Health Services Research

Evaluation of Implementation Outcomes After Initiation of a Shared Decision-making Program for Men With Prostate Cancer

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OBJECTIVE	To evaluate barriers to implementation of patient decision aids (PDAs) issued in an electronic medical record (EMR). We undertook an implementation outcomes analysis focused on what proportion of men eligible for the PDA received it (penetration), and of the men who received it, how many used it as intended (fidelity). We also evaluated various patient-centered outcomes related to decision-making.
MATERIALS AND METHODS	Men with incident localized prostate cancer were recruited from at UCLA from 2013 to 2017. PDA eligibility was determined via weekly EMR review. We also performed a retrospective chart review of all patients seen in clinic for one sample week to identify patients that were missed by the initial eligibility algorithm, and investigated the cause for miscategorization. We analyzed differences in patient-centered outcomes between those who did and did not receive the PDA.
RESULTS	About 314/374 men with incident prostate cancer completed the PDA conferring 84% fidelity. PDA penetration under initial identification prospective algorithm was assessed at 100% ($n = 2/n = 2$). However, penetration assessed by manual retrospective chart review was 20% ($n = 2/n = 10$). Improvements to the identification algorithm, including new EMR visit types, were identified. PDA completion was associated with less decisional conflict and higher perceived Shared decision-making (all $P<.03$).
CONCLUSION	No previous studies have investigated the challenges of implementing a PDA facilitated by the EMR. We identified modifiable system and EMR-related factors that limited program penetration. Our PDA showed decisional quality benefits. UROLOGY 132: 94−100, 2019. © 2019 Elsevier Inc.

Shared decision-making (SDM) is an integral component of patient-centered care that occurs when a healthcare choice is made collaboratively by the patient with one or more healthcare professionals.[1] The American Urological Association endorses SDM as the optimal decision-making approach for many common urologic conditions.[2-5] In SDM, individual patient values and preferences are identified, and evidence is used to understand how to achieve those goals through treatment.[6,7] Despite professional endorsement, implementation of SDM has faced barriers, in part due to perceptions of the clinician time required for robust SDM.[8] Studies suggest patients exposed to decision aids feel more knowledgeable, clearer about their values, perceive decreased decisional conflict, and increased treatment satisfaction.[8,9] Still, implementation of patient decision aids (PDAs) has faced challenges. Obstacles that have prevented the use of patient decisional support and, by extension, limited the adoption of SDM, have not been investigated thoroughly.[10]

PDAs face barriers on the individual clinician level. Researchers have documented barriers including inadequate training, lack of perception of the clinical benefit of PDAs, lack of confidence in PDA contents, assumptions that SDM will increase the time of consultation, and concerns about disrupting workflows.[11] System-level barriers to implementation of SDM may also exist. While some of these have been assessed at the organizational level, little is known about implementation barriers related to use of the electronic medical record (EMR). The efficiency necessary to operate SDM programs at scale within high-volume urologic practices could be achieved by leveraging the EMR. Integration with EMR system workflows may

present additional barriers to the implementation of PDAs within healthcare systems.

Implementation science has been described as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services."[12] To assess the barriers of system-level uptake of PDA implementation, we focused on scaling implementation of a PDA for men with a recent diagnosis of prostate cancer.

Prostate cancer treatment is highlighted by many professional societies as one that is emblematic of the need for SDM.[4,5] Men with localized prostate cancer face a difficult decision because treatments offer distinct tradeoffs between quality and quantity of life.[8] Furthermore, men newly diagnosed with prostate cancer who do not participate in SDM may be exposed to overtreatment.[8] We undertook a type 3 hybrid effectiveness-implementation outcomes analysis as described by Curran et al focused on factors impacting what proportion of men eligible for the PDA received it (penetration), and of the men who received it, how many used it as intended (fidelity).[13] We also evaluated the proportion of physicians who opted in the use of the PDA and continued to use it in their practice (adoption) as well as various patient-centered outcomes related to decision-making. Implementation outcomes were evaluated based on the RE-AIM framework.[14]

METHODS

Cohort Initial Identification Algorithm

Patients offered the PDA were seen at UCLA Health from 2013 to 2017. Prior to operationalizing the PDA, UCLA clinicians were educated about the design and goals of the PDA implementation. As patient appointments were scheduled in the EMR system, clinic assistants classified appointments based on the patient's chief complaint. We identified visit types that were most likely for men with newly diagnosed prostate cancer, which included: *New Patient − Prostate cancer, New Patient − Urology General, PCC Uro New, New,* and *New Direct Referral.* These visit types were flagged for further review. Subsequently, we examined administrative scheduling notes to parse out visits pertaining to an incident prostate cancer. Patients deemed appropriate for the PDA met the following criteria: prostate specific antigen (PSA) level lower than 20; no evidence of metastatic disease; incident prostate cancer without prior treatment, including on active surveillance; no diagnosis of dementia; and ability to read English.

Patient Decision Aid

Patients were contacted via phone and offered the PDA ("WiserCare") prior to their clinic visit. Patients who agreed to review the PDA were issued a secure link to access the internet-based PDA. The PDA-educated patients about available treatment options for prostate cancer and used conjoint analysis to explore their treatment goals and personal preferences. Through real-time decisional analysis in its online interface, the PDA quantified the "expected value" of evidence-based treatment options for prostate cancer, using the preference values as weights in the analysis. Upon completion of the PDA, patients received an electronic report that contained a chart displaying their clinical data (eg, PSA, Gleason score, and staging), their personal values and goals in the order of importance, and a list of treatment options ranked from highest "expected value" to lowest "expected value." The report also contained additional educational information on each listed treatment option including the associated risks and benefits. Physicians received a one-page summary of this report prior to their appointment via email.

Measuring the Clinical Effectiveness and Implementation Outcomes of the PDA

We evaluated effectiveness of the PDA using a patient experience questionnaire. Patients completed the patient experience questionnaire after their clinic visit in the clinic, or at home, and included the following measures:

Decisional Conflict. The validated Decisional Conflict Scale screens for evidence of decisional conflict regarding treatment choice.[15] Patients respond "Yes," "Probably Yes," "Unsure," "Probably no," and "No" to each of 16 items, and a score was calculated for five domains: "informed," "values/clarity," "support," "uncertainty," and "effective decision." These domains measure uncertainty in choosing among options, modifiable factors contributing to uncertainty such as feeling uninformed, effectiveness of decision-making, and satisfaction with choice.

Shared Decision-Making. The validated Shared Decision Making Questionnaire 11 assesses patient perception that SDM occurred between themselves and their clinician during the consultation.[15]

Clinician and Institution Satisfaction/Loyalty. Net Promoter Score evaluates a patient's willingness to refer a friend to the provider with whom they received their care and to the institution where they received their care. Patients respond by selecting from 5 response options ("Very likely," "Likely," "Neither likely or unlikely," "Unlikely," and "Very unlikely") on how likely they would be to make the referrals. Patients are divided into "Detractors" ("Neither likely or unlikely," "unlikely," and "very unlikely"), "Passive" ("Likely"), and "Promoters" ("Very likely"). The Net Promoter Score is calculated for a group by subtracting the percentage of "Promoters" from the percentage of "Detractors."

To assess the clinical effectiveness of the PDA, usual care patients that were not offered the PDA also received the same patient experience questionnaire after the clinician consultation. Usual care patients were accrued during 2 time periods: during the PDA piloting period from November 2012 to January 2013, and during the wider scaling of the PDA from October 2017 to December 2017.

Implementation Outcomes. Implementation outcomes were evaluated by analyzing program adoption, penetration, and fidelity. Program adoption was calculated as the percentage of physicians who actively participated in the PDA-supported SDM process among all clinicians who counsel men with newly diagnosed prostate cancer. Program penetration of the PDA was calculated as the percentage of patients who received the PDA among those eligible to receive the PDA based on the eligibility algorithm. We assessed eligibility in 2 ways: (a) with the initial prospective identification criteria based on visit types and (b) with a thorough retrospective chart review of all patients without reference to the visit type in order to validate and modify

the initial criteria in (a). Both were calculated from the same sample week to allow direct comparison of the penetration rates. Program fidelity was defined as the percentage of patients who completed the PDA-supported SDM process as designed among all patients who were offered the PDA.

Data Abstraction
After initial implementation of the PDA, clinicians were queried about missing reports for incident prostate cancer patients who had not received the PDA. To identify reasons for eligible patients not receiving a decision aid, a retrospective chart review was completed for the week of 6/5/17. We analyzed implementation outcomes of program penetration and fidelity. The scheduling notes and visit types of "missed" patients (men identified as eligible for the PDA in the retrospective chart review but who were not identified under the initial screening criteria) were documented for analysis. The penetration of the PDA was calculated as the percentage of patients who were identified to receive PDA under the initial screening algorithm divided by the hypothetical number of patients who should qualify for PDA based on the detailed retrospective chart review. Program adoption and fidelity were also calculated as described above.

Statistical Analysis
We performed univariate analysis to compare patient demographic, decisional conflict, patient satisfaction, SDM, clinician and institution loyalty, control preference, and prostate cancer knowledge between the implementation and usual care groups using Student's t test and chi-square test (Fisher's exact, if necessary). A significance level of $P<.05$ (2-sided) was used to determine statistical significance. All analyses were performed in SAS v9.4 and R v3.5.1.

RESULTS

Implementation Outcomes
Program Adoption. All 15 clinicians in the Departments of Urology and Radiation Oncology who had encountered patients appropriate for PDA during the initial implementation period agreed to use the PDA. One withdrew from use, conferring a program adoption of 93% (14/15).

Program Penetration

a. Using the first definition described above, a total of 369 appointments of all patients who visited the UCLA Urology Clinic during the week of 6/5/17 were included for review (Fig. 1). Forty-two of the 369 patients of the sample week had one of the 5 visit types described above and were included for appointment note review. Nineteen out of these 42 patients had scheduling notes that indicated their appointments were potentially regarding prostate cancer. Of these, 17 patients were determined to be ineligible due to following reasons: lack of medical records supporting eligibility ($n = 7$), past history of prostate cancer ($n = 8$), same-day scheduling resulting in insufficient time for PDA enrollment ($n = 1$), and PSA higher than 20 ($n = 1$). The remaining 2 patients that were identified to be eligible to receive the PDA did receive the PDA resulting in a penetration of our program of 100%.

b. Using the second definition described above, we used the data from the retrospective review of every chart of the sample week without reference to visit type. This analysis identified an additional 8 eligible patients, totaling 10. The visit types of eligible patients who were not identified under the initial prospective screening criteria were: *Biopsy Result* ($n = 6$), *New Patient Prostate Cancer* ($n = 2$), and *Uro Return* ($n = 2$). Among these patients, the 2 patients under New Patient Prostate Cancer were classified as ineligible under the initial screening criteria because their medical records were not uploaded into the system prior to their visits. The penetration of the PDA for the sample week under this evaluation approach was calculated to be 20% (2/10)

Program Fidelity. Over the 4-year implementation period, 374 men were prospectively identified for PDA distribution and invited to complete the PDA prior to their cancer consult. Of men issued the PDA, 314 participants completed it with reports generated prior to their appointments. Patient fidelity for the PDA was calculated to be 84%.

Clinical Effectiveness Outcomes
Decisional Conflict. Patients who received the PDA scored significantly lower on the Decisional Conflict Scale. The total decisional conflict score of patients who received the PDA had a mean of 8.1 (SD 8.9) compared to 16.5 (SD 20.8) for patients who received usual care (Table 1). The implementation group also demonstrated significantly higher scores on the domains of feeling informed ($P= .0010$) and values/clarity ($P= .0120$), significantly lower scores on the dominas of uncertainty ($P= .0076$), and confidence in an effective decision ($P= .0007$). Specifically, more patients in the implementation group agreed to 13 out of the total 16 items on the decisional conflict scale.

Shared Decision-Making. SDM was significantly higher in the PDA group than the usual care group in the areas of weighing treatment options, discussing options with the doctor, knowing the treatment advantages, knowing which treatment is best for me, and reaching an agreement with my doctor.

Clinician and Institution Satisfaction/Loyalty. About 89% of patients who received PDA indicated they would recommend UCLA Health to others as compared to 68% of usual care patients ($P= .0079$; Table 2). These data are used to calculate the "Net Promoter Score" which was 89% and 63% for the implementation and usual care groups, respectively.

DISCUSSION
We result several significant findings. First, the retrospective review of the sample week helped identify several barriers to implementing the PDA related to the EMR. Past research has elucidated barriers to implementation inherent to the decision aid itself, individual practitioner/patient, and organizational workflow.[16-18] No previous studies have specifically investigated the challenges of implementing a patient decision aid facilitated by the EMR. Urology practices
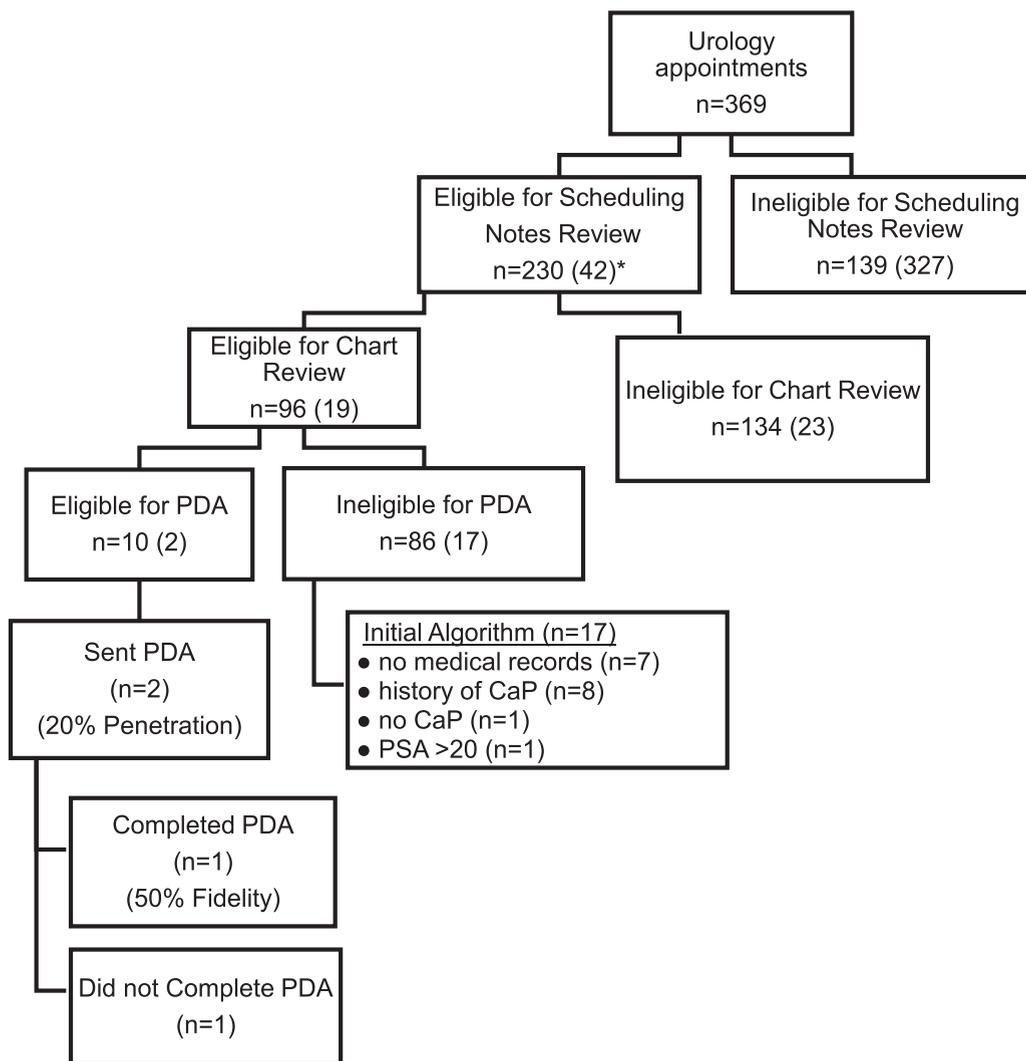
Figure 1. Flowchart comparing patient decisional aid implementation under retrospective chart review vs initial prospective identification criteria for the sample week of 6/5/17.

* First number (ie, $n = 230$) indicates number of patients identified under proposed identification criteria. In parenthesis (ie, 42) is the number of patients identified under current prospective identification criteria.

seeking to implement SDM at scale may benefit from an initial chart review to identify all clinically eligible patients, and then identifying the visit types they were assigned in the scheduling system, in addition to clinician and administrative staff querying. It is also important to recognize our intervention to scale benefitted from pilot implementation as discussed by others.[19]

System factors also presented implementation barriers. A detailed look at the patients under *Biopsy Result* showed that all 6 patients were not informed of their positive biopsy results prior to their clinic visits. This clinical practice pattern (not notifying patients of biopsy results by telephone prior to the counseling visit) makes previsit decision support using the EMR impossible; patients must know their diagnosis prior to using a disease-specific PDA. Our practice is looking to harmonize practice patterns in this regard. Additionally, the lack of available patient medical records prior to the appointment also hampered PDA penetration.

We are updating our identification protocol with patient care support staff to include all the visit types identified above, create a workflow to allow clinicians to notify patients of their positive results prior to a cancer consult, and remind patients to submit their medical records prior to their visits. The hypothetical screening result of the sample week under the gold standard identification algorithm compared to the initial screening algorithm is shown in Figure 1. Under our current criteria, 230 patients would be included for scheduling notes review based on the expanded visit types in the first step. The medical charts of 96 patients would have been reviewed as their scheduling notes indicated a potential consult on prostate cancer. Finally, we would be able to identify all 10 patients eligible for PDA, reaching a penetration of 100% (12/12) from 20% under the initial identification algorithm.

Implementation outcomes from our analysis, and recommendations for improvement, have been summarized utilizing the RE-AIM framework in Table 3.

Table 1. Decisional conflict scale

Scales, mean(SD)	Implementation n= 123	Usual Care n= 49	P
Total	8.1 (8.9)	16.5 (20.8)	.0006
Informed	5.3 (10.0)	14.0 (23.7)	.0010
Values/clarity	7.0 (11.0)	13.8 (24.1)	.0120
Support	6.2 (9.1)	10.1 (16.3)	.0503
Uncertainty	17.8 (19.9)	28.7 (30.0)	.0076
Effective decision	7.3 (11.5)	15.8 (18.8)	.0007
Items, % agree			
1. Know which options are available	100% (123)	91% (43)	.0053*
2. Know benefits of each option	98% (120)	85% (40)	.0051*
3. Know risks/side effects of each option	95% (116)	85% (40)	.0292
4. Clear about which benefits matter most	95% (116)	85% (40)	.0292
5. Clear about risks/side effects matter most	98% (120)	89% (42)	.0378*
6. Clear about which is more important	99% (122)	89% (42)	.0065*
7. Have enough support from others	99% (122)	96% (45)	.1854*
8. Choosing without pressure from others	98% (121)	94% (44)	.1302*
9. Enough advice to make choice	94% (115)	80% (37)	.0065
10. Clear about best choice for you	88% (108)	74% (34)	.0282
11. Feel sure about what to choose	85% (104)	74% (35)	.1278
12. Decision easy to make	78% (95)	59% (27)	.0130
13. Made an informed choice	91% (107)	79% (37)	.0376
14. Decision show what is important	97% (117)	81% (38)	.0016*
15. Expect to stick with your decision	97% (118)	85% (39)	.0103*
16. Satisfied with your decision	92% (109)	79% (34)	.0287

* Fisher's exact test.

Arterburn et al evaluated the use of a PDAs for hip and knee osteoarthritis.[20] The intervention was associated with lower costs for surgical procedures for this condition. However, they report program penetration of about 33%, though limited implementation data were available regarding reasons for this. Methods such as those described in this study may offer a way to improve penetration and the related benefits of SDM for patient through rigorous analysis of reasons for low penetration and related remediation.

Second, we found the fidelity for our program acceptable in light of data from prior programs and we found that our PDA was well adopted by clinicians. The fidelity of our PDA is higher than several decisional aids for conditions including Diabetes Mellitus (information card), prostate cancer (pamphlet presented by trained

Table 2. Net promoter

	Implementation n= 123 % agree	Usual Care n= 26 % agree	P
Net promoter – doctor			
Promoter	92% (111)	83% (19)	.0985*
Passive	8% (10)	13% (3)	
Detractor	0% (0)	4% (1)	
Net promoter – UCLA			
Promoter	89% (108)	68% (15)	.0079*
Passive	11% (13)	27% (6)	
Detractor	0% (0)	5% (1)	

* Fisher's exact test.

educator), and breast cancer (computer program).[17,18,21] Reports on other prostate cancer PDAs indicate fidelity similar to ours, though they were not software scalable implementations.[18,22-24] Studies containing data regarding PDA adoption among physicians are scarce, yet a study on breast cancer PDA in the format of a video tape with an accompanying workbook also showed high program adoption, supporting the notion that physicians can be receptive to incorporating PDAs into their daily practice when properly engaged.[21]

Third, we found that our PDA program showed decisional quality benefits in men who received it. As shown in Table 1, the PDA group scored 8.4 points lower than the usual care group on the Decisional Conflict Scale (DCS). This result is congruent with the 2017 Cochrane review of effectiveness studies of PDAs, which strongly supports the influence of PDAs in decreasing decisional conflict. Moreover, the decrease in DCS score seen in our analysis is well above the average decrease in DCS in patients who completed PDAs for other conditions.[25]

Our EMR-based PDA intervention was also effective in promoting patient satisfaction and loyalty toward the healthcare institution (Net Promoter Score) (Table 2). Interestingly, our intervention did not show a significant difference in physician Net Promoter Score. The marked increase in only the institutional promoting score can potentially be explained by patients attributing their satisfaction toward the availability of information after completing the PDA to the healthcare institution instead of their healthcare providers. While past studies on PDA's effects on patient satisfaction and loyalty produced mixed results, our clinical intervention clearly

Table 3. Implementation outcomes summarized within RE-AIM framework

RE-AIM	Results	Recommendations
Reach	A total of 374 men with newly diagnosed localized prostate cancer were prospectively identified as appropriate for the decision aid over the 4-year implementation period. We identified ways to improve reach, by doing a retrospective chart review for one sample week. Sample week review revealed reach of decision aid to be 20% (2/10), when considering all clinical evidence in the chart instead of only factors available in the EMR scheduling notes. Mislabeled visit types and absent medical records contributed to this discrepancy. Clinical practice patterns, that is, not notifying patients of biopsy results prior to appointments, also contributed.	Reach in EMR based interventions may be optimized by piloting efforts as described here prior to launch of an intervention. Practice patterns that support EMR-based identification of patients can then be revised prior launch.
Effectiveness	Those who completed the decision aid showed significant differences in decisional conflict, perceived shared-decision making, and institutional satisfaction/loyalty.	Our results are congruent with the 2017 Cochrane review of effectiveness of decision aids, indicating that decision aids can improve decision quality. The demonstrated increase in institutional loyalty (Net Promoter Score) may be useful in making the "business case" for systematic shared decision-making to executive leaders considering resourcing these programs.
Adoption	About 14/15 (93%) clinicians adopted the decision aid within their clinical practice.	Our PDA was well adopted by clinicians. Studies containing data regarding PDA adoption among physicians are scarce. We incorporated physician training about the decision aid and responded to physician concerns prior to launch. We also included outcome metrics relevant to physicians (eg, Net Promoter Score).
Implementation	About 314/374 (84%) men who received the decision aid used it as intended over the 4-year implementation period.	The decision aid was introduced as "recommended by your physician" which may have improved engagement. The software was designed with UI experts to enhance engagement as well.
Maintenance	This program is part of routine care, 3 years after launch.	Addressing the goals all stakeholders, including patients, physicians, and health-system leadership, helps to facilitate maintenance.

EMR, electronic medical record; PDA, patient decision aids.

indicated our PDA to be an effective patient loyalty promoter towards the institution.[25,26] Such data can be useful at making the "business case" for systematic shared decision-making to executive leaders considering resourcing these programs. Net Promoter Score has been associated with growth in organizations which score highly vs those that do not.[27]

Our other results align well with existing literature. The SDM scale showed significant increase in the PDA group in multiple aspects of SDM on the SDM subscale.

Our findings should be considered in context of our study's limitations. Our analysis took place at a large academic institution with a relatively homogenous, well-educated population. It is necessary to evaluate external validity with larger studies involving more diverse populations. Regarding the retrospective review, it is probable that the selected sample week may not have captured all possible implementation obstacles.

CONCLUSION

Our intervention identified opportunities for improvement of the implementation of a SDM tool for newly diagnosed localized prostate cancer (Table 3). The intervention showed decisional quality benefits. We achieved reasonable fidelity (84%) compared to other interventions. Penetration could be improved by review of clinic administrative notes prior to launching a SDM program.

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