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Interventions to Promote Health and Increase Health Care Efficiency: Technical Appendix

The Washington State Legislature directed the Washington State Institute for Public Policy (WSIPP) to "calculate the return on investment to taxpayers from evidence-based prevention and intervention programs and policies."¹ Additionally, WSIPP's Board of Directors authorized WSIPP to work on a joint project with the MacArthur Foundation and Pew Charitable Trusts to extend WSIPP's benefit-cost analysis to certain health care topics.

We summarize our benefit-cost and meta-analytic results for ten health care topics in the December 2015 WSIPP report: *Interventions to Promote Health and Increase Health Care Efficiency: December 2015 Update.*² We provide more extensive discussions of interventions, methodological issues, and meta-analytic findings for six topics in this appendix. These topics include: 1) diabetes prevention, 2) continuous labor support, 3) transitional care, 4) patient-centered medical homes, 5) accountable care organizations, and 6) patient cost sharing.

| Appen | ndix | |
|-------|---|---|
| I. | Lifestyle Interventions to Prevent Diabetes | 2 |
| II. | Continuous Labor Support | |
| III. | Transitional Care Programs | |
| IV. | Patient-Centered Medical Homes | |
| V. | Accountable Care Organizations | |
| VI. | Patient Cost Sharing | |
| | | |

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¹ Engrossed Substitute House Bill 1244, Chapter 564, Laws of 2009.

² Bauer, J., Barch, M., Kay, N., Aos, S., Burley, M., Hirsch, M., . . . Lemon, M. (2015). *Interventions to promote health and increase health care efficiency: December 2015 updates* (Doc. No. 15-12-3402). Olympia: Washington State Institute for Public Policy.

 $http://www.wsipp.wa.gov/ReportFile/1622/Wsipp_Interventions-to-Promote-Health-and-Increase-Health-Care-Efficiency-December-2015-Update_Report.pdf$

A. Background

Diabetes Disease Burden

People with type 2 diabetes, the most common form of the disease, do not produce enough insulin or cannot use it properly (insulin resistance). Blood glucose levels rise, which damages blood vessels, nerves, and organs. Over time, two types of complications can arise. "Microvascular" complications result in blindness, kidney disease, and foot problems. "Macrovascular" complications increase the risk of heart disease and stroke. Cardiovascular disease is the leading cause of death for individuals with diabetes and a major contributor to the costs of the disease.³

Prevalence rates of diabetes in the US more than doubled over the last 20 years, in large part due to rising levels of obesity.⁴ An estimated 29 million Americans—including 16% of adults ages 45 to 64—have diabetes.⁵

The federal Centers for Disease Control and Prevention estimate that diabetes cost the US \$245 billion in 2012, including direct medical costs of \$176 billion and \$69 billion from indirect costs (due to disability, work loss, and early death).⁶

Medicare pays for over half of the medical costs associated with diabetes. Medicaid is also a major payer, particularly through support for individuals who are eligible for both Medicaid and Medicare (dual-eligibles).⁷ Medicaid expenses are substantial, in part, because a quarter of nursing home residents have diabetes.⁸

Diabetes Management

While not the focus of our research review in this report, proper management of the disease can reduce complications and mortality.⁹ Damage to the eyes, kidneys, and nerves can be reduced though intensive control of blood glucose levels at early stages of the disease.¹⁰ The effect of intensive glucose control on cardiovascular disease is less clear. It appears to be more effective in reducing cardiovascular complications among newly diagnosed patients, rather than those with more advanced diabetes.¹¹ Diabetes patients also tend to have other risk factors for heart disease, such as high blood pressure and

³ Khavandi et al., (2013); Gillett et al., (2012); Fradkin, (2012); Uusitupa et al., (2011); DeFronzo & Abdul-Ghani, (2011); Villarivera et al., (2012); American Diabetes Association, (2014); Aroda & Ratner, (2008); Matfin & Pratley, (2010); Yeboah et al., (2011); and Hajhosseiny et al., (2014).

⁴ Khavandi et al., (2013) and Uusitupa et al., (2011).

⁵ Centers for Disease Control and Prevention. (2014). National Diabetes Statistics Report.

⁶ Ibid.

⁷ United Health (2010) estimates that 37% of Medicare and Medicaid dual-eligibles have type 2 diabetes, with annual medical costs per case of \$10,320.

⁸ Fradkin, (2012).

⁹ Some interventions for managing diabetic complications have been found to be cost-beneficial. Li et al., (2010).

¹⁰ American Diabetes Association, (2014); Fradkin, (2012); and Ryden et al., (2013).

¹¹ American Diabetes Association, (2014); Hajhosseiny et al., (2014); Ryden et al., (2013); Simmons et al., (2010).

poor cholesterol levels. Controlling glucose, blood pressure, and cholesterol levels has reduced mortality among individuals with type 2 diabetes.¹²

Diabetes Prevention

Prevention—the focus of this report—is important because as diabetes progresses it becomes more difficult to manage complications.¹³ Within the health care setting, diabetes prevention includes lifestyle interventions and drug therapies.¹⁴

We focus on evidence for the effectiveness of lifestyle programs. These programs typically target individuals with "prediabetes." People diagnosed with prediabetes have elevated glucose levels because their bodies do not use insulin effectively. Not everyone with prediabetes eventually develops the disease, but they are at high risk of doing so. One study found that 70% of people with prediabetes eventually develop the disease.¹⁵ The overall goal of the prevention programs reviewed here is to reduce that rate.

A number of clinical trials have evaluated the effectiveness of long-term, intensive lifestyle programs with individual counseling.¹⁶ Two of the most intensive interventions for which short- and long-term outcomes have been evaluated, are the US Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study (DPS).¹⁷ More recent studies examine shorter-term, group-based counseling programs that have been developed to provide diabetes prevention at lower cost in community settings (for example, YMCAs or churches). These interventions tend to have fewer sessions and rely on group rather than individual counseling.¹⁸ Some additional studies examine less-intensive programs with individual counseling. We examine the effects of all these programs in our meta-analysis.

B. Research Studies

To identify all rigorous evaluations that have been undertaken, we searched for studies in PubMed, Google Scholar, and the Cochrane Library. The search was supplemented with citations from published systematic reviews. After examining abstracts, we conducted full reviews of 125 diabetes prevention studies, of which 44 are included in the meta-analysis. The other studies were excluded due to methodological or reporting issues.

The 44 studies are based on 26 trials with a total of 4,552 intervention participants in 13 countries.¹⁹ These studies and the interventions they evaluate are described in our report Diabetes Prevention Programs: A Review of the Evidence.²⁰

¹³ Fradkin et al., (2012); Khavandi et al., (2013); Griffin et al., (2011); Mannucci et al., (2013); and Hajhosseiny et al. (2014).

¹² Fradkin, (2012) and Ryden et al., (2013).

¹⁴ The most commonly used drug therapy is Metformin. It has been found to be effective in diabetes prevention, and the American Diabetes Association recommends it for those at higher risk of developing the disease, especially if they fail to respond to lifestyle intervention—American Diabetes Association, (2014) and Moutzouri et al., (2011).

¹⁵ Prediabetes may include two types of insulin resistance—impaired fasting glucose (IFG) or impaired glucose tolerance (IGT). Up to 70% of people with prediabetes eventually develop diabetes. Villarivera et al., (2012) and Perreault et al., (2012). In 2012, an estimated 86 million in the US had prediabetes—US Centers for Disease Control and Prevention, (2014).

¹⁶ For reviews of these and other trials, see: Baker et al., (2011); Venditti & Kramer, (2013); DeFronzo & Abdul-Ghani, (2011); Ryden et al., (2013); Orozco et al., (2008); Tabak et al., (2012); and Hopper et al., (2011).

¹⁷ These two programs had three years of active intervention and included individual counseling sessions and supervised exercise classes.

¹⁸ Program staffing in the lower-cost programs ranges from nurses to community lay workers.

¹⁹ Countries include Australia, Canada, China, Finland, Germany, India, Italy, Japan (three studies), the Netherlands, Spain, Sweden (two), the UK (four), and the US (eight).

C. Meta-Analytic Findings

Diabetes incidence is the primary outcome of interest in this review. Studies also reported impacts on weight change, glucose levels, and cardiovascular risk factors.

Where possible, we report average effect sizes for a) all programs, b) long-term intensive programs with individual counseling, and c) shorter-term, group-based counseling programs. The group-based programs are less costly than the more intensive, individual-based counseling programs.

Outcome: Diabetes Incidence

We located 11 methodologically sound studies that report effects on diabetes incidence at the end of active intervention. Program duration and intensity vary, but these studies largely represent interventions with relatively long durations and individual counseling.²¹

The studies provide clear evidence for the effectiveness of lifestyle interventions. The average effect size on diabetes incidence is highly significant (Exhibit 1). Programs typically reduce the risk of diabetes onset by about a half by the end of active intervention.

Exhibit 1 Lifestyle Program Effects on Diabetes Incidence

| | Average effect size | Standard error | Number of studies | Number in treatment groups |
|--|------------------------|-------------------|----------------------|-------------------------------|
| All studies | -0.387** | 0.050 | 11 | 2,812 |
| Long-term, intensive, individual counseling* | -0.533** | 0.098 | 2 | 1,344 |

Estimates are for the end of active intervention.

* Includes the US Diabetes Prevention Program and the Finnish Diabetes Prevention Study.

** Results are statistically significant based on a p-value of < 0.001.

²⁰ See Exhibit A1 and Exhibit A2 of Bauer, J. (2015). http://www.wsipp.wa.gov/ReportFile/1584/Wsipp_Diabetes-Prevention-Program-

A-Review-of-the-Evidence_Report.pdf

²¹ Ibid.

Effects are larger for the more intensive, longer-term programs with individual counseling.²² Unfortunately, the more recent studies that evaluate shorter-term, group-based interventions typically have short follow-up (often one year or less), and measured outcomes are often limited to weight loss. The only group-based intervention included among the studies in Exhibit 1 is the HELP-PD program.²³ This study was not designed to detect effects on diabetes incidence, but reductions were observed.

Long-term follow up results are available for three of the international trials. Program effects on diabetes incidence persist over time, but effect sizes typically decline as more of these high-risk individuals eventually experience disease onset (Exhibit 2). Despite this decline, significant reductions in incidence remain after long-term follow up. For example, the largest study in the US found that, after ten years, the incidence of diabetes was reduced from 52% for those who did not participate in the program to 42% for those who did.²⁴

| | a | Follow-up | Effect | Percent with diabetes | | |
|-----------------------------------|----------|-----------|--------|-----------------------|---------------|--|
| Trial | Country | (years) | size | Lifestyle group | Control group | |
| Diabetes Prevention Program | | 3 | -0.534 | 14% | 29% | |
| | US | 10 | -0.244 | 42% | 52% | |
| | | 3 | -0.525 | 10% | 23% | |
| Disketes provention study | Finland | 4 | -0.398 | 18% | 30% | |
| Diabetes prevention study | Finianu | 7 | -0.340 | 32% | 46% | |
| | | 13 | -0.295 | 49% | 64% | |
| Da Qing diabetes prevention study | China | 6 | -0.432 | 43% | 66% | |
| | China | 20 | -0.340 | 80% | 93% | |

Exhibit 2 Program Effects on Diabetes Incidence over Time

Effect sizes are estimated based on data reported by Knowler et al., (2002) & (2009); Tuomilehto et al., (2001); Lindstrom et al., (2006) & (2013); and Li et al., (2008).

Outcome: Weight Change

Weight loss is critical in preventing type 2 diabetes.²⁵ Seventeen studies that met the criteria for our review report results for weight change. Average weight loss varies across programs and over time within trials, due to a tendency for participants to regain weight.²⁶

²² The US Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study (DPS) interventions lasted three years. These were intensive interventions. The US DPP, for example, included 16 individual counseling sessions, phone contacts between sessions, and twice weekly supervised exercise classes during the first six months. This was followed by a 30-month maintenance period, with group or individual sessions every two months. The program was delivered by registered dietitians and staff with masters' degrees in exercise physiology or psychology.

²³ Evaluated by Katula et al., (2013).

²⁴ Knowler et al., (2009). Note that interpretation of the long-term US DPP results is complicated by fact that a group-based lifestyle program was offered to the control group after the end of original DPP. This was effective in reducing incidence among the former control participants.

²⁵ Hamman et al., (2006) and Knowler et al., (2009).

²⁶ See Bauer, (2015). Appendix Exhibit A2 for reported weight loss at different follow-up durations.

Exhibit 3 summarizes results for the studies that report average weight losses at (or around) 12-months follow-up.²⁷ Lifestyle programs produce significant weight loss. The average effect size for shorter-term, group-based programs is smaller than that for the longer-term individual programs. However, some group-based programs have achieved weight losses comparable or close to that for the more intensive programs.²⁸ Participants typically lose an average of 4% to 6% of body weight in these group-based programs at 12 months follow-up. It is important to note that the existing research studies on group-based programs do not measure the long-term effects on weight loss or diabetes incidence.²⁹

| Study | Follow-up (months) | Average effect size | Standard error | Number of studies | Number in treatment groups |
|---|-----------------------|------------------------|-------------------|----------------------|----------------------------------|
| All studies | 12-15 | -0.221* | 0.034 | 12 | 2,457 |
| Long-term, intensive, individual counseling | 12 | -0.298* | 0.052 | 2 | 1,344 |
| Shorter-term, group counseling | 12-15 | -0.235* | 0.068 | 6 | 547 |

Exhibit 3 Diabetes Prevention Program Effects on Weight Change

Estimates are based on studies reporting results at (or around) 12 months follow-up.

* Results are statistically significant based on a p-value of < 0.01.

Outcome: Fasting Glucose

Diabetes is the result of rising blood glucose levels. Several shorter-term, group-based programs report effects for blood glucose levels, and we can compare these to results from the intensive programs with individual counseling (Exhibit 4).³⁰ Glucose level effects vary across the group-based studies. The average effect is significant, though smaller than that for the US Diabetes Prevention Program trial.³¹

Outcome: Cardiovascular Risk

Twelve rigorous studies report effects on several cardiovascular risk factors. Pooling the data from these studies, we find lifestyle interventions have significant beneficial effects on blood pressure, total cholesterol, and triglyceride levels (Exhibit 5).³² The average effects for HDL and LDL cholesterol, however, were not significant.³³

²⁷ Estimates use an intraclass correlation coefficient (ICC) of 0.02 to correct of participant clustering; based on studies by Parker et al., (2005); West et al., (2011); and Wing et al., (2014). Sensitivity analysis, allowing the ICC to vary between 0.02 and 0.04, indicates that estimates do not change substantially across this range of plausible ICC values.

²⁸ The DEPLOY (YMCA), HELP-PD, E-LITE programs achieved 6% or greater weight loss at 12 months.

²⁹ Katula et al., (2011); Whittemore, (2011); Johnson et al., (2013); Ali et al., (2012); and Venditti & Kramer, (2013).

³⁰ Estimates use an intraclass correlation coefficient (ICC) of 0.02 to correct of participant clustering; based on studies by Parker et al., (2005) and Littenberg & MacLean (2006). Sensitivity analysis, allowing the ICC to vary between 0.02 and 0.06, indicates that estimates do not change substantially across this range of ICC values.

³¹ Four group-based counseling studies report results for glycated hemoglobin (HbA1c), a measure of average plasma glucose concentration over prolonged periods. Across these studies, programs have a marginally significant effect (with an average effect size of -0.183 and p-value of 0.059). The studies include: Ackermann et al., (2008), Parikh et al., (2010), Ockene et al., (2012), and Kulzer et al., (2009).

³² Estimates use an intraclass correlation coefficient (ICC) of 0.04 for most outcomes to correct for participant clustering—Parker et al., (2005); Littenberg & MacLean, (2006). Exceptions were the ICCs for HDL cholesterol (0.01) and triglycerides (0.02). Sensitivity analysis, allowing ICCs to vary across a plausible range, were performed for diastolic blood pressure and HDL cholesterol.

³³ These findings are consistent with published reviews. See: DeFronzo & Abdul-Ghani, (2011); Orozco et al., (2008); and Orchard et al., (2013).

Exhibit 4

Diabetes Prevention Program Effects on Fasting Glucose Levels

| Trial | Follow-up (months) | Average effect size | Standard error | Number of studies | Number in treatment groups |
|--|-----------------------|---------------------|-------------------|----------------------|----------------------------------|
| Long-term, intensive, individual counseling ⁽¹⁾ | 12 | -0.453* | 0.053 | 2 | 1344 |
| Shorter-term, group counseling ⁽²⁾ | 6-15 | -0.292* | 0.074 | 7 | 763 |

* Results are statistically significant based on a p-value of < 0.01.

Studies included in the meta-analysis:

(1) Haffner et al., (2005) and Tuomilehto et al., (2001).

(2) Katula et al., (2011); Mason et al., (2011); Moore et al., (2011); Parikh et al., (2010); Ockene et al., (2012); Ma et al., (2013); and Kulzer et al., (2009).

| | Diabetes i reventio | | | |
|---|------------------------|----------------|----------------------|-------------------------------|
| | Average effect size | Standard error | Number of studies | Number in treatment groups |
| Diastolic blood pressure ⁽¹⁾ | -0.112 | 0.046* | 11 | 2,539 |
| Systolic blood pressure ⁽²⁾ | -0.100 | 0.041* | 12 | 2,568 |
| Total cholesterol ⁽³⁾ | -0.128 | 0.050* | 8 | 1,280 |
| HDL cholesterol ⁽⁴⁾ | 0.068 | 0.050 | 8 | 916 |
| LDL cholesterol ⁽⁵⁾ | -0.030 | 0.054 | 6 | 1,349 |
| Triglycerides ⁽⁶⁾ | -0.193 | 0.041* | 6 | 1,857 |

Exhibit 5 Diabetes Prevention Program Effects on CVD Risk Factors

* Results are statistically significant base on a p-value of < 0.015.

Studies included in meta-analyses:

(1) Bhopal et al., (2014); Kulzer et al., (2009); Li et al., (2008): Lindstrom et al., (2003): Ma et al., (2013); Oldroyd et al., (2001); Parikh et al., (2010); Ratner et al., (2005); Roumen et al., (2008); Saito et al., (2011); and Wing et al., (1998).

(2) Ackermann et al., (2008); Bhopal et al., (2014); Kulzer et al., (2009); Li et al., (2008); Lindstrom et al., (2003): Ma et al., (2013); Oldroyd et al., (2001); Parikh et al., (2010); Ratner et al., (2005); Roumen et al., (2008); Saito et al., (2011); and Wing et al., (1998).

(3) Ackermann et al., (2008); Kulzer et al., (2009); Li et al., (2008): Lindstrom et al., (2003): Ma et al., (2013); Oldroyd et al., (2001); Saito et al., (2011); and Wing et al., (1998).

(4) Ackermann et al., (2008); Kulzer et al., (2009); Lindstrom et al., (2003): Ma et al., (2013); Oldroyd et al., (2001); Roumen et al., (2008); Saito et al., (2011); and Wing et al., (1998).

(5) Ma et al., (2013); Oldroyd et al., (2001); Parikh et al., (2010); Ratner et al., (2005); Roumen et al., (2008); and Wing et al., (1998).
(6) Lindstrom et al., (2003); Kulzer et al., (2009); Ma et al., (2013); Ratner et al., (2005); Saito et al., (2011); and Wing et al., (1998).

Other Outcomes: Strokes, Heart Attacks, and Mortality

While we found evidence that lifestyle programs can reduce diabetes incidence and certain cardiovascular risk factors, we searched for, but did not locate, sufficient evidence regarding the impact of these programs on cardiovascular disease (e.g., strokes and heart attacks) and mortality. It is not yet clear what effects diabetes prevention programs have on these outcomes.

Given the lags between program enrollment, diabetes onset, and the appearance of complications, it could take decades to observe effects on cardiovascular disease. We found only three diabetes prevention

evaluations that report long-term cardiovascular disease and mortality outcomes—one study for the Finnish Diabetes Prevention Study (DPS) and two for the Chinese Da Qing Diabetes Prevention Study (DQS).³⁴ Uusitupa et al. (2009) examined participants in the Finnish DPS ten years after program recruitment. They did not find significant lifestyle program effects on cardiovascular disease or mortality.³⁵ Li et al. (2008) also failed to find significant effects on these outcomes for Chinese DQS participants after 20 years of follow-up.³⁶ A more recent study which examined DQS participants after 23 years, reported significant effects on cardiovascular and all-cause mortality—but the effects were significant only for women.³⁷

D. Diabetes Prevention Studies Included in the Meta-Analysis

- Ackermann, R.T., Finch, E.A., Brizendine, E., Zhou, H., & Marrero, D.G. (2008). Translating the Diabetes Prevention Program into the community. The DEPLOY Pilot Study. *American Journal of Preventive Medicine*, *35*(4), 357-63.
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³⁴ Knowler et al., (2009) examined outcomes for US Diabetes Prevention Program participants ten years after recruitment. The authors concluded that cardiovascular complications were too infrequent over the ten years for an analysis of treatment effects.
³⁵ Based on reported outcomes in Uusitupa et al., (2009), we estimate program effect sizes of 0.025 (p-value 0.904) for cardiovascular disease and -0.131 (p-value 0.526) for all-cause mortality.

³⁶ Based on reported outcomes in Li et al., (2008), we estimate program effect sizes of -0.014 (p-value 0.917) for cardiovascular disease, -0.076 (p-value 0.557) for cardiovascular mortality, and -0.023 (p-value 0.859) for all-cause mortality.

³⁷ Li et al., (2014); Based on reported outcomes in Li et al., (2014), we estimate program effect sizes of -0.239 (p-value 0.068) for cardiovascular mortality and -0.229 (p-value 0.080) for all-cause mortality. Note that the DQS study population had especially high diabetes prevalence (Exhibit 2) and the results may have limited applicability to the US population; Selph et al., (2014). For discussions of these studies, see: Tabak et al., (2012); Hopper et al., (2011); Khavandi et al., (2013); Uusitupa et al., (2011); Matfin & Pratley, (2010); Fradkin et al., (2012); Mannucci et al., (2013); DeFronzo & Abdul-Ghani, (2011); Orchard et al., (2013); and Selph et al., (2014).

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II. Continuous Labor Support

A. Background

There has been growing academic and practitioner interest in the possibility that continuous emotional and physical support could help women in labor.³⁸ Several meta-analyses have evaluated the relationship between non-clinical support—as provided by doulas, ³⁹ nurses, or volunteers—and medical interventions and labor outcomes.⁴⁰ Both Oregon and Minnesota have expanded state Medicaid coverage to include doula support for laboring women. As part of a general exploration of non-clinical interventions to reduce cesarean sections (C-sections), we evaluated the influence of continuous emotional and physical support on the likelihood of a C-section delivery. This section of the Technical Appendix will provide general information on the background, health consequences, and economic costs of C-section rates, as well as a discussion of the results from our meta-analysis and benefit cost analysis.

Cesarean Rates

Between 1996 and 2009, Washington State's C-section rate increased by 73%, one of the largest jumps of any state in the country.⁴¹ There were several reasons behind this increase; changing demographics, including more advanced maternal age and increased rates of obesity; the prevalence of constant electronic fetal monitoring; pressure on physicians to perform "defensive medicine" in order to avoid malpractice suits; greater acceptance of C-sections as a safe and standard method of delivery; and a reduced rate of vaginal delivery for women with a prior C-section (VBAC).⁴² National and local organizations and hospitals responded with a package of data collection efforts and reforms designed to reduce the C-section rate.⁴³ While these efforts have begun reversing this trend in Washington, C-section rates still vary significantly by hospital and county. In 2011, those county-level rates ranged from a low of 10% to a high of 39%.⁴⁴ Regional differences in the risk factors of patients cannot account for the extent of this variation; instead, it appears that medical practices may play a role.⁴⁵

Health Consequences

There are clear benefits from cesarean delivery in the case of breech births; twin pregnancy; and labor complications or specific medical indications, including placenta previa or severe preeclampsia.⁴⁶ However, unnecessary C-sections are problematic because of the increased likelihood of poor health outcomes. There is considerable evidence of greater risk for obstetric hemorrhage and infection, the two leading causes of hospital readmission for women who have recently given birth.⁴⁷ While severe morbidity from primary C-

³⁸ For example, in 2014, the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine published a consensus statement that continuous support for women in labor is "probably underutilized." http://www.acog.org/Resources-And-Publications/Obstetric-Care-Consensus-Series/Safe-Prevention-of-the-Primary-Cesarean-Delivery

³⁹ The Doula Organization of North America (DONA) defines a doula as someone who provides continuous emotional reassurance and comfort for the entire labor. http://www.dona.org/PDF/Birth%20Position%20Paper_rev%200912.pdf

⁴⁰ E.g. Khunpradit et al., (2011), Chaillet et al., (2014), and Fortier & Godwin, (2015).

⁴¹ Menacker & Hamilton (2010).

⁴² For a thorough discussion of the many reasons behind the rise of cesarean deliveries see: King et al., (2013).

⁴³ These organizations include the Washington State Health Care Authority, the Washington State Hospital Association, the Robert Bree Collaborative, the Foundation for Health Care Quality, Washington State Perinatal Collaborative, and the Department of Health and the Department of Social and Health Services.

⁴⁴ Bree Collaborative, (2012).

⁴⁵ http://www.doh.wa.gov/portals/1/documents/5300/csectionsinwa.pdf

⁴⁶ Menacker, & Hamilton, (2010).

⁴⁷ Liu et al., (2005).

section is unlikely, risk to the mother rises with each additional C-section, particularly for life-threatening hemorrhages or morbidity due to placental implantation problems.⁴⁸ Additionally, some studies suggest that infants born via C-section may be more vulnerable to certain health problems, particularly breathing problems like asthma⁴⁹ and metabolic diseases including childhood-onset diabetes.⁵⁰

Economic Costs

In 2014, of the 88,561 live births in Washington, half were funded by Medicaid. Between 2001 and 2011, Medicaid expenditures per pregnancy increased by 59%, bringing annual expenditures on maternal and infant services to over \$750 million.⁵¹ Calculating the amount that unnecessary cesarean deliveries contribute to that overall cost can be difficult for two main reasons.

First, the true difference in cost between vaginal and C-section births in terms of physician time and resources consumed can be difficult to estimate.⁵² The Washington State Health Care Authority (HCA) has equalized Medicaid payments for cesarean and vaginal deliveries to incentivize physicians to reduce C-section rates. This equalization obscures the true difference in costs in Washington. However, a national sample from the Medical Expenditure Panel Survey (MEPS) dataset from 2009-2013 shows a price difference of approximately \$3,000 between modes of delivery for Medicaid patients, and an analysis from the Healthcare Cost and Utilization Project (HCUP) found a similar difference of \$2,500 in 2008 dollars.⁵³

A second factor that makes estimating the true economic cost difficult is the disagreement about the appropriate C-section rate. For example, the World Health Organization recommends an upper bound of 15%, while the US Department of Health and Human Services has set its goal rate for 2020 at 23.9% for low-risk births (full-term, singleton, vertex presentation with no prior C-sections).⁵⁴ The total C-section rate in Washington State in 2011 was 29% of all births in the pooled Medicaid and private insurance populations. 17% of all women delivered via a first-time or primary C-section, and 12% delivered via a repeat C-section.⁵⁵

Program Description

There is growing academic and government attention to the possibility that continuous support of women in labor could reduce the C-section rate.⁵⁶ This support is typically provided by a doula, which the Doula Organization of North America (DONA) defines as someone who provides continuous emotional reassurance and comfort for the entire labor.⁵⁷ This support can take the form of physical touch or massage; suggestions for relaxation and breathing; recommendations for labor positions; or encouragement and verbal support. Unlike physicians, nurses, or midwives, doulas do not provide clinical services.

B. Research Studies

We conducted a search for quasi-experimental and randomized controlled trials of continuous support in labor using PubMed, Google scholar, and EBSCOhost. We identified 68 studies for a more thorough review;

⁴⁸ Silver et al., (2006).

⁴⁹ For a recent meta-analysis of these studies, see: Huang et al., (2014).

⁵⁰ Cardwell et al., (2008).

⁵¹ Statewide Perinatal Advisory Committee, DSHS Division of Research and Data Analysis, & DOH Office of Healthy Communities (2013).

⁵² For a discussion of the difficulty in using medical prices to represent costs for cesarean deliveries, see Henderson et al., (2001).

⁵³ Podulka et al., (2011).

⁵⁴ See Healthy People 2020 at: https://www.healthypeople.gov/sites/default/files/HP2020_brochure_with_LHI_508_FNL.pdf

⁵⁵ Bree Collaborative, (2012).

⁵⁶ Both Minnesota and Oregon Medicaid have recently begun reimbursing doula services.

⁵⁷ http://www.dona.org/PDF/Birth%20Position%20Paper_rev%200912.pdf

ten of those studies satisfied WSIPP's methodological standards. Studies were typically excluded for failing to account for patient self-selection; inadequately compensating for variation in C-section risk between the control and treatment populations; or providing insufficient methodological detail.

We conducted a third round of review, which resulted in five final studies. Exclusion criteria in this final round was based on the nature of the control group. Specifically, studies that used a control group of women in labor who were not allowed any support person were excluded from the final analysis as not comparable to the typical situation of a laboring mother in Washington State.

The nature of support administered and the identity of the provider also varied. Some doulas met with the laboring mothers and provided labor education prior to admission in the hospital. Others were assigned to laboring mothers only after they were admitted for labor and delivery. While doulas provided support in the majority of studies, some interventions were conducted by volunteers or nurses with additional training. We excluded no study from our meta-analysis based on the nature of the practitioner.

C. Meta-Analytic and Benefit-Cost Findings

As outlined in Exhibit 6 below, our meta-analysis found that continuous support for women in labor moderately reduces the likelihood of a C-section delivery, but the effect is not significant. We conducted the benefit-cost analysis separately for the Medicaid and private insurance populations. Women with private insurance are more likely to deliver via C-section, and they also experience a greater cost difference between those two modes of birth than Medicaid patients.

The benefits of the program were calculated using the price difference between the modes of birth and the decreased likelihood of hospital readmission for new mothers. As discussed previously, Washington State has largely equalized Medicaid payments to physicians for cesarean and vaginal births. Therefore, the benefits of lowering the C-section rate as outlined in Exhibit 6 would not translate directly to less Medicaid spending in Washington State. However, it could result in the reduced use of physician time and resources.

The cost of the program was set at Minnesota's current Medicaid reimbursement rate for the labor and delivery services only for doulas.⁵⁸ This does not include reimbursement for additional prenatal or postnatal education and/or counseling. For both private and Medicaid populations, the benefits do not exceed the costs of continuous support. Note that the current analysis only evaluates the cost-effectiveness of doula care in reducing C-sections, not for any additional outcomes evaluated in the literature including breastfeeding rates, the incidence of postpartum depression, etc.

| | Meta-a | analysis results | |
|------------------------|---------|------------------------|-------------------------------|
| Unadjusted effect size | p-value | Number of effect sizes | Number in treatment groups |
| -0.093 | 0.304 | 5 | 4,327 |

Exhibit 6

Meta-Analysis Results: Continuous Support for C-Section Reduction

⁵⁸ This approach likely underestimates the cost of a doula's services for private patients.

| Exhibit 7 |
|--|
| Benefit-Cost Results: Continuous Support for C-Section Reduction |

| Benefit-cost analysis results | | | | | |
|-------------------------------|----------------|---------|--|--------------------------|--------------------------------------|
| Population | Total benefits | Costs | Benefits minus costs (net present value) | Benefit to cost ratio | Chance benefits will exceed costs |
| Private Population | \$9 | (\$257) | (\$248) | \$0.04 | 4% |
| Medicaid Population | (\$32) | (\$257) | (\$289) | (\$0.12) | 0% |

D. Continuous Support Studies Included in the Meta-Analysis

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III. Transitional Care Programs

A. Background

Hospital readmissions are common and costly. According to the federal Agency for Healthcare Research and Quality (AHRQ), in 2011, about 14.7% of all hospital stays resulted in re-admissions among adult patients in the US. These readmissions were associated with about \$41.3 billion in hospital costs—about \$12,500 per readmission.⁵⁹ Exhibit 8 displays national hospital readmission rates.

The federal Medicare Payment Advisory Commission estimates that three quarters of readmissions among Medicare beneficiaries may be avoidable, accounting for \$12 billion in excess health care costs.⁶⁰

Several factors appear to contribute to avoidable readmissions. At the health care system level, inadequate communication between providers, poor patient education, a lack of continuity of care, and limited access to services have been found to be important.⁶¹ At the patient level, readmission rates are higher among those with chronic conditions, functional deficits, cognitive impairments, and emotional problems. According to one study, older patients with heart failure have the highest readmission rates.⁶²

| оз поѕрітаї г | Redumission Rat | .es. 2011 |
|---|------------------------|--|
| Insurance type | Number of readmissions | Percent of admissions that were readmitted* |
| Medicare Adults, age 65+ | 1,800,000 | 17.2% |
| Medicaid Adults, age 18-64 | 700,000 | 14.6% |
| Privately insured Adults, age 18-64 | 600,000 | 8.7% |
| Uninsured Adults, age 18-64 | 200,000 | 10.6% |
| Total (adults, age 18+) | 3,300,000 | 14.7% |

Exhibit 8 US Hospital Readmission Rates: 2011

*30-day all-cause readmission rate.

Source: AHRQ, (2014).

Since October 2012, the Centers for Medicare and Medicaid Services have imposed financial penalties for hospitals with higher than expected 30-day readmission rates among Medicare enrollees.

In Washington State, hospitals have the opportunity to earn incentive payments for actions taken to reduce readmissions under the Medicaid Quality Incentive Program, administered by the Washington State Health Care Authority.

⁵⁹ Agency for Healthcare Research and Quality, (2014).

⁶⁰ Hansen et al., (2011).

⁶¹ Naylor et al., (2004).

⁶² Ibid.

We examined evidence for the effectiveness of transitional care services in reducing hospital readmissions. These services include coaches, patient education, medication reconciliation, individualized discharge planning, scheduling follow-up provider visits, provider communication, and telephone and home visit followup.

B. Research Studies

We searched for studies in PubMed, Google Scholar, and the Cochrane Library. After examining abstracts, we conducted full reviews of 142 studies; 30 were included in the meta-analysis. These studies: a) met our methodological requirements; b) reported all-cause hospital readmission rates for one to three months after discharge;⁶³ c) included patients discharged to home rather than a nursing facility; and d) excluded pediatric, obstetric, and psychiatric patient populations.

Among the selected studies, 29 were randomized controlled trials, and one had a quasi-experimental design. Half the studies were from countries other than the US.

C. Meta-Analytic Findings

Transitional care programs vary in terms of intervention services and patient populations. In terms of services, we categorized programs as "comprehensive" or "post-discharge only."⁶⁴ Comprehensive interventions include pre-discharge assistance (e.g., a coach, enhanced discharge planning, and primary care provider communication) and post-discharge services. Post-discharge interventions include only patient assistance after release from the hospital. Many of these programs recruit high-risk, elderly, or chronically ill patients. Others recruit from general populations of admitted patients, without regard to age or medical condition.⁶⁵

In all, we located 30 rigorous evaluations of transitional care programs.⁶⁶ We find that these programs can reduce hospital readmissions (Exhibit 9). For example, the average program could reduce readmission rates from 14.7% to 11.8%.

Programs in the US have larger mean effects than those based in other countries. This is partially due to the mix of intervention types and recruited patient populations. Studies outside the US are less likely to evaluate comprehensive programs and are more likely to recruit non-chronically ill, elderly patients. Differences in health care systems may also contribute to differences in program effects across countries.⁶⁷

Our analysis of intervention types focuses on studies conducted in the US. Transitional care programs in the US typically recruit high-risk, elderly, and/or chronically ill patients (with chronic heart disease, coronary artery disease, diabetes, and stroke). Fewer studies recruit from general populations of admitted patients.

⁶³ Most studies (20) report 30-day rates, which is the current policy focus in the US.

⁶⁴ Six studies did not fall into these categories. Two studies reported on interventions with only pre-discharge services (treatment review and patient education). Four non-US studies examined other specific services that were difficult to categorize (e.g., follow-up at a clinic, pharmacist only interventions).

⁶⁵ See Bauer, J. (2015). *Reducing hospital readmissions: A review of the* evidence. (Doc. No. 15-01-3403). Olympia: Washington State Institute for Public Policy—Appendix Exhibit A1 for study descriptions and citations.

http://www.wsipp.wa.gov/ReportFile/1587/Wsipp_Reducing-Hospital-Readmissions-A-Review-of-the-Evidence_Report.pdf ⁶⁶ The 30 included studies produced a total of 32 effect sizes.

⁶⁷ Jaarsma et al., (1999) and Shepperd et al., (2013). We used weighted OLS regression to examine the effects of US versus non-US study location, controlling for one versus three-month readmission rate measurement, phone versus home visit follow-up, and participant population (elderly, chronic, and general) on study effect sizes. The analysis included 15 studies of comprehensive interventions. Study location was found to be a significant factor determining effect sizes.

Exhibit 10 and Exhibit 11 present mean effect sizes for US studies by intervention type and patient population.⁶⁸ We find that transitional care programs can reduce hospital readmissions, especially the comprehensive programs and those that target high risk patients.⁶⁹ For example, the typical comprehensive program reduced readmission rates from a base of 22% down to 15%.

Other reviews of the literature have found similar evidence indicating that transitional care programs do reduce readmission rates.⁷⁰

| Location | Average effect size | Standard error | p-value | Number of effect sizes | Number in treatment groups |
|----------|------------------------|----------------|---------|------------------------|-------------------------------|
| All | -0.152 | 0.041 | 0.000 | 32 | 4,901 |
| US | -0.205 | 0.056 | 0.000 | 17 | 2,590 |
| Non-US | -0.091 | 0.060 | 0.125 | 15 | 2,311 |

| Exhibit 9 |
|--|
| Transitional Care Effects on Readmissions: All, US, and Non-US Studies |

Exhibit 10

Transitional Care Effects on Readmissions: US Studies by Intervention Type

| Intervention type | Average effect size | Standard error | p-value | Number of effect sizes | Number in treatment groups |
|-------------------|------------------------|----------------|---------|------------------------|-------------------------------|
| Comprehensive* | -0.289 | 0.061 | 0.000 | 11 | 1,597 |
| Post-discharge** | -0.143 | 0.089 | 0.107 | 5 | 750 |

* Includes pre- and post-discharge services (coaches, patient education, enhanced discharge planning, primary care physician communication, and home or phone follow-up).

** Includes only post-discharge home or phone follow-up.

Exhibit 11

Transitional Care Effects on Readmissions: US Studies by Patient Population

| Patient Population | Average effect size | Standard error | p-value | Number of effect sizes | Number in treatment groups |
|-----------------------|------------------------|----------------|---------|------------------------|-------------------------------|
| High risk* | -0.278 | 0.060 | 0.000 | 12 | 1,375 |
| General | -0.155 | 0.107 | 0.147 | 4 | 972 |

* High-risk populations include the elderly and/or chronically ill.

⁶⁸ We use an intraclass correlation coefficient (ICC) of 0.01 to adjust estimates for studies that do not take participant clustering into account. This ICC is based on estimates reported by Kul et al., (2014); Li et al., (2012); and Singh et al., (2013). Sensitivity analysis, allowing the ICC to vary between 0.01 and 0.05, suggests that most inferences are not sensitive to choice of ICC. Note that a higher ICC value does increase the size and statistical significance for the mean effect size of post-discharge only interventions, though the effect remains smaller than that for comprehensive programs.

⁶⁹ We could not assess the relative effectiveness of home versus phone follow-up because of differences in patient populations across studies.

⁷⁰ See Leppin et al., (2014)and Naylor et al., (2011).

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IV. Patient-Centered Medical Homes

A. Background

The Patient-Centered Medical Home (PCMH) model attempts to increase health care efficiency by restructuring primary care. Definitions of PCMH vary, but medical homes typically include the following features:⁷¹

- Team-based: care is provided by a cohesive clinical team; a primary point of contact coordinates care where team members have defined roles and shared accountability.
- Comprehensive: most health care needs (preventive, acute, chronic, and mental health) are addressed by medical home providers.
- Coordinated: a care manager coordinates services with primary care providers, specialists, hospitals, and community service providers.
- Quality and safety: practices adopt system-based approaches to quality: evidence-based medicine, clinical decision-support tools, electronic health records, methods to track care, and identification of high-risk patients.
- Patient-centered: care is responsive to patient preferences and needs; decision-making is shared; patients are given self-management support.
- Enhanced access: expanded office hours, shorter waiting times for urgent needs, and enhanced communication (online or telephone) are emphasized.

Medical homes span two dimensions—provider structure and patient population. Both physician-led primary care practices and integrated health delivery systems have established medical homes. Some PCMHs include general patient populations, while others recruit high-risk elderly or chronically ill patients.

The *Medicaid Health Home*, a more recent variant of the PCMH model, focuses on comprehensive care for patients with serious mental illness and substance abuse disorders.⁷² Because WSIPP has previously reviewed the literature on health homes, in this appendix, we review PCMH studies with general patient populations, chronically ill patients, and elderly patients.

PCMH providers typically receive a per-member per-month (PMPM) care management payment, in addition to traditional fee-for-service payments, for establishing medical homes. Payers (private health insurers, Medicaid, Medicare) may also provide pay-for-performance bonuses, usually for meeting certain quality measures.

About half the states, including Washington, have implemented PCMH pilot projects for Medicaid enrollees.⁷³ Most pilot projects pay providers a PMPM fee aligned with a set of qualification standards, usually the National Committee for Quality Assurance (NCQA) medical home recognition.

⁷¹ See Peikes et al., (2011); Jackson et al., (2013); and Bao et al., (2013). PCMH definitions have been proposed by the Patient Centered Primary Care Collaborative, the Agency for Healthcare Research and Quality (AHRQ) and the National Committee for Quality Assurance (NCQA). The NCQA has set standards for medical homes and offers PCMH certification to providers. Some evaluations rely on NCQA certification to identify medical homes; others define medical homes based on practices having implemented many of the components listed above.

⁷² See Bao et al., (2013). WSIPP has reviewed the evidence on health homes; those findings are reported on our website:

http://www.wsipp.wa.gov/BenefitCost

⁷³ Takach, (2012) & (2011).

B. Research Studies

For this review, we searched PubMed, Google Scholar, and the Cochrane Library for studies published through September 2014. After examining abstracts, we conducted full reviews of 67 studies and 11 of these were included in the meta-analysis. The included studies met our methodological requirements and reported the outcomes of interest discussed earlier. Only two evaluations utilized a randomized controlled study design. The majority of included studies used an observational, quasi-experimental design, which typically examined outcomes before and after PCMH implementation relative to a comparable group of physician practices.

While the evidence base is growing, researchers face methodological challenges in evaluating and comparing outcomes for PCMH implementations.

Small sample sizes and patient clustering

Most studies of PCMHs include relatively small numbers of clinics or physician practices. Medical homes are established at the practice or clinic level, and the number of practices included in a study is critical to the validity of an evaluation. For example, a study might include thousands of patients. However, if these patients are based in only a few large clinics, the study may lack the statistical power to identify variation in medical home providers and detect effects on utilization or costs.

The number of practices required for an evaluation depends on the extent to which patient outcomes are correlated (or clustered) within a practice. If providers strongly influence patient outcomes, this clustering issue would be important, and evaluation results might vary substantially depending on which providers were included in intervention and comparison groups. Studies that fail to explicitly account for clustering in medical practices can overstate the statistical significance of their findings.⁷⁴

Substantial variation in utilization and costs

A related problem occurs when there is wide variation in costs of care and utilization rates for some services (e.g., hospital admissions) across providers. The high variance makes it difficult to isolate the effects of medical homes from disparities that may normally occur (random variation). Patient outcomes in the general population typically display wide variation—a portion of the population has little or no utilization and another segment may have heavy utilization. By including this range of outcomes, it is typically more difficult to observe program impacts. On the other hand, studies may find significant effects for chronically ill patients since utilization and costs vary less among this subset of high-risk patients.⁷⁵

Study design and selection bias

Only a few randomized controlled trials of PCMHs have been conducted. Most completed studies are observational, examining outcomes before and after implementation in practices that choose to become medical homes. The more rigorous evaluations identify comparison practices that are similar to pilot practices in terms of numbers of providers, physician specialties, use of healthcare information technology, patient demographics, and baseline utilization and costs. Without random assignment of provider practices, even the best observational

⁷⁴ Peikes et al., (2011). In our meta-analyses we used intra-class correlation coefficients to account for patient clustering when studies did not do so.

⁷⁵ Ibid.

studies are subject to potential selection biases. This selection bias can occur because practices volunteer to become medical homes.⁷⁶ Selection bias can also arise when patients can opt into medical homes.⁷⁷

C. Meta-Analytic Findings

We reviewed evidence on the effectiveness of PCMHs in reducing emergency department visits, hospitalizations, and total medical costs. We report average effect sizes for all PCMHs, those in integrated health systems, those in physician-led practices, and models that recruit high-risk patients.⁷⁸

Emergency Department Visits

We find emerging evidence that PCMHs can reduce emergency department visits (Exhibit 12).⁷⁹ Across the eight studies in our analysis, medical homes reduce visits by about 3%. The most significant result is for a PCMH in a large integrated health delivery system.⁸⁰ Among those in smaller, physician-led practices, the results are less robust.⁸¹

In addition to our own meta-analysis of the effect of PCMHs on emergency department visits, we located two other systematic reviews. These other reviews also report mixed results for PCMH effects on emergency department utilization.⁸²

⁷⁶ See Peikes et al., (2012); Alexander & Bae, (2012); and Devries et al., (2012).

⁷⁷ For example, Medicare members in Geisinger Health Plan had the opportunity to opt into practices implementing the Personal Health Navigator medical home model. Ackroyd & Wexler (2014) note that outcomes are compared between those who opted in versus those who did not, potentially confounding results.

⁷⁸ See Bauer, J., & Burley, M. (2015). *Patient-centered medical homes: A review of the evidence*. (Doc. No. 15-01-3402). Olympia: Washington State Institute for Public Policy. Appendix Exhibit A1 for individual study descriptions and findings.

⁷⁹ We use an intraclass correlation coefficient (ICC) of 0.038 to adjust estimates for studies that do not take participant clustering into account. This ICC is based on estimates reported by Dale & Lundquist, (2011); Huang et al., (2005); Leff et al., (2009); Littenberg & MacLean, (2006); and Rosenthal et al., (2013). Sensitivity analysis, allowing the ICC to vary between 0.01 and 0.10, suggests that inferences are not sensitive to choice of ICC.

⁸⁰ Reid et al., (2013) examined a PCMH pilot project at Group Health Cooperative in Washington State.

⁸¹ Three studies also report effects on ambulatory care sensitive (ACS) emergency department visits—Friedberg et al., (2014); Rosenthal et al., (2013); and Werner et al., (2013). The average effect size for ACS visits is also not significant.

⁸² Jackson et al., (2013) and Williams et al., (2012).

| Exhibit 12 |
|---|
| Emergency Department Utilization Effects |

| Implementation type | Average effect size | Standard error | p-value | Number of studies | Number in treatment groups |
|---|------------------------|-------------------|---------|----------------------|----------------------------------|
| All types ⁽¹⁾ | -0.019 | 0.010 | 0.049 | 8 | 459,478 |
| Integrated health system ⁽²⁾ | -0.032 | 0.004 | 0.000 | 1 | 305,578 |
| Physician-led practices (by target populations) All populations ⁽³⁾ | -0.015 | 0.010 | 0.148 | 7 | 153,900 |
| General patient populations ⁽⁴⁾ | -0.013 | 0.012 | 0.251 | 5 | 122,753 |
| High-risk patients ⁽⁵⁾ | -0.034 | 0.030 | 0.252 | 3 | 31,147 |

Studies included:

(1) Reid et al., (2013); Boult et al., (2011); Werner et al., (2013); David et al., (2014); Wang et al., (2014); Friedberg et al., (2014); Rosenthal et al., (2013); and Fifield et al., (2013).

(2) Reid et al., (2013).

(3) Boult et al., (2011); Werner et al., (2013); David et al., (2014); Wang et al., (2014); Friedberg et al., (2014); Rosenthal et al., (2013); and Fifield et al., (2013).
(4) Werner et al., (2013); David et al., (2014); Friedberg et al., (2014); Rosenthal et al., (2013); and Fifield et al., (2013).

(5) Boult et al., (2011); David et al., (2014); and Wang et al., (2014).

Hospital Admissions

We located eight studies that measure hospital admissions as an outcome.⁸³ We find no observable effect of PCMHs on hospital admissions, on average (Exhibit 13).⁸⁴

Total Cost of Care

We located six studies that measure total cost of care. We find no significant effect on total cost of care (Exhibit 14).⁸⁵ Again, our meta-analytic result is consistent with published systematic reviews conducted by others.⁸⁶ Cost and utilization measures may or may not be an indication of health status or well-being.

⁸³ Reid and colleagues (2010) evaluated a medical home implementation at Group Health Cooperative, a large integrated health care system in Washington. They found the PCMH reduced admissions. In a later study for Group Health Cooperative, included in our analysis, Reid and colleagues (2013) found no significant effect on hospital admissions after accounting for patient clustering.

⁸⁴ Estimates use an intraclass correlation coefficient (ICC) of 0.022 to correct of participant clustering when the study does not; this ICC is based on averaging across estimates reported by Dale & Lundquist, (2011); Huang et al., (2005); Leff et al., (2009); and Rosenthal et al., (2013). Sensitivity analysis, allowing the ICC to vary between 0.01 and 0.10, indicates that estimates do not change substantially.

⁸⁵ We use an intraclass correlation coefficient (ICC) of 0.026 to adjust estimates when a study does not take participant clustering into account. This ICC is based on averaging across estimates reported by Dale & Lundquist, (2011) and Campbell et al., (2001). Sensitivity analysis, allowing the ICC to vary between 0.01 and 0.10, indicates that inferences are not sensitive to the choice of ICC.

⁸⁶ A comprehensive review by Peikes et al., (2012) identified four rigorous evaluations reporting effects on total patient costs. Only one evaluation found evidence of savings for a high-risk subgroup of Medicare enrollees. Two other systematic reviews found no evidence of cost savings—Williams et al., (2012) and Jackson et al., (2013).

Exhibit 13 Hospital Admission Effects

| Implementation type | Average effect size | Standard error | p-value | Number of studies | Number in treatment groups |
|---|---------------------|----------------|---------|----------------------|----------------------------|
| All types ⁽¹⁾ | 0.001 | 0.003 | 0.847 | 8 | 385,985 |
| Integrated health system ⁽²⁾ | 0.001 | 0.004 | 0.766 | 2 | 314,212 |
| Physician-led practices ⁽³⁾ | -0.0004 | 0.005 | 0.934 | 6 | 71,778 |

Studies included:

(1) Reid et al., (2013); Boult et al., (2011); Werner et al., (2013); Wang et al., (2014); Friedberg et al., (2014); Rosenthal et al., (2013); Fifield et al., (2013); and Gilfillan et al., (2010).

(2) Reid et al., (2013) and Gilfillan et al., (2010).

(3) Boult et al., (2011); Werner et al., (2013); Wang et al., (2014); Friedberg et al., (2014); Rosenthal et al., (2013); and Fifield et al., (2013).

Exhibit 14 Total Cost of Care Effects

| Implementation type | Average effect size | Standard error | p-value | Number of studies | Number in treatment groups |
|---|---------------------|-------------------|---------|----------------------|----------------------------|
| All types ⁽¹⁾ | 0.004 | 0.006 | 0.431 | 6 | 75,632 |
| Integrated health system ⁽²⁾ | -0.021 | 0.071 | 0.771 | 2 | 15,652 |
| Physician-led practices ⁽³⁾ | 0.005 | 0.006 | 0.416 | 4 | 59,980 |
| High-risk patients (4) | -0.040 | 0.029 | 0.178 | 3 | 12,472 |

Studies included:

(1) Reid et al., (2010); Werner et al., (2013); Wang et al., (2014); Friedberg et al., (2014); Fifield et al., (2013); and Gilfillan et al., (2010).

(2) Reid et al., (2010) and Gilfillan et al., (2010).

(3) Werner et al., (2013); Wang et al., (2014); Friedberg et al., (2014); and Fifield et al., (2013).

(4) Wang et al., (2014); Gilfillan et al., (2010); and Fishman et al., (2012). These include two integrated health system and one physician-led practice implementation.

Other Outcomes

Our meta-analysis focuses on outcomes where costs and benefits can be determined through economic analysis—emergency department visits, hospital admissions, and total cost of care.

Evaluations completed to date have found mixed results for other outcomes associated with PCMHs. Studies find small to moderate positive effects on both patient and provider experiences and on some measures of care quality.⁸⁷ However, the evidence on health outcomes is inconclusive; a few studies find improvements in patient outcomes while other studies show no effect.⁸⁸ It is difficult to estimate monetary benefits for many outcomes included in these studies.

⁸⁷ Jackson et al., (2013); Williams et al., (2012); Friedberg et al., (2014); and Arend et al., (2012).

⁸⁸ Jackson et al., (2013); Peikes et al., (2012); Williams et al., (2012); and Jaen et al., (2010).

D. Patient-Centered Medical Home Studies Included in the Meta-Analysis

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E. Additional Patient-Centered Medical Home Studies

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IV. Accountable Care Organizations

A. Background

Description

An Accountable Care Organization (ACO) is a group of medical providers responsible for the cost and quality of care for a patient population. ACO contracts offer financial incentives to increase efficiency. Providers may receive a share of cost savings relative to a spending target and bonus payments for meeting quality benchmarks.⁸⁹

ACO contracts impose varying degrees of financial risk on providers. In some contracts, with "upside and downside" risk, providers are required to absorb a portion of costs that exceed spending targets. In contracts with "upside risk" only, ACOs may share in cost savings below the target but are not responsible for costs above it. However, even in these contracts, providers are at risk of not recouping the investments required to become an ACO (e.g., spending on improvements in information technology and hiring additional staff).

Commercial insurers, state Medicaid programs, and the federal Centers for Medicare and Medicaid Services (CMS) have established ACOs. As of January 2015, there were 744 ACOs covering 23.5 million individuals.⁹⁰ Integrated delivery systems (e.g., Kaiser Permanente, Group Health Cooperative), hospitals, multi-specialty physician groups, and independent physician practice associations have entered ACO contracts.

Strategies

ACOs can achieve cost savings by reducing utilization and by shifting services to lower-cost settings and providers. Organizations attempt to achieve these through both supply-side medical management (e.g., referral management to specialists, prior authorization for selected services) and demand-side management (e.g., case management, disease management, transitional care programs).⁹¹ Opportunities for cost savings vary across patient populations and types of coverage. In Medicare, fees are standardized and potential savings come mainly through reduced utilization (fewer hospital admissions and readmissions). In commercial contracts, where there is greater price variation, savings may also be obtained by managing referrals.⁹²

Challenges

Several challenges may constrain ACO cost performance. First, it is difficult to set valid spending targets for the organizations. Among the 13 organizations that left the Medicare Pioneer ACO program, for example, CMS cost benchmarks appear to have underestimated actual savings, and low incentive payments were a factor in their decisions to leave.⁹³ In particular, targets are difficult to set among providers that are already efficient, with few opportunities to cut spending.

Second, it is difficult to allocate shared savings across providers in the organization. Attributing cost savings to individual physicians is hard because of differences in case mix and random variation in patient outcomes.

⁸⁹ See: Auerbach et al., (2013); Barnes, Chukmaitov, & van Ginneken, (2014); Damberg et al., (2014); Lewis et al, (2014); Shortell et al., (2014).

⁹⁰ Muhlestein, (2015).

⁹¹ Fitch, Murphy-Barron, & Mirkin, (2010); Silow-Carroll and Edwards, (2013).

⁹² Song et al., (2014).

⁹³ McWilliams et al., (2015).

Also, there are ethical concerns about giving financial incentives that may limit provision of care.⁹⁴ Therefore, in many ACOs financial incentives are not passed through to individual physicians. Meanwhile, specialists, who continue to receive fee-for-services payments, and hospitals, which are paid flat rates per stay, benefit from higher utilization.⁹⁵

Third, provider organizations that participate in an ACO may also have fee-for-service contracts with other payers. The organizations benefit from shared-savings payments in their ACO contracts if utilization is reduced. However, changes in their care practices may also lower revenues from their fee-for-service contracts.⁹⁶

Finally, there is concern that ACOs may reduce competition, resulting in higher prices in the long-term. ACO implementation may promote consolidation among hospitals and physicians, enhancing their negotiating power with health plans.⁹⁷

B. Research Studies

We reviewed 35 studies of ACOs and included 11 in our meta-analysis. We excluded studies that: 1) were descriptive only, 2) did not include adequate comparison groups, 3) failed to provide sufficient information to assess methodology, and 4) did not provide information required to calculate effect sizes

The included studies evaluated three ACOs: 1) the Alternative Quality Contract for commercial insurance plans in Massachusetts, 2) the Physicians Group Practice Demonstration for Medicare beneficiaries, and 3) the Medicare Pioneer ACO Program. Evidence for recent Medicaid ACO implementations is emerging, but studies do not yet support a meta-analysis.

The typical study includes pre-post designs with a comparison group (difference-in-differences), uses propensity score matching or weighting, controls for patient demographics and risk (health conditions), and accounts for clustering of patients into physician practices or provider groups. A potential weakness in these studies is that systematic, unobserved differences between ACO and comparison group providers may exist due to the self-selection of organizations into these contracts.

C. Meta-Analytic Findings

Studies examined ACO effects on costs and quality of care. We focus on the extent to which ACOs have been able to reduce total medical costs. Our primary outcome is the percentage change in medical costs per person. We use inverse variance weights, based on the standard errors for estimates, to calculate average effects for ACOs.

Evaluations of health care policies and programs often measure two broad types of outcomes: 1) those that reflect the health status of people (e.g., disease incidence), and 2) those that reflect health care system costs and utilization. Cost and utilization measures may or may not be an indication of health status or well-being.

⁹⁴ Friedberg et al., (2015).

⁹⁵ Song et al., (2014); Friedberg et al., (2015); Pope et al., (2014); and Landon, (2012).

⁹⁶ Friedberg et al., (2015); Toussaint et al., (2013).

⁹⁷ Frech et al., (2015); Berenson et al., (2012); Song, (2014); Friedberg et al., (2015).

Commercial ACOs

Blue Cross Blue Shield, Cigna, Aetna, United Healthcare and other insurers have established ACOs.⁹⁸ We were able to estimate effect sizes for one of the largest and most heavily studied commercial ACOs, the Alternative Quality Contract (AQC) implemented in 2009 by Blue Cross Blue Shield (BCBS) of Massachusetts. BCBS pays providers a fixed payment reflecting total expected costs for a patient population, shared savings relative to targets, and incentive payments for meeting quality thresholds. Providers are at risk for costs above the target.

The AQC achieved substantial reductions in medical costs. On average, between 2009 and 2012, AQC provider costs were 8% lower relative to comparison group providers (see Exhibit 15). Savings, as a percentage of total costs, increased from 2.4% in 2009 to 10% by 2012. Initial savings were largely achieved through shifting referrals to less expensive providers and settings. In the later years, savings were from both reduced utilization and reduced prices.⁹⁹

These cost reductions do not represent net savings to BCBS. Song and colleagues (2014) report that BCBS incentive payments (including shared savings, quality bonuses, and infrastructure investments) ranged from 6% to 13% of claims costs over the four years. Incentive payments exceeded cost savings during the first three contract years, but BCBS had modest net savings in the fourth year.¹⁰⁰

Medicare Demonstration

The CMS implemented the Medicare Physician Group Practice Demonstration (PGPD) between 2005 and 2009. Ten provider organizations entered five-year ACO contracts. They were eligible to receive up to 80% of savings relative to spending targets, conditional on their performance on quality measures. Providers were not responsible for costs above target, but they were at risk of not recouping the investments required to become an ACO (e.g., improvements in information technology and additional staffing).¹⁰¹

Over the five years, the organizations reduced costs by an average of 2% relative to comparison groups (see Exhibit 15). Net savings to Medicare, which paid performance bonuses to these organizations, was lower.¹⁰² Performance varied substantially across the ten organizations, with some achieving large savings and others none.¹⁰³

PGPD provider organization strategies for increasing efficiency included: establishing electronic medical records, using evidence-based guidelines, creating disease registries, improving care management and care transitions, and expanding the role of non-physician providers. Cost reductions accrued mainly from reduced hospitalizations.¹⁰⁴

Savings estimates are sensitive to how studies adjust for patient risk. The CMS adjusts spending targets for changes in patient risk scores (based on diagnoses codes). Risk scores increased more rapidly for some

⁹⁸ Lewis et al., (2014).

⁹⁹ Song et al., (2012); Song et al., (2014).

¹⁰⁰ Estimated AQC savings in 2012 were 10% in terms of total claims costs; incentive payments were in the range of 6% to 9%. Song et al., (2014).

¹⁰¹ ACO investments during the first year averaged \$1.7 million. Berenson et al., (2012).

¹⁰² Pope and colleagues estimate that cost savings averaged \$171 (2.0%) per beneficiary person year, Medicare paid performance bonuses averaging \$102 per person year, yielding a net savings estimate of \$69 (0.8%) per person year. Pope et al., (2014).

¹⁰³ Colla et al., (2012); Pope et al., (2014).

¹⁰⁴ Colla et al., (2014); Pope et al., (2014).

demonstration organizations than for comparison groups, raising a concern that some of the apparent savings may have been due to changes in coding practices.¹⁰⁵

Medicare ACOs

The CMS began to implement Medicare ACOs in 2012. There are two main models with different levels of financial risk for providers. In the Medicare Shared Savings Program, ACOs may receive up to 50% of savings relative to cost benchmarks and are not responsible for costs that exceed targets. In the Pioneer ACO program, organizations can receive up to 60% of savings relative to a spending benchmark, but they are also responsible for costs above target. In both models, cost sharing payments are contingent upon performance on quality of care measures.

The studies included in our meta-analysis evaluated the Pioneer ACO program. Thirty-two organizations entered the Pioneer ACO program in 2012 but 13 subsequently withdrew from the program. Patient populations were elderly, with an average age of 71 years.

Studies have examined performance over the first two contract years. On average, Pioneer ACOs achieved a 2% cost reduction relative to comparison groups (see Exhibit 15). Again, these reductions do not represent net savings to Medicare. The estimates do not reflect cost-sharing payments made to providers or the CMS costs in administering the program.

Medicare ACO strategies have focused on improving care coordination for patients with chronic conditions.¹⁰⁶ Savings where achieved though decreases in inpatient hospital costs, lower skilled nursing facility utilization, and by shifting care from hospital outpatient settings to lower-priced office settings.¹⁰⁷

| Topic and specific outcomes measured | Number of effect sizes | Average effect size | Standard error | p-value | Number in treatment groups |
|---|------------------------|------------------------|-------------------|---------|----------------------------------|
| Accountable Care Organizations: Alternati | ve Quality Contract | (AQC) | | | |
| Health care costs* | 4 | -0.075 | 0.013 | 0.001 | 1,348,235 |
| Emergency department visits* | 1 | 0.007 | 0.013 | 0.607 | 380,142 |
| Prescription drug costs* | 1 | -0.002 | 0.019 | 0.923 | 332,624 |
| Accountable Care Organizations: Medicare | e Physician Group P | ractice Demonstrat | tion (PGPD) | | |
| Health care costs* | 2 | -0.019 | 0.002 | 0.001 | 1,213,380 |
| Accountable Care Organizations: Medicare | e Pioneer ACOs | | | | |
| Health care costs* | 3 | -0.021 | 0.010 | 0.030 | 1,683,614 |
| Hospital costs (inpatient)* | 3 | -0.025 | 0.009 | 0.004 | 1,683,614 |
| Hospital costs (outpatient)* | 3 | -0.027 | 0.016 | 0.092 | 1,683,614 |
| Skilled nursing facility costs* | 3 | -0.019 | 0.004 | 0.001 | 1,683,614 |

Exhibit 15 Meta-Analytic Results for Accountable Care Organizations

*The effect size for this outcome indicates percentage change, not a standardized mean difference effect size.

¹⁰⁵ Colla et al., (2014); Pope et al., (2014).

¹⁰⁶ Dupree et al., (2013); Barnes et al., (2014); Lewis et al., (2014).

¹⁰⁷ McWilliams et al., (2015).

D. Accountable Care Organization Studies Included in the Meta-Analysis

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E. Additional Accountable Care Organization Studies

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VI. Patient Cost Sharing

A. Background

Healthcare reform elevated the visibility of patient cost sharing on state policy agendas. Medicaid expansion and new federal regulations allow for more extensive use of cost sharing in public health insurance programs for low-income populations. Also, individuals, many with moderate incomes, are opting for high-deductible health plans offered in state health exchanges.¹⁰⁸

Definitions

Copays, coinsurance rates, deductibles and out-of-pocket maximums determine cost-sharing levels in health insurance plans. The following are definitions for cost-sharing mechanisms:

- Copays—a fixed amount paid for a service (for example, \$20 per office visit)
- Coinsurance—a percentage of total charges for a service, paid after the deductible is exceeded (for example, 20% of allowable charges for a hospital stay)
- Deductible—amount that the insured must pay before insurance pays a claim
- High-Deductible Health Plan (HDHP)—insurance plans with higher deductible levels than traditional plans (per 2016 IRS regulations, HDHPs have deductibles of at least \$1,300 for individuals and \$2,600 for families)
- Health savings accounts (HSAs)—funds used to cover patient cost-shares in HDHPs, both employers and employees can contribute to the account, employee-owned (portable), funds can accumulate
- Health reimbursement arrangements (HRAs)—funds used to cover patient cost-shares in HDHPs, funded by employers, employer-owned (not portable), unused amounts may rollover
- Out-of-pocket maximum—the maximum amount an insured person has to pay during a year (for example, 2016 IRS guidelines specify HDHP maximums of \$6,550 individual/\$13,100 family)

B. Research Studies

We reviewed 113 studies that examine the effects of patient cost sharing, and 42 were included in our metaanalyses. We excluded studies that: 1) failed to address self-selection of individuals into health plans, 2) had no comparison group or did not control for differences between groups, 3) did not provide sufficient information to access methodology, 4) did not report data required to calculate effect sizes, and 5) were unable to isolate effects of cost sharing changes from other benefit or enrollment changes.

Methodological Challenges

The typical study includes a pre-post design with a comparison group, propensity score matching or weighting, and controls for differences in patient demographics and risk (health conditions) across groups. The main potential for bias arises from self-selection into health plans with different levels of cost-sharing. There is a tendency for plans with lower cost sharing to attract higher-risk people who expect to need more medical care (adverse selection). Younger, healthier people tend to opt for less generous plans, which have lower premiums. Evaluations attempt to minimize this bias by studying individuals where cost sharing levels

¹⁰⁸ Wharam et al., (2013). Wharam et al., (2013).

are determined by decisions made by employers. For example, several studies examined cases where an employer shifts from offering a traditional plan to a high-deductible health plan on a full-replacement basis.¹⁰⁹

The effect of cost-sharing on medical costs and utilization may be indirect, take years to occur, and, therefore, be difficult to identify. For example, an increase in office visit copays may affect use of prescription drugs. Prescription drug copays may reduce medication adherence, resulting in increased hospitalizations a few years later.¹¹⁰ Finally, it may not be possible, in some cases, to isolate the effects of increased cost sharing from changes in other factors that occur at the same time (e.g., implementation of disease management programs, tighter program eligibility requirements, and falling enrollment levels).

C. Meta-Analytic Findings

Our meta-analysis examines several outcomes, including: medical costs, utilization of selected medical services (emergency departments, prescription drugs), potential adverse impacts (reduced medication adherence and receipt of preventive services), offsets to cost savings (hospitalizations), and effects on health. Average effect sizes for these outcomes are calculated using inverse variance weights. In cases were the effect size is a percentage change in the outcome, inverse variance weights are derived from standard error estimates.

Effects vary by the level and type of cost sharing (e.g., modest copays versus high-deductible health plans). Effects also vary across different patient populations (general, low-income, and chronically ill). We report effect sizes, where possible, by type of cost sharing and population. In some of these cases, effect sizes are based on only one or two studies. Meta-analytic results are summarized below. We do not yet know the long-term health effects that might arise from high levels of cost-sharing and have not conducted a benefit-cost analysis for this topic.

Evaluations of health care policies and programs often measure two broad types of outcomes: 1) those that reflect the health status of people (e.g., disease incidence), and 2) those that reflect health care system costs and utilization. Cost and utilization measures may or may not be an indication of health status or well-being.

Medical Spending & Utilization

We find that higher coinsurance rates, larger copays, and replacement of traditional insurance with highdeductible health plans (HDHPs) reduce medical spending, at least in the short-term. People respond to higher prices by reducing utilization. Among general patient populations, a 10% increase in the price of medical services reduces expenditures by about 2% (a price elasticity of -0.2). We find a similar price effect for low-income individuals, but spending by the chronically ill appears to be less responsive to price increases.¹¹¹

We find evidence that cost sharing has substantial effects on utilization and spending (see Exhibit 16). For example:¹¹²

- A 25% coinsurance rate (versus free care) reduces total medical expenditures by 19%.
- Emergency department (ED) copays of \$25 to \$50 (2014 dollars) reduce ED visits by 12% among the general population.

¹⁰⁹ This may limit the generalizability of results across employers. Baicker et al., (2011); Haviland et al., (2015).

¹¹⁰ Baicker & Goldman, (2011).

¹¹¹ Manning, (1987); Chandra et al., (2014).

¹¹² Please see our website for a complete listing of all effect sizes for this topic. http://www.wsipp.wa.gov/BenefitCost?topicId=6

- Modest increases in prescription drug copays (\$3 to \$5) reduce drug spending by 8% in a public health insurance program serving low-income children (CHIP).
- Replacing traditional insurance with high deductible health plan reduces medical spending, on average, by 18%.¹¹³ Effects vary with the type of optional health spending accounts; costs were reduced by 24% in plans with HSA accounts versus 15% in those with HRAs.

Higher cost sharing could reduce medical costs by inducing individuals to 1) reduce utilization and 2) search for lower price providers (price shopping). Evidence from the RAND Health Insurance experiment and a more recent study of HDHP implementation find that most of the effect is from reduced utilization.¹¹⁴

Unintended Effects

These cost reductions may have unintended, potentially adverse effects—especially for individuals with modest incomes and chronic illnesses. In our meta-analysis, we find (see Exhibit 16):

- Cost sharing, in some cases, reduces both "low-severity" and "high-severity" ED visits. In the RAND Health Insurance Experiment, having a coinsurance rate of 25% or higher (versus free care) reduced less-urgent ED visits by 47%, but "urgent" visits also fell by 23%.¹¹⁵ Among low-income members of high-deductible health plans in Massachusetts, higher-severity visits declined by 25%.¹¹⁶
- Prescription drug copays reduce adherence to drugs used to treat chronic conditions, such as high blood pressure and cholesterol; reducing copays improves adherence. Medication adherence is also reduced modestly in HDHPs when prescription drug costs are subject to the high deductibles.
- HDHPs moderately reduce utilization of cancer screening (breast, cervical, colorectal), preventive office visits, and preventive lab tests. This occurs even though these services are not subject to the high deductibles, possibly because of reduced contact with medical providers. Across the studies included in our analysis, HDHP implementation reduced colorectal cancer screening rates by 2 to 5 percentage points, mammography screening by 3 percentage points, and cervical cancer screening rates by 2 to 5 percentage points.

Medicaid nonemergent ED copays

ED copays reduce ED visits among general and low-income (non-Medicaid) populations. Medicaid plans, however, may impose copays only for ED visits that are determined to be nonemergent. Two studies examined the experience of states these copays and found no significant effects on ED visits.¹¹⁷ ED copays for nonemergent use are difficult to implement, in part because a patient's presenting conditions do not predict well whether or not the patient requires emergency care.¹¹⁸

Health Outcomes

In our review of the research, we found little information on the long-term health effects that might arise from high levels of cost-sharing and have not conducted a benefit-cost analysis for this topic.

¹¹³ This estimate is for HDHPs with individual deductibles of \$1000 or more.

¹¹⁴ RAND, 2006; Brot-Goldberg et al., 2015.

¹¹⁵ O'Grady et al., 1985.

¹¹⁶ Wharam et al., 2013.

¹¹⁷ Siddiqui et al., (2015).

¹¹⁸ Raven et al., (2013) and Ollove, (2015).

The RAND Health Insurance Experiment in the 1970s found that, on average, there were minor or no effects on health from higher cost sharing. The experiment did find, however, cost sharing had an adverse effect on blood pressure control among low income persons in poorer health.¹¹⁹ Some have argued that the RAND findings may be less relevant today. There are now more effective treatments for chronic diseases, and the adverse health effects may be greater.¹²⁰

Cost Offsets

We did not find evidence that the cost reductions from copays and HDHPs are offset through more hospitalizations in either general or low-income populations. One study found that higher prescription drug office visit copays among elderly, Medicare beneficiaries was associated with an increase in hospital costs per member.¹²¹

| Topic and specific outcomes measured | Number of effect sizes | Average effect size | Standard error | p-value | Number in treatment groups |
|--|------------------------|------------------------|-------------------|---------------|----------------------------------|
| Cost sharing: Coinsurance (25% rate or higher |) versus no cost | sharing, general p | atient popula | tion | |
| Health care costs** | 1 | -0.170 | 0.020 | 0.001 | 1,137 |
| Health care costs* | 1 | -0.189 | 0.047 | 0.001 | 1,137 |
| Emergency department visits* | 1 | -0.210 | 0.081 | 0.010 | 2,296 |
| Emergency department visits (higher-severity)* | 1 | -0.230 | 0.059 | 0.001 | 5,392 |
| Emergency department visits (lower-severity)* | 1 | -0.470 | 0.049 | 0.001 | 5,392 |
| Diastolic blood pressure | 1 | 0.079 | 0.036 | 0.027 | 2,339 |
| Cholesterol | 1 | -0.036 | 0.037 | 0.327 | 2,262 |
| Cost sharing: Copay increases across multiple | services, low-in | come population | | | |
| Health care costs** | 1 | -0.158 | 0.064 | 0.014 | 122,456 |
| Emergency department costs** | 1 | -0.207 | 0.152 | 0.175 | 122,456 |
| Hospital costs (inpatient)** | 1 | -0.115 | 0.250 | 0.646 | 122,456 |
| Prescription drug costs** | 1 | -0.131 | 0.074 | 0.076 | 122,456 |
| Cost sharing: Copay increases across multiple | services, low-in | come and chronica | ally-ill populat | tion | |
| Health care costs** | 1 | -0.057 | 0.094 | 0.545 | 37,961 |
| Cost sharing: Copays for prescription drugs, a | dults with a chr | onic illness | | | |
| Medication adherence | 2 | -0.602 | 0.118 | 0.001 | 652 |
| Cost sharing: Copay reductions for prescriptio adults with chronic illnesses | n drugs used to | treat chronic cond | ditions (Value | Based Insuran | ce Design), |
| Medication adherence | 10 | 0.045 | 0.005 | 0.001 | 76,223 |
| Cost sharing: Copays for prescription drugs, g | eneral patient p | opulation | | | |
| Hospitalization (general) | 1 | 0.000 | 0.015 | 1.000 | 6,881 |
| Prescription drug costs** | 1 | -0.041 | 0.009 | 0.001 | 16,783 |

Exhibit 16 Meta-Analytic Results for Cost Sharing

* The effect size for this outcome indicates percentage change, not a standardized mean difference effect size.

** The effect size for this outcome represents an elasticity, not a standardized mean difference effect size.

¹¹⁹ Brook, 1984.

¹²⁰ Chernew & Newhouse, (2008).

¹²¹ Chandra et al., (2010).

Exhibit 16 (Continued)

Meta-Analytic Results for Cost Sharing

| Topic and specific outcomes measured | Number of effect sizes | Average effect size | Standard error | p-value | Number in treatment groups |
|---|------------------------|------------------------|----------------------|-----------------|----------------------------------|
| Cost sharing: Copays for prescription drugs, lo | ow-income child | ren (CHIP) | | | |
| Prescription drug costs* | 1 | -0.079 | 0.031 | 0.009 | 17,200 |
| Cost sharing: Copays for prescription drugs, lo | - | | | | 17,200 |
| Prescription drug costs* | 1 | -0.036 | 0.014 | 0.009 | 4,644 |
| Cost sharing: Copays for prescription drugs, N | | | 0.011 | 0.005 | 1,011 |
| Hospital costs (inpatient)* | 1 | 0.054 | 0.019 | 0.005 | 35,456 |
| Prescription drug costs* | 1 | -0.320 | 0.026 | 0.001 | 35,456 |
| Cost sharing: Emergency department copays, | _ | | 0.020 | 0.001 | 55,150 |
| Emergency department visits* | 2 | -0.121 | 0.003 | 0.001 | 1,158,999 |
| Emergency department visits (higher-severity)* | 1 | -0.058 | 0.095 | 0.543 | 30,276 |
| Emergency department vists (lower-severity)* | 1 | -0.292 | 0.046 | 0.001 | 30,276 |
| Hospitalization (general)* | 2 | -0.039 | 0.009 | 0.001 | 1,158,999 |
| Cost sharing: Emergency department copays, | - | | 0.005 | 0.001 | 1,130,333 |
| Emergency department visits* | 1 1 | -0.153 | 0.006 | 0.001 | 254,431 |
| Hospitalization (general)* | 1 | -0.053 | 0.000 | 0.001 | 254,431 |
| | _ | | | | 234,431 |
| Cost sharing: Copays for nonemergent emerg | 2 | 0.031 | 0.064 | 0.630 | 21 074 |
| Emergency department visits* | — | | | | 21,074 |
| Cost sharing: Various High-Deductible Health | Plan designs (m | noderate to high d | eductibles, wit | th and withou | t HKAs or |
| HSAs), general patient population | | | | | |
| Health care costs* | 10 | -0.116 | 0.026 | 0.001 | 5,052,573 |
| Emergency department costs* | 2 | -0.071 | 0.086 | 0.407 | 52,058 |
| Emergency department visits* | 1 | -0.150 | 0.032 | 0.001 | 15,847 |
| Emergency department vists (lower-severity)* | 1 | -0.196 | 0.047 | 0.001 | 15,847 |
| Emergency department visits (higher-severity)* | 1 | -0.097 | 0.098 | 0.323 | 15,847 |
| Hospitalization (general)* | 1 | -0.118 | 0.091 | 0.196 | 15,847 |
| Prescription drug costs* | 3 | -0.047 | 0.013 | 0.001 | 63,193 |
| Medication adherence | 8 | -0.092 | 0.038 | 0.016 | 4,865 |
| Preventive services | 11 | -0.046 | 0.010 | 0.001 | 152,096 |
| Primary care visits* | 1 | -0.090 | 0.015 | 0.001 | 7,953 |
| Cost sharing: Various High-Deductible Health | Plan Designs (n | noderate to high d | eductible leve | ls, with or wit | hout HSAs), |
| low-income patient population | | | | | |
| Emergency department visits* | 1 | -0.046 | 0.046 | 0.319 | 5,854 |
| Emergency department visits (higher-severity)* | 1 | -0.245 | 0.103 | 0.017 | 5,854 |
| Emergency department vists (lower-severity)* | 1 | -0.037 | 0.051 | 0.471 | 5,854 |
| Preventive services | 6 | -0.031 | 0.012 | 0.008 | 29,449 |
| Cost sharing: High-Deductible Health Plans w | ith moderate de | ductibles (individ | ual < \$1000), c | jeneral patien | |
| Health care costs* | 3 | -0.029 | 0.014 | 0.044 | 85,731 |
| Cost sharing: High-Deductible Health Plans w | ith higher dedu | | | eral patient p | - |
| Health care costs* | 8 | -0.178 | 0.024 | 0.001 | 142,933 |
| | - | | | | - |
| Cost sharing: High-Deductible Health Plans w patient population | ith higher dedu | ctibles (individual | > \$1000) and | HKA accounts | , general |
| Health care costs* | 4 | -0.152 | 0.028 | 0.001 | 89,701 |
| Cost sharing: High-Deductible Health Plans w | ith higher dedu | ctibles (individual | > \$1000) and | HSA accounts | , general |
| patient population | - | | | | |
| Health care costs* | 2 | -0.238 | 0.057 | 0.001 | 14,364 |

* The effect size for this outcome indicates percentage change, not a standardized mean difference effect size.

** The effect size for this outcome represents an elasticity, not a standardized mean difference effect size.

D. Patient Cost Sharing Studies Included in the Meta-Analysis

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