What You Don’t Know Might Hurt You: Cost Variations for Fecal Immunochemical Tests in Primary Care Practices

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Abstract

Background

Colorectal cancer (CRC) screening can improve health outcomes, but screening rates remain low across the US. Fecal immunochemical testing (FIT) is an effective way to screen more people for colorectal cancer, but barriers exist to implementation in clinical practice. Little research examines the impacts of cost on FIT selection and implementation.

Methods

We administered a multi-modal, cross-sectional survey to 252 primary care practices to assess readiness and implementation of direct mail fecal testing programs, including the cost and types of FIT used. We analyzed the range of costs for the tests, and identified practice and test procurement factors. We examined the distributions of practice characteristics for FIT use and costs answers using the non-parametric Wilcoxon rank-sum test. We used Pearson's chi-squared test of association and interpreted a low p-value (e.g. <0.05) as evidence of association between a given practice characteristic and knowing the cost of FIT or fecal occult blood test (FOBT).

Results

Among the 84 practice survey responses, more than 10 different types of FIT/FOBTs were in use; 76% of practices used one of the five most common FIT types. Only 40 practices (48%) provided information on the cost of their FIT/FOBTs. Thirteen (32%) of these practices received the tests for free while 27 (68%) paid for their tests; median reported cost of a FIT was $3.04, with a range from $0.83 to $6.41 per test. Costs were not statistically significant different by FIT type. However, practices who received FITs from vendors were more likely to know the cost ($p=0.0002$) and, if known, report a higher cost ($p=0.0002$).

Conclusions

Our findings indicate that most practices without lab or health system supplied FITs are spending more to procure tests. Cost of FIT may impact the willingness of practices to distribute FITs in clinic-based encounters as well as through population outreach strategies, such as mailed FIT. Differences in the ability to obtain FIT tests in a cost-effective manner could have far reaching consequences for addressing colorectal cancer screening disparities in primary care practices.

Background

Colorectal cancer (CRC) mortality and incidence rates continue to be one of the highest among cancers globally and in the US (1, 2), despite the availability of multiple effective screening modalities. While CRC screening supports detection and treatment and is recommended by the United States Preventive Service Task Force (USPSTF) (3, 4), rates of screening are still quite low in the US population and disparities persist. For example, CRC incidence and mortality are disproportionately high among rural residents and Medicaid enrollees; due in part to different adherence to screening guidelines (5, 6).

Expanding the use of fecal immunochemical testing (FIT) could be a critical noninvasive and cost-effective approach to addressing disparities in CRC screening (7–11). In addition, FIT testing, and especially mailed FIT outreach, has been identified as an important strategy to addressing the CRC screening delays caused by the COVID pandemic(12, 13). While 2020 rates have rebounded a little since the 90% drop in colonoscopies and biopsies in mid-April compared to 2019, endoscopy rates are not back to prior numbers (14). In addition, surveys indicate patients might be more reluctant to be screened due to fears of infection (13, 15) and mailing a test to people's homes offers a non-visit-based way to reach people for screening (14).

While over 160 different types of FIT or fecal occult blood testing (FOBT) are approved for use by the FDA, tests can vary greatly by clinical effectiveness and features (such as detection, positivity threshold, patient use, and cost) (16). Evidence encourages health care practices to select FITs that are clinically effective and display patient preferred features, such as using a single sample and probe/vial collection tubes (17). However, we do not know what factors actually influence primary care practices' choice of FIT, and some literature indicates community-based primary care practices use a wide variety of FITs, many of which do not have strong evidence of efficacy (17, 18).

A significant gap in the literature exists in evaluating the role cost has on FIT selection as well as the impact FIT costs have on implementation of FIT screening outreach programs. To implement a screening program, practices must consider the cost of individual FITs in addition to the associated costs of lab processing and supportive outreach activities (e.g., prompts, reminder calls). Costs for implementing mailed FIT programs may be accrued by the practice, health system or health plan depending on the model used (19, 20). A practice's willingness to implement these effective programs, or the model preferred, may be influenced by cost.

While some literature examines the cost of implementing colorectal cancer screening programs, most of those studies focus on the labor and organizational costs that make up the vast majority of the expense of implementing such programs (21, 22). One federally funded CRC screening demonstration program found that FIT costs varied more than two-fold between the two screening sites: from $3 per kit (Nebraska site, n = 1264 persons) to $7 per kit (Greater Seattle n = 867 persons) (23). While studies have reported the overall cost of mailed FIT programs (24, 25), few have explored the factors impacting cost of FIT procurement.

Therefore, this study aimed to investigate the impact individual FIT cost has on primary care practices and if cost disparities influence the type of FIT being administered to patients. Initial study hypotheses were designed to determine if smaller practices paid more for FITs than larger practices, based on anecdotal evidence from prior studies. Our study findings explore the intersection of FIT cost, type of FIT, and procurement source in primary care practices.

Methods

This cross-sectional, survey-based study was approved by the Oregon Health & Science University Institutional Review Board (#17952). Participants reviewed an information sheet outlining the study purposes and risks and were instructed to contact study staff with questions; completion of the survey constituted informed consent.

Participants and Setting:

We initially identified 298 primary care practices in Oregon as potential study participants. This list was compiled from a database of all practices that had participated in research over the previous three years with the Oregon Rural Practice-based Research Network (ORPRN). ORPRN is a practice-based research network that was established in 2002 to promote research, education, and community engagement activities in partnership with rural primary care practices (26). After review by two members of the study team (MMD, RG), 13 of the 298 potential practices were excluded as they did not provide primary care services. Prior to data collection, in the fall/winter of 2018, a member of the study team called the remaining practices to verify the contact information of each practice's listed point of contact and to determine preferred method of survey delivery (email, mail, or fax). Thirty-three additional practices were excluded at this point, as they were healthcare systems with a single point of contact for multiple affiliated practices. This left a final count of 252 eligible primary care practices.

Data Collection and Survey Measures:

We administered a multi-modal, cross-sectional survey to the 252 ORPRN primary care practices to assess readiness and implementation of direct mail FIT programs, including the cost and types of tests in current use. The 26 item "Understanding Practice Readiness to Increase Colorectal Cancer Screening via Direct Mail Programs" survey was broken into 5 sections: practice-specific CRC screening data, FIT or FOBT use & costs, direct mail program use, general practice characteristics, and use of strategies to improve CRC screening rates. The FIT/FOBT use and costs section included four questions addressing which type of test was used, where the tests were obtained (lab, vendor, health system), and cost of individual kits. Our survey asked about both FIT and FOBT because some practices still use FOBT for CRC, but we have utilized "FIT" generically throughout the manuscript for clarity and simplicity. The survey in its entirety was designed to take less than 15 minutes to complete. We pilot tested an initial version of the survey with three practices and made minor changes based upon feedback (e.g., adding free text answer options for certain fields) prior to deployment.

The survey was launched in January 2018 and was administered by email (N = 173) and fax (N = 79), depending on stated preferences. If the point of contact (primarily administrative staff such as quality improvement leads or practice managers) had not returned the survey within 1 week, reminders were made by email or phone. Over the course of the next 7 months, up to 5 reminder contacts were made. In July 2018 the list of non-responding practices was reviewed with ORPRN's regional practice facilitators, (27, 28) who were asked to contact practices in their regions to encourage survey return.

Data Management and Analysis:

Practices were classified based on yes or no responses to the question, "Do you know how much a FIT/FOBT kit costs your practice?" We examined the distributions of practice characteristics using descriptive statistics, reported as mean and range, or as counts and percents for categorical variables. Practice size was based on the reported number of medical clinicians (MD, DO, NP, and/or PA). We determined geographic location as frontier, rural, or urban using the ZIP code from the practice's physical address; classifications are provided by the Oregon Office of Rural Health (29). Patient visits per week, percent of patients with Medicaid coverage, current CRC screening rate, number of ongoing quality improvement (QI) projects related to CRC screening, priorities and opinions, and source of FIT/FOBT kits are presented as reported by respondents.

In response to the question regarding FIT/FOBT kit costs, if the answer was formulated as the cost per a certain number of kits (e.g. "$137 for 30 tests"), we calculated the cost of an individual test. Four practices reported costs that were outliers ($17–31 per FIT, compared with a maximum of $7 for the remainder). Analyses comparing costs by source were performed both with and without these four observations; results presented here omit those values as follow-up calls confirmed that one of these responses included lab processing in addition to the cost of the FIT itself, thus we suspect these four values were not comparable to the other test cost values.

When comparing proportions, we used Pearson's chi-squared test of association and interpreted a low p-value (e.g. <0.05) as evidence of association between a given practice characteristic and knowing the cost of FIT. We tested differences in the distributions of continuous variables (e.g. the cost per kit, given that a cost was reported) using the non-parametric Wilcoxon rank-sum test. We performed exploratory regression analyses (linear and logistic) to better understand some relationships, such as between practice size, source of FIT kits, knowing kit cost, and (square-root transformed) cost. Statistical analyses were completed using Stata Statistical Software/IC Release 15 (StataCorp, LLC, 2017) and utilized the user-contributed *tabcount* command (30).

Results

At the close of the survey in August 2018, 90 surveys had been returned from 85 practices. Of these 85 unique responses, only 78 provided answers in the "FIT/FOBT use and costs" section and only 23 respondents initially knew the cost of their FIT. In the summer of 2019, a member of the research team re-contacted practices and obtained additional responses to this section, bringing the total to 84 responses. Based on ZIP codes, responding practices were more likely than non-respondents to be located in frontier (12% vs 3%, respectively) and rural (48% vs 41%) areas and less likely to be in urban areas (40% vs 57%; p = 0.004).

INSERT Table 1 HERE

Across the 84 practices that responded to the survey (33% response rate), more than 10 different types of FIT kits were in use, see Table 1. Five tests were used by more than 10% of the response sample, including: Hemosure® by Hemosue, Inc. (30%), OC Auto® by Polymedco (19%), Insure® by Clinical Genomics (13%), Hemoccult-ICT® by Beckman Coulter (12%) and OC-Light® iFOBT by Polymedco (11%). Three out of four practices (64 out of 84, 76%) used one of these more common FITs. In addition, some practices (n = 7) reported using multiple FIT tests simultaneously, depending on various insurance coverage requirements or if the practice was part of a screening outreach initiative.

As displayed in Table 1, 40 practices (48%) provided information on the cost of their FITs. Thirteen (32%) of these practices received the FITs for free while 27 (68%) paid for the FIT kits; median reported cost of a FIT was $3.04, with a range from $0.83 to $6.41 per test. The remaining respondents did not know the cost of their FIT.

Characteristics of the 84 practices appear overall and by practices with known/unknown FIT costs appear in Table 2. The majority of responding practices had less than 10 providers (73%) and over half were located in rural or frontier regions (61%). Fifty-seven percent of respondents obtained their FITs from a Lab; otherwise FITs were procured directly from the Vendor (30%) or a Health System (12%). There were no significant differences in preference for FIT or preferred CRC screening modality between practices with known/unknown FIT costs.

INSERT Table 2 HERE

Because of the high proportion of practices that did not know their cost of FIT, we examine the practice characteristics associated with FIT costs using descriptive analysis on the sub-sample of practices that knew their costs. While we cannot assume that practices with unknown FIT costs have the same distribution of costs as the known practices, we examined the relationship between practice size, source of FIT, and cost per study objectives with results described below.

Source of FIT and Cost Relationship

Practice size and source of FIT were both significantly associated with knowledge of FIT costs ($p = 0.031$ and 0.001 respectively), see Table 2. However, when practice size and source are considered in the same model, practice size was no longer statistically significant. This is likely because clinic size and source were related; 13.6% of large practices obtain kits from vendors compared to 34% of small to medium sized practices (2.5 times as likely) and 50% of solo/partnerships (3.67 times as likely; $p = .026$ for nonparametric test for trend). Thus, cost differences were primarily driven by source of FITs (i.e., supplied by a lab, vendor, or health system).

In Fig. 1, we show the relationship between knowing the FIT cost and source of procurement (i.e., lab/health system vs. vendor), and in median FIT costs if known. We combined the lab and health system categories as sources, because health system was small and observed cost patterns were very similar to lab. Practices who received FITs from vendors were more likely to know the cost ($p = 0.0002$) and, if known, had a higher cost (p = 0.0002). Costs were not significantly different by FIT type, even when we factored in source.

*Practices obtaining kits from either the lab or health system were combined due to small sample size and similar cost patterns. Practices who received FITs from vendors were more likely to know the cost (p = 0.0002) and, if known, had a higher cost (p = 0.0002).

Discussion

Our study explored which FITs were being used by primary care practices across Oregon and what the cost was for the practices to purchase FIT tests. While 87% of the respondents knew the type of FIT in use, only 40% could report on the costs; 32% of those reporting costs received their FITs for free. This lack of cost information is an interesting finding because it raises the possibility that either that the FIT purchasing decision is not made by the primary care practice manager or quality improvement lead, or that the cost of the test is not typically a criteria for FIT selection. Of the practices that did know the cost of their FITs, we found no cost patterns by type of FIT or rurality.

Our analysis, however, identified an interesting relationship between cost and the *source* of the FIT. If a FIT was supplied by a laboratory or health system, it was more likely to be free of cost to the practices, while FITs procured from a vendor were more likely to have a cost associated with it. Our findings indicate that most practices without lab or health system supplied kits are spending more for their FIT tests. There is a highly statistically significant difference between costs of FITs that are vendor-supplied as opposed to lab- or health plan-supplied FITs. While many practices didn't know the cost, it seems that in general, the labs and health plans are providing FITs for free or low cost while vendors are charging practices a higher rate per FIT.

Responding practices used a wide variety of tests, and only 43% of the practices surveyed were using FIT tests with strong evidence of clinical effectiveness (both high sensitivity and specificity: OC Auto®, OC Light®, and Insure®) in the literature (31). More than 10 different FITs were used across the 84 practices, and 75% of respondents used one of five tests: Hemosure®, OC Auto®, Insure®, Hemoccult-ICT®, and OC-Light® iFOBT. Of the 160 tests approved by FDA, the American Cancer Society recommends only about 10 of them (16) and the USPSTF evidence review identified only OC Auto® and OC Light® as having adequate data demonstrating high sensitivity and specificity (3).

These key findings must be considered within the larger context of clinical provision of CRC screening. Over half our survey respondents were located in rural or frontier regions of Oregon, and the majority had fewer than 10 providers. Rural areas are home to about 60 million people in the US, and Medicaid covers nearly 1 in 4 rural residents under age 65 (24%)(32), but rural and frontier residents have lower rates of cancer screening (33). Differences in the FIT quality and ability to obtain FITs in a cost-effective manner could have far reaching consequences for addressing CRC screening disparities in these small community practices.

Our survey findings might indicate that organizational constraints drive FIT selection more than either cost or test quality. Cost structures can vary greatly depending on who is purchasing FITs, where lab processing occurs, and who receives reimbursement for it, as well as external incentives for screening, such as state or federal incentive metrics. In addition, we found that some practices used 2–3 different FIT types simultaneously; clarifying information from these practices suggest that FIT type depended on insurance coverage or whether the clinic was part of a health plan partnered mailed screening outreach initiative. One feature of interventions to implement FIT outreach programs should likely include working with practices to evaluate if changes are needed in their current FIT, and to advocate for tests that have clinical and patient preferred characteristics (17).

Cost of FIT may impact the willingness of practices to distribute FIT kits through effective strategies like mailed FIT. Mailed FIT programs are known to increase CRC screening rates, in a range of anywhere from 15–28% (34, 35) and they are especially effective at reaching patient groups at higher risk for being unscreened(36, 37). However, the structure of a mailed FIT program (20–22) makes it more susceptible to cost of FIT variations. First, patients generally have a higher chance of completing a FIT given to them by their provider in-person (38, 39) and clinics may have concerns regarding costs associated with distributing FITs that are not completed. If a larger percentage of the FITs mailed to patients might not be processed compared to in-clinic distribution, primary care practices might be more reluctant to purchase and mail FIT kits to the entire population overdue for CRC screening. A small difference in the cost of FIT is magnified in this approach, such that FITs procured at the minimum cost reported here of $0.83 versus the maximum of $6.41 could lead to an almost 8-fold difference ($83 vs $641) if mailed FITs were distributed to 100 patients in a clinic. Second, clinics serving a smaller patient population may be more likely to be impacted by FIT costs when implementing a mail out program. The Center for Disease Control and Prevention (40) found that, in cost data from 124 screening programs, those that screened a larger volume of people achieved a lower cost per person screened than those screening a smaller population and attributed the finding to economies of scale.

By knowing the cost of the FIT tests themselves, primary care practices can better evalutate the return on investment of FIT outreach programs, and also whether investments in activities that increase rates of return would help offset the costs of unreturned FIT tests. A population-based FIT testing approach is even more effective when paired with interventions to decrease barriers to CRC screening, such as patient reminders, patient or provider incentives, education, or FIT mailing programs (25, 41). Our results might make it easier for primary care practices to assess the cost-benefit of implementing these programs to increase rates of FIT returns.

Limitations

Our study does have certain limitations. First, this was a cross-sectional survey of primary care practices within one state and there may be different cost patterns in the non-responding practices. However, our response rate of 33% is similar to prior surveys (42). Second, our findings must be interpreted cautiously because a large number of respondents could not tell us the cost of their FITs, therefore we are not able to do regression analysis by clinical characteristics of the full sample. We cannot determine if the practices with unknown FIT costs have same distribution as known costs. For example, it is possible that the practices who did not know the cost of their FITs were mostly practices who had the FITs provided for free or at a low cost. Third, many of the FITs in use lack evidence of clinical effectiveness; yet they were clearly the preferred test for these clinical sites. Qualitative work, for example, could explore the relationships between practices, vendor, lab, and FIT selection to determine the driving factors as well as to explore why practices may still utilize poorer quality FIT/FOBTs. Finally, purchase of a certain type of FIT does not equate to the full costs of using FIT to screen patients, since it excludes lab processing costs and implemention of any labor or staffing for outreach programs. Our survey data does not let us explore when the purchase of the FITs are offset by lab processing reimbursements of those tests. In other words, there might be broader system-level cost considerations that a health care practice takes into account. Despite these limitations, primary care clinics could use these data to examine return on investment of various CRC screening outreach approaches (cost per test/cost per completed test) and to negotiate for FITs at a better price.

Conclusions

A high percentage of practices in our survey sample were unable to report on the cost of their FIT tests. In the sub-group that knew the FIT test cost, we found a significant relationship between source of FIT and costs, rather than type of FIT. Primary care practices that purchase FITs from a vendor might need to spend more than practices that have FIT tests supplied by either health plans or labs. Future research could examine how practices choose their FIT, whether practices are constrained to certain FITs by organizational purchasing restrictions, and how FIT cost specifically impacts visit-based test distribution as well as willingness to implement mailed outreach programs. Differences in the ability to obtain FIT tests in a cost-effective manner could have far reaching consequences for addressing CRC screening disparities in primary care practices.

Abbreviations

CRC: colorectal cancer

FIT: fecal immunochemical testing

EHR: electronic health record

FOBT: fecal occult blood test

ORPRN: Oregon Rural Practice-Based Network

QI: Quality Improvement

Declarations

Ethics approval and consent to participate

The Institutional Review Board at Oregon Health & Science University approved this study (#17952). Participants reviewed an information sheet outlining the study purposes and risks and were instructed to contact study staff with questions; completion of the survey constituted informed consent.

Consent for publication

Not applicable.

Availability of Data and Materials

The datasets used and/or analyzed for the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors have no competing interests in this publication.

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Authors' contributions

JC was the lead author of the paper, contributed to interpretation of analysis results, and drafted initial and subsequent drafts of the manuscript. KR prepared the analytic dataset and statistical analyses and contributed to interpretation, including drafting sections of manuscript text. RG and JJ supported data collection, data interpretation and helped draft manuscript content. MD was the senior member of the research team and led study conceptualization, acquired financial support, and participated in all stages of the publication from data collection, study implementation, interpretation of study analysis and results and writing the article. All authors read and approved the final manuscript.

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Tables

Table 1. Type of FIT/FOBT and Reported Costs from 84 Health Practice Respondents

					Purchase kits			
Kit Name	**N***	**%**	**Unknown cost, N**	**Free, N***	**Known Cost, N**	**Median ($)**	**Min.**	**Max.**
Hemosure® One-Step iFOBT Test (Hemosure, Inc)	25	(30)	8	6	10	3.43	0.83	6.41
OC Auto® FIT** (Polymedco)	16	(19)	10	4	2	1.57	1.13	2.00
Insure® FIT (Clinical Genomics)	11	(13)	5	2	3	2.32	1.70	6.00
Hemoccult-ICT® (Beckman Coulter)	10	(12)	7	0	1	0.99	0.99	0.99
OC-Light® iFOBT Test** (Polymedco)	9	(11)	6	2	1	1.50		
McKesson Consult® FOBT	3	(4)	0	1	2	3.44	0.88	6.00
Seracult®	2	(2)	1	0	1	2.13		
QuickVue® iFOBT (Quidell)	2	(2)	2	0	0			
Lochness Medical®	1	(1)	0	0	1	5.00		
Rapid Response® FIT (BTNX Inc.)	1	(1)	0	0	1	3.75		
HemaPrompt®	1	(1)	0	0	1	1.41		
Unknown	11	(13)	11	0	0			
Overall	**84**	**(100)**	**44**	**13**	**27**	**3.04**	**0.83**	**6.41**

** Note that FIT numbers do not add to the total because clinics could report multiple FIT types.*

*** USPSTF evidence review identified this FIT with adequate data to support high sensitivity and specificity*

Table 2. Participating Practice Characteristics Overall and by Cost of FIT (Known, Unknown)

	Overall Respondents		Known Cost		Unknown Cost		
	N	%	N	%	N	%	P
Total N	**84**	**(100)**	**40**	**(100)**	**44**	**(100)**	
Practice size							
Solo/partnership (1-2)	10	(12)	8	(20)	2	(5)	0.031
Small to medium (3-10)	51	(61)	25	(63)	26	(59)	
Large (>10)	23	(27)	7	(18)	16	(36)	
Geographic location							
Frontier	10	(12)	6	(15)	4	(9)	0.61
Rural	41	(49)	20	(50)	21	(48)	
Urban	33	(39)	14	(35)	19	(43)	
Source for FIT/FOBT kits							
Laboratory	47	(57)	17	(43)	30	(71)	0.001
Vendor	25	(30)	20	(50)	5	(12)	
Health System	10	(12)	3	(8)	7	(17)	
Practice Characteristics							
Patient visits per week (mean, range)	427	(32-5250)	314	(32-1200)	554	(105-5250)	0.07
Medicaid/CHIP/OHP %	30	(2-85)	30	(2-75)	30	(5-85)	0.93
Current CRC screening rate (mean, range)	59	(10-97)	56	(23-85)	62	(10-97)	0.14
# QI projects related to CRC screening	1	(0-6)	1	(0-3)	1	(0-6)	0.86
CRC improvement as priority in year ahead (1 no priority, 10 highest priority)	8	(1-10)	8	(1-10)	8	(5-10)	0.74
Preferred CRC screening modality							
FIT/FOBT	7	(8)	3	(8)	4	(9)	0.96
Colonoscopy	10	(12)	5	(13)	5	(11)	
Both (colonoscopy & FIT/FOBT)	67	(80)	32	(80)	35	(80)	
Preference for FIT/FOBT (1=hate, 10 =	7	(1-10)	7	(1-10)	7	(3-10)	0.18

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Figures

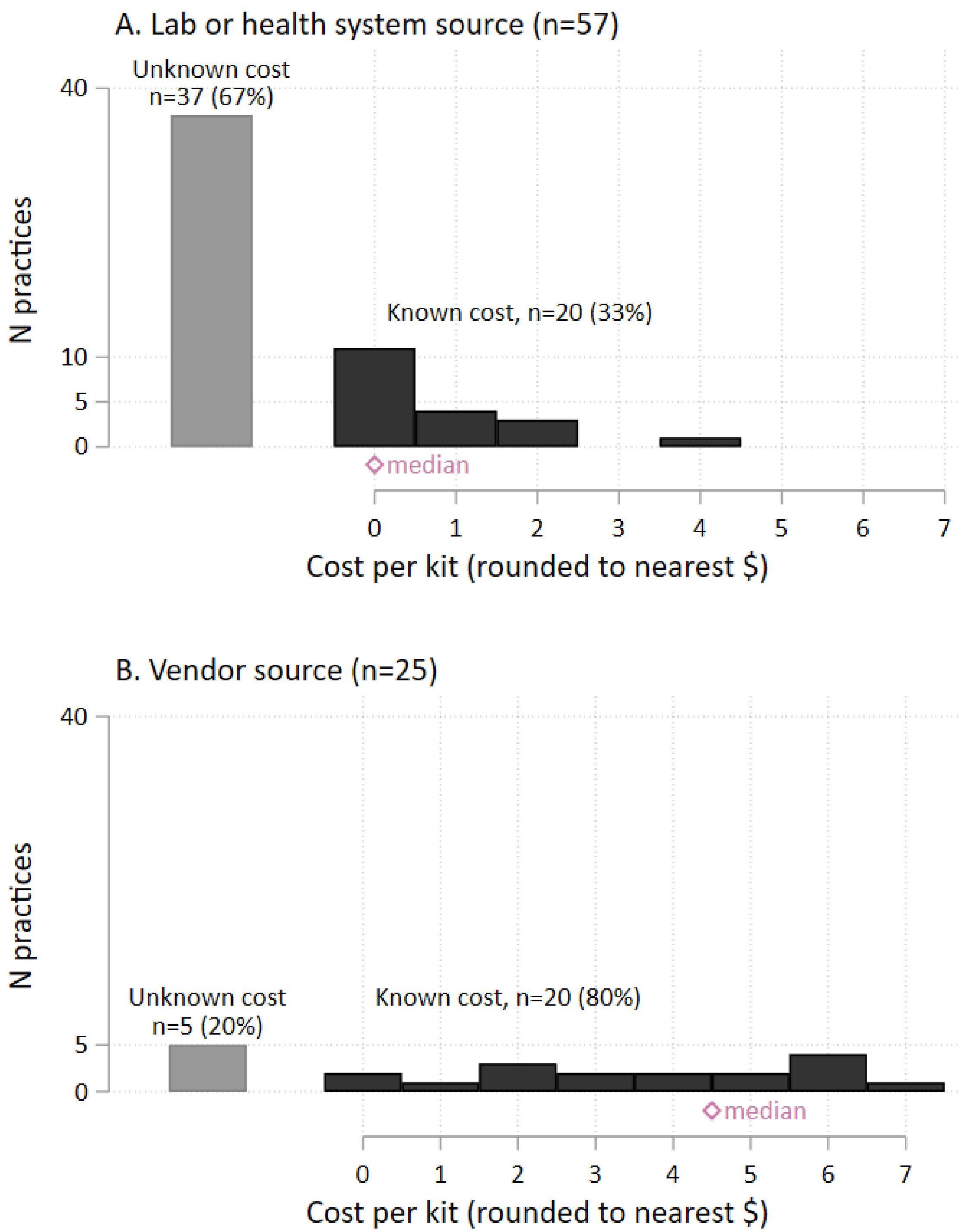

Figure 1

a. Lab or Health system source, N = 57. b. Vendor source, N = 25 practices. Grey bar = Unknown cost; Black bar = Known cost; Red diamond = Median reported cost

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- BMCHSRFITCostcoverletter.docx
- ReadinessAssessmentFinalRev.pdf
- STROBEchecklistcrosssectionalFITCostpaper.docx