaging community and professional stakeholders; transitional funding; and formative and summative evaluation (data)	elucidate characteristics of successful quality improvement efforts to transform primary care towards achievement of AHRQ triple aim. Broad sampling (international) Weakness: no discussion of where the stakeholders who provided feedback were from, or how they were sampled?

APPENDIX B

SWOT ANALYSIS TABLE

Strengths	**Weaknesses**
• Experienced providers • Anecdotal reports of success • Informal results of cost savings, quality outcome measures already support DPC model • Supportive and engaged clinic leadership • Clinic leadership DNP with QI capability • Clinic RN has previous QI experience • Availability of no-cost, reliable survey tool (SM) • Availability of simple and valid measure (PCPCM) • EMR provides some quality reporting metrics (Cost, ED saves) • Dedicated patients for survey sample	• Minimal administrative resources available • EMR does not have robust quality reporting features • Small sample size
Opportunities	**Threats**
• Ability to document progress and improve care • Affordable access to care desperately needed by uninsured, underinsured, high deductible health plan (HDHP) consumers • Growing number of uninsured, underinsured, HDHP with expiration of individual mandate • DPC uniquely contracts with lab, diagnostic services for discounted rates which may be more widely available to the community under DPC membership contracts • Recent legislation approving use of health savings account (HSA) funds for DPC membership fees	• Potential for emerging competition rumored in community • Possibility of negative survey feedback which would then be publicly available when project is disseminated • Potential for poor response rate to survey

• Legislation labeled use of DPC + catastrophic wraparound insurance as acceptable benefit for employers needing to provide employee health insurance	

APPENDIX C

IMPLEMENTATION TABLE/MODIFIED IHI PLANNING FORM

Original 12-week Timeline

AIM	SMART GOAL	TASK	Timeline (in weeks)											
			1	2	3	4	5	6	7	8	9	10	11	12
1	Use automation to deliver results	Design SurveyMonkey PCPCM	X											
2	Provide access to outcome data	Gather individual responses to PCPCM	X	X	X	X	X	X	X	X				
3	Align outcomes with values	Analyze responses to PCPCM									X	X	X	X

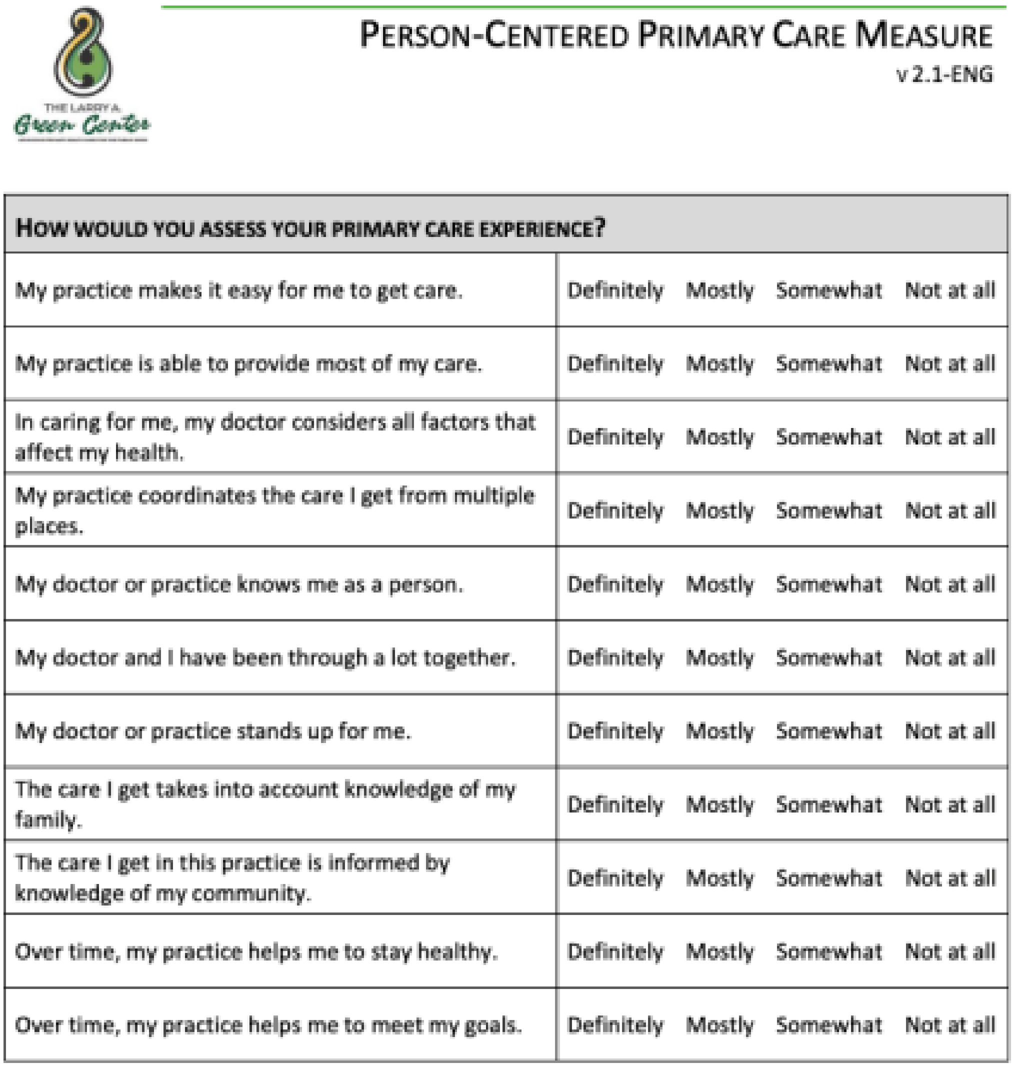
Modified 3-week Timeline

AIM	SMART GOAL	TASK	Timeline (in weeks)				
			1		2		3
1	Use automation to deliver results	Design SurveyMonkey PCPCM	X				
2	Provide access to outcome data	Gather individual responses to PCPCM	X		X		X
3	Align outcomes with values	Analyze responses to PCPCM					X

APPENDIX D

PATIENT-CENTERED PRIMARY CARE MEASURE

Thank you for providing feedback about your experience at the clinic! Your participation in this survey is entirely voluntary. You may stop at any time and may choose not to answer any questions that you do not wish to answer. We appreciate your time and input!



THE LARRY A. Green Center

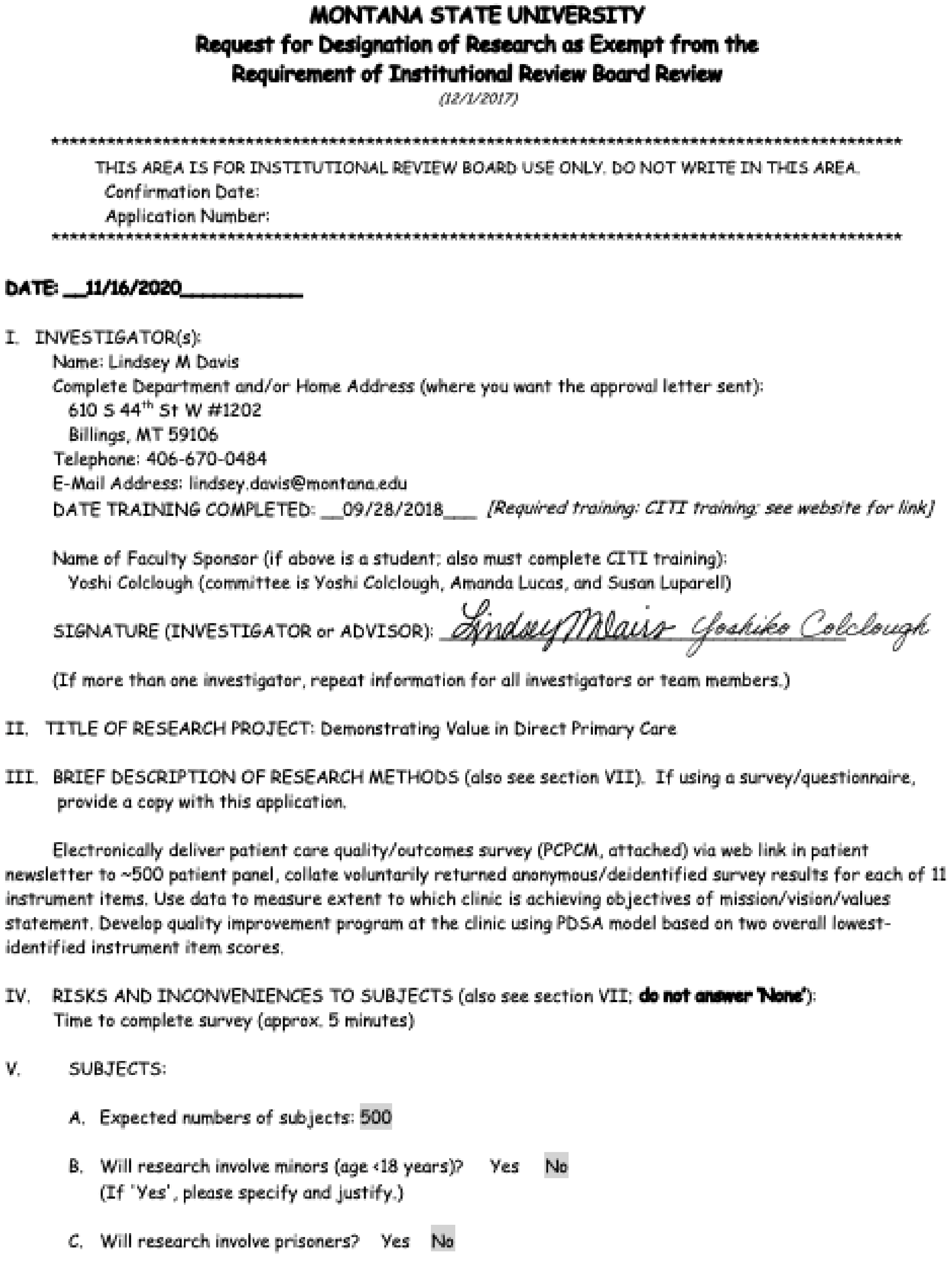
PERSON-CENTERED PRIMARY CARE MEASURE

v 2.1-ENG

HOW WOULD YOU ASSESS YOUR PRIMARY CARE EXPERIENCE?				
My practice makes it easy for me to get care.	Definitely	Mostly	Somewhat	Not at all
My practice is able to provide most of my care.	Definitely	Mostly	Somewhat	Not at all
In caring for me, my doctor considers all factors that affect my health.	Definitely	Mostly	Somewhat	Not at all
My practice coordinates the care I get from multiple places.	Definitely	Mostly	Somewhat	Not at all
My doctor or practice knows me as a person.	Definitely	Mostly	Somewhat	Not at all
My doctor and I have been through a lot together.	Definitely	Mostly	Somewhat	Not at all
My doctor or practice stands up for me.	Definitely	Mostly	Somewhat	Not at all
The care I get takes into account knowledge of my family.	Definitely	Mostly	Somewhat	Not at all
The care I get in this practice is informed by knowledge of my community.	Definitely	Mostly	Somewhat	Not at all
Over time, my practice helps me to stay healthy.	Definitely	Mostly	Somewhat	Not at all
Over time, my practice helps me to meet my goals.	Definitely	Mostly	Somewhat	Not at all

APPENDIX E

IRB EXEMPTION FORM



MONTANA STATE UNIVERSITY
Request for Designation of Research as Exempt from the Requirement of Institutional Review Board Review

(12/1/2017)

****

THIS AREA IS FOR INSTITUTIONAL REVIEW BOARD USE ONLY. DO NOT WRITE IN THIS AREA.
Confirmation Date:
Application Number:

****

DATE: __11/16/2020____________

I. INVESTIGATOR(s):
Name: Lindsey M Davis
Complete Department and/or Home Address (where you want the approval letter sent):
610 S 44th St W #1202
Billings, MT 59106
Telephone: 406-670-0484
E-Mail Address: lindsey.davis@montana.edu
DATE TRAINING COMPLETED: __09/28/2018___ *[Required training: CITI training; see website for link]*

Name of Faculty Sponsor (if above is a student; also must complete CITI training):
Yoshi Colclough (committee is Yoshi Colclough, Amanda Lucas, and Susan Luparell)

SIGNATURE (INVESTIGATOR or ADVISOR): Lindsey M Davis Yoshiko Colclough

(If more than one investigator, repeat information for all investigators or team members.)

II. TITLE OF RESEARCH PROJECT: Demonstrating Value in Direct Primary Care

III. BRIEF DESCRIPTION OF RESEARCH METHODS (also see section VII). If using a survey/questionnaire, provide a copy with this application.

Electronically deliver patient care quality/outcomes survey (PCPCM, attached) via web link in patient newsletter to ~500 patient panel, collate voluntarily returned anonymous/deidentified survey results for each of 11 instrument items. Use data to measure extent to which clinic is achieving objectives of mission/vision/values statement. Develop quality improvement program at the clinic using PDSA model based on two overall lowest-identified instrument item scores.

IV. RISKS AND INCONVENIENCES TO SUBJECTS (also see section VII; **do not answer 'None'**):
Time to complete survey (approx. 5 minutes)

V. SUBJECTS:

A. Expected numbers of subjects: 500

B. Will research involve minors (age <18 years)? Yes [✓ No]
(If 'Yes', please specify and justify.)

C. Will research involve prisoners? Yes [✓ No]

D. Will research involve any specific ethnic, racial, religious, etc. groups of people?
(If 'Yes', please specify and justify.) Yes [✓ No]

E. Will a consent form be used? (Please use accepted format from our website. Be sure to indicate that participation is voluntary. Provide a stand-alone copy. Do not include the form here.) [✓ No]

VI. FOR RESEARCH INVOLVING SURVEYS OR QUESTIONNAIRES:
(Be sure to indicate on each instrument, survey or questionnaire that participation is voluntary.)

A. Is information being collected about:
Sexual behavior? Yes [✓ No]
Criminal behavior? Yes [✓ No]
Alcohol or substance abuse? Yes [✓ No]
Matters affecting employment? Yes [✓ No]
Matters relating to civil litigation? Yes [✓ No]

B. Will the information obtained be completely anonymous, with no identifying information linked to the responding subjects? [✓ Yes] No

C. If identifying information will be linked to the responding subjects, how will the subjects be identified? (Please circle or bold your answers)
By name Yes [✓ No]
By code Yes [✓ No]
By other identifying information Yes [✓ No]

D. Does this survey utilize a standardized and/or validated survey tool/questionnaire? [✓ Yes] No

VII. FOR RESEARCH BEING CONDUCTED IN A CLASSROOM SETTING: [✓ n/a]

A. Will research involve blood draws? (If Yes, please follow protocol listed in the "Guidelines for Describing Risks: blood, etc.", section I-VI.)

VIII. FOR RESEARCH INVOLVING PATIENT INFORMATION, MATERIALS, BLOOD OR TISSUE SPECIMENS RECEIVED FROM OTHER INSTITUTIONS: [✓ n/a]

A. Are these materials linked in any way to the patient (code, identifier, or other link to patient identity)? Yes No

B. Are you involved in the design of the study for which the materials are being collected?
Yes No

C. Will your name appear on publications resulting from this research?
Yes No

D. Where are the subjects from whom this material is being collected?

E. Has an IRB at the institution releasing this material reviewed the proposed project?
(If 'Yes", please provide documentation.) Yes No

F. Regarding the above materials or data, will you be:

Collecting them Yes No
Receiving them Yes No
Sending them Yes No

G. Do the materials already exist? Yes No

H. Are the materials being collected for the purpose of this study? Yes No

I. Do the materials come from subjects who are:

Minors Yes No
Prisoners Yes No
Pregnant women Yes No

J. Does this material originate from a patient population that, for religious or other reasons, would prohibit its use in biomedical research?

Yes No Unknown source

IX. FOR RESEARCH INVOLVING MEDICAL AND/OR INSURANCE RECORDS

A. Does this research involve the use of:

Medical, psychiatric and/or psychological records Yes [✓ No]
Health insurance records Yes [✓ No]
Any other records containing information regarding personal health and illness Yes [✓ No]

If you answered "Yes" to any of the items in this section, you must complete the HIPAA Worksheet.