

Establishment of a Web-based System for Collection of Patient-reported Outcomes After Radical Prostatectomy in a Statewide Quality Improvement Collaborative



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OBJECTIVE	To report on the establishment of a unified, electronic patient-reported outcome (PRO) infrastructure and pilot results from the first 5 practices enrolled in the web-based collection system developed by the Michigan Urological Surgery Improvement Collaborative.
MATERIALS AND METHODS	Eligible patients were those undergoing radical prostatectomy of 5 academic and community practices. PRO was obtained using a validated 21-item web-based questionnaire, regarding urinary function, erection function, and sexual interest and satisfaction. Data were collected preoperatively, at 3 months, and 6 months postoperatively. Patients were provided a link via email to complete the surveys. Perioperative and PRO data were analyzed as reports for individual patients and summary performance reports for individual surgeons.
RESULTS	Among 773 eligible patients, 688 (89%) were enrolled preoperatively. Survey completion rate was 88%, 84%, and 90% preoperatively, at 3 months, and 6 months. Electronic completion rates preoperatively, at 3 months, and 6 months were 70%, 70%, and 68%, respectively. Mean urinary function scores were 18.3, 14.3, and 16.6 (good function ≥ 17), whereas mean erection scores were 18.7, 7.3, and 9.1 (good erection score ≥ 22) before surgery, at 3 months, and 6 months. Variation was noted for erectile function among the practices.
CONCLUSION	Collection of electronic PRO via this unified, web-based format was successful and provided results that reflect expected recovery and identify opportunities for improvement. This will be extended to more practices statewide to improve outcomes after radical prostatectomy. UROLOGY 107: 96–102, 2017. © 2017 Elsevier Inc.

Although often successful from an oncological perspective, radical prostatectomy can lead to long-term side effects that impact a patient's quality of life, particularly urinary incontinence and erectile dysfunction.¹⁻³ Given the long natural history of prostate cancer and range of management options, patients and their physicians must balance cure with minimizing side effects

from treatment. Thus, the ability to accurately characterize the risk of these side effects as well as factors that may worsen this risk are essential to make appropriate decisions and ultimately improve patient outcomes and satisfaction with surgical care.⁴

Despite the importance of preserving quality of life, functional outcomes from radical prostatectomy vary widely in the literature.^{1,2,4-6} Physician-reported outcomes are biased by the surgeon's perceptions and the patient's reluctance to report a negative outcome.⁷ Patient-reported outcomes (PROs) reduce these biases.⁸ Additionally, reported outcomes are influenced by the type of treatment center, patient demographics, surgeon, and surgical technique.⁹⁻¹² As a result, much of the literature reflects outcomes from high-volume and tertiary referral centers. To truly understand PROs after radical prostatectomy and make them more widely applicable, it is important to include

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a multitude of clinical settings with varying populations. As these factors become more understood, we can begin to focus on clinical processes and surgical techniques that might improve outcomes.

In this study, we report the establishment of a unified, electronic PRO system for radical prostatectomy, including initial findings from 5 pilot practices among a surgical collaborative of more than 40 practices in the state of Michigan. We specifically report the rate of practice and patient participation and data collection over time. Additionally, we report early outcomes of urinary and erectile function.

MATERIALS AND METHODS

Michigan Urological Surgery Improvement Collaborative

Established in 2011, the Michigan Urological Surgery Improvement Collaborative (MUSIC) is a statewide, physician-led quality improvement consortium funded by Blue Cross Blue Shield of Michigan. The collaborative represents approximately 85% of urologists in the state of Michigan, and collects clinical information for patients newly diagnosed with prostate cancer at 43 participating practices. Patient data are entered prospectively from the time of prostate biopsy, by trained abstractors into the MUSIC clinical registry, a registry that currently contains more than 29,000 patients (16,436 patients with prostate cancer). The participating practices represent a broad spectrum of academic and community practices, and each site obtains regulatory exemption from their local institutional review boards to participate in MUSIC and its quality improvement-focused goals. MUSIC PRO was launched at 5 pilot sites across the state of Michigan, beginning in April 2014.

MUSIC Patient-reported Outcomes

MUSIC PRO uses a validated 21-item questionnaire, similar to Symptom Tracking and Reporting (STAR), a web-based survey

developed by Vickers et al at Memorial Sloan Kettering Cancer Center.¹³ Five questions evaluate urinary function (score range 0-21), with a score of >17 indicating good function. Six questions evaluate erectile function (score range 0-30), with a score of >22 indicating good function. Erection function scores included only patients with erections and interest in sexual function before surgery, because the survey prompts the responder to skip the scored questions if he reports no activity or interest. The questionnaire also includes 5 additional questions related to their sexual interest and satisfaction taken from the Patient-Reported Outcomes Measurement Information System Sexual Function and Satisfaction questionnaire.¹⁴ Other questions address the patients' overall quality of life, relationship status, and use of erectile aides (Fig. S1). This survey offered the advantage of prior web-based validation, rapidity of completion, and adaptiveness to patient responses regarding sexual function.

All patients undergoing radical prostatectomy (open or robotic) were eligible to participate in MUSIC PRO (Fig. 1). After the patient chose radical prostatectomy, he was given a brochure describing MUSIC PRO and asked to provide an email address. Following registration in MUSIC by the surgeon's office, the coordinating center sent an email on behalf of the surgeon, which provided a link to the web-based survey. Patients who did not have email or opted out of web-based collection, received postal questionnaires. Patients who did not complete their questionnaire 2 weeks before surgery received automatic email reminders, and those who failed to complete their web-based or postal questionnaire 7-10 days before their surgery date received a telephone call reminder from the MUSIC Coordinating Center.

After surgery, a similar process, including reminders, was followed to prompt completion of the same questionnaire at 3 and 6 months. Patients who did not complete questionnaires before their clinic appointments could complete these in paper or electronic form at the time of their clinic visit.

Electronic survey responses were recorded instantaneously in the MUSIC registry. At any point during the pre- or postoperative period, MUSIC surgeons can log on to the registry to view survey responses from individual patients. The surgeon can see

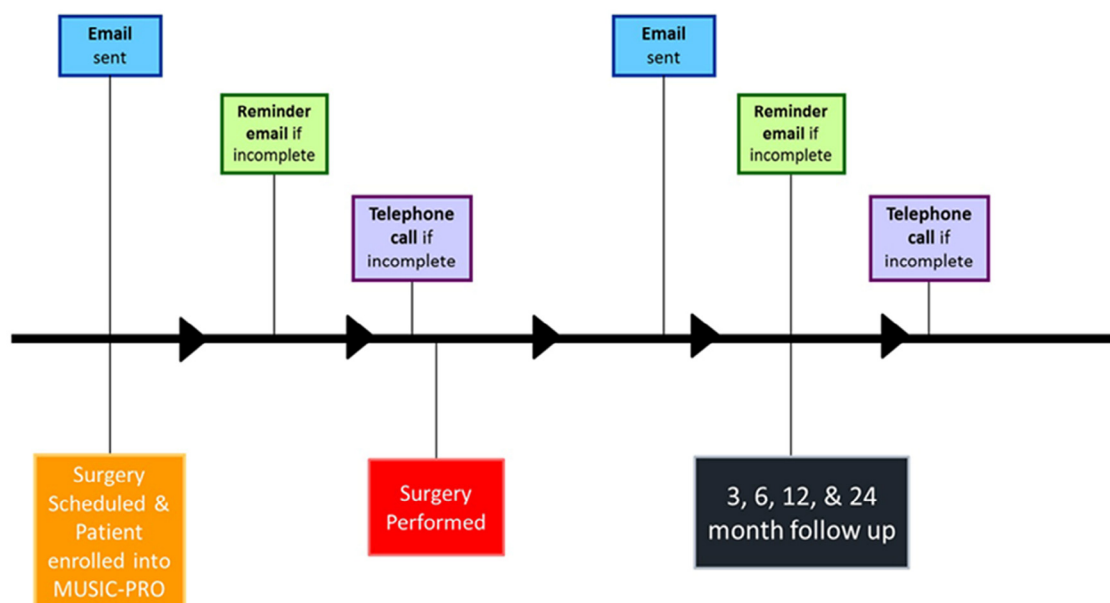


Figure 1. Process by which patients are instructed to complete surveys at baseline, 3, 6, 12, and 24 months.

patient-reported responses to individual questions; summary data were also presented in graphical format (Fig. S2). Individual physician PRO reports were available to the physicians, with aggregated information about response rates, their own patients' PRO responses, and comparison with other participating MUSIC PRO response sites (Fig. S2). The surgeon reports also included comparative performance feedback on margin status, lymph node dissection, and nerve-sparing.

Statistical Analysis

For this study, we analyzed all PRO data from April 21, 2014 to June 25, 2015, an interval representing the pilot phase of data collection in 5 MUSIC practices. We specifically assessed the feasibility and utilization of MUSIC PRO regarding the overall response rate, and web-based vs postal utilization at various time points. Target enrollment rate was set at 90%, with a target survey completion rate of 75%. Urinary and erectile function PROs were reported as unadjusted scores.

RESULTS

In 5 pilot practices, 688 of the 773 eligible patients (89%) undergoing RP were enrolled into MUSIC PRO before surgery. Of these enrolled patients, 605 (88%) completed their preoperative questionnaire (Table 1). Among patients from the 5 pilot practices, demographic, pathologic, and operative factors showed some variation (Table 2).

At 3 and 6 months following surgery, 84% and 90% of patients completed their MUSIC PRO questionnaire, respectively. Web-based questionnaires were used approximately 70% of the time. Telephone reminders were used approximately 30% of the time. Reasons for not using the web-based format provided by patients when asked included: lack of email or internet access, infrequent email usage, shared email accounts, or browser incompatibility when they accessed the questionnaire online.

Self-reported mean urinary function scores were 18.3, 14.3, and 16.6 before surgery, at 3 months, and 6 months after surgery, respectively (Fig. 2A). Most men reported good urinary function before surgery. A decline in function was seen at 3 months across all practices, with notable variation in degree. At 6 months, 3 practices showed return to preoperative function, whereas 2 others were slightly below. Percentages of patients using 0-1 pads at 3 and 6 months were 66% (216 of 325 patients) and 84% (159 of 189 patients).

Mean erectile function scores across the 5 pilot practices were 18.7, 7.3, and 9.1 preoperatively, at 3 months, and 6 months, respectively (Fig. 2B). Practice level outcomes demonstrated erectile function scores ranging from

3.1 to 9.2 at 3 months, whereas at 6 months, PROs for erectile function ranged from 3.6 to 10.0, considerably lower than that reported before surgery.

COMMENT

In this study, we demonstrated the feasibility of a state-wide system for the electronic collection of PROs for men undergoing radical prostatectomy. As a data collection initiative, the MUSIC PRO system was successful in capturing a high proportion of patients being treated with radical prostatectomy, with baseline enrollment approaching the MUSIC target of 90% and a questionnaire completion rate (88%) that exceeded the completion target of 75%. Survey completion rate continued to remain high at 3 and 6 months. These were obtained at multiple practices through an integrated central coordinating structure. However, not all patients responded to a web-based collection, with approximately 25% requiring postal questionnaires for completion.

Survey completion rate for PROs in this study was comparable with other studies. Several large studies collected surveys via phone, mail, and in-person contact over a follow-up between 24 months and 12 years, with response rates ranging from 64% to 93%.^{1,5,10,11} In contrast to these studies, the primary method of contact for the patients in our study was automated emails. We found that with such a system, approximately 70% of questionnaires were completed electronically preoperatively, at 3 months, and 6 months.

Among electronically based PRO surveys, we achieved a relatively high response rate. With a 17-item questionnaire in the STAR system, 1538 patients at Memorial Sloan Kettering completed the survey 78% of the time when at least 1 email was sent to invite them to complete the survey.¹³ This was similar to the response rate observed in our series. In a separate single-institution study, 293 of 514 (57%) patients responded to an online survey when sent an electronic link by email.¹⁵ This survey required a median 15 minutes to complete, and was longer than our 21-item questionnaire, possibly contributing to a higher response rate in our series.

Other factors apart from the length of the PRO questionnaire influence response rate. Parker et al contacted 1030 patients receiving external radiation therapy in Canada to complete an online survey.¹⁶ Patients were contacted only once, with a response rate of 34.8%. However, other investigators have shown that repeat contact improves the response rate to a certain degree.¹⁵ In our PRO system, we developed a systematic method by which repeat contact

Table 1. Survey collection rates relative to target goals for the 5 pilot practices at baseline, 3 months, and 6 months

	MUSIC Target	Baseline (%)	3 Months	6 Months
Patients enrolled	90%	89%	96%	100%
Questionnaire completed	75%	88%	84%	90%
Web-based questionnaires	>80%	70%	70%	68%
Patients requiring return phone call	<10%	28%	23%	22%

Table 2. Preoperative and intraoperative characteristics of patients among the 5 pilot practices

	Aggregate	Practice A	Practice B	Practice C	Practice D	Practice E	P Value
Pathologic Gleason (%)							
≤6	96 (15%)	7	11	11	33	19	.3376
=7	461 (73%)	81	78	72	45	69	
8-10	76 (12%)	12	11	17	22	12	
Pathologic stage (%)							
T2x/T2a-c	410 (64%)	66	66	72	79	60	.3544
T3/T4	229 (36%)	34	34	28	21	40	
Median volume cm ³ (range)	36 (13-250)	24.7 (13.1-77.5)	46.3 (15-250)	32 (13.9-51)	35.5 (17-107)	35.4 (13-125.4)	<.0001
CCI							
0	452 (71%)	66	65	61	68	79	.0014
1	100 (16%)	20	15	28	11	15	
2+	83 (13%)	14	20	11	21	6	
Median BMI kg/m ² (range)	28.8 (19.8-60.7)	28.6 (20.2-41.8)	29.0 (19.8-60.7)	29.8 (24.5-37.3)	28.8 (23-38.5)	28.5 (20.6-45.3)	.7396
Race (%)							
Caucasian	434 (82%)	100	91	44	83	73	<.0001
African American	77 (14%)	0	6	56	17	22	
Other	19 (4%)	0	3	0	0	5	
Nerve-sparing (%)							
Bilateral	548 (87%)	46	83	35	78	99	<.0001
Partial	58 (9%)	27	14	30	11	1	
None	28 (4%)	27	3	35	11	0	
PSA, median (range)	5.9 (0.1-52.8)	5.7 (2.7-39.8)	6.3 (0.3-38.8)	6.5 (0.6-41.5)	5.4 (2.7-21.9)	5.4 (0.1-52.8)	.0247

BMI, body mass index; CCI, Charlson comorbidity index; PSA, prostate-specific antigen.

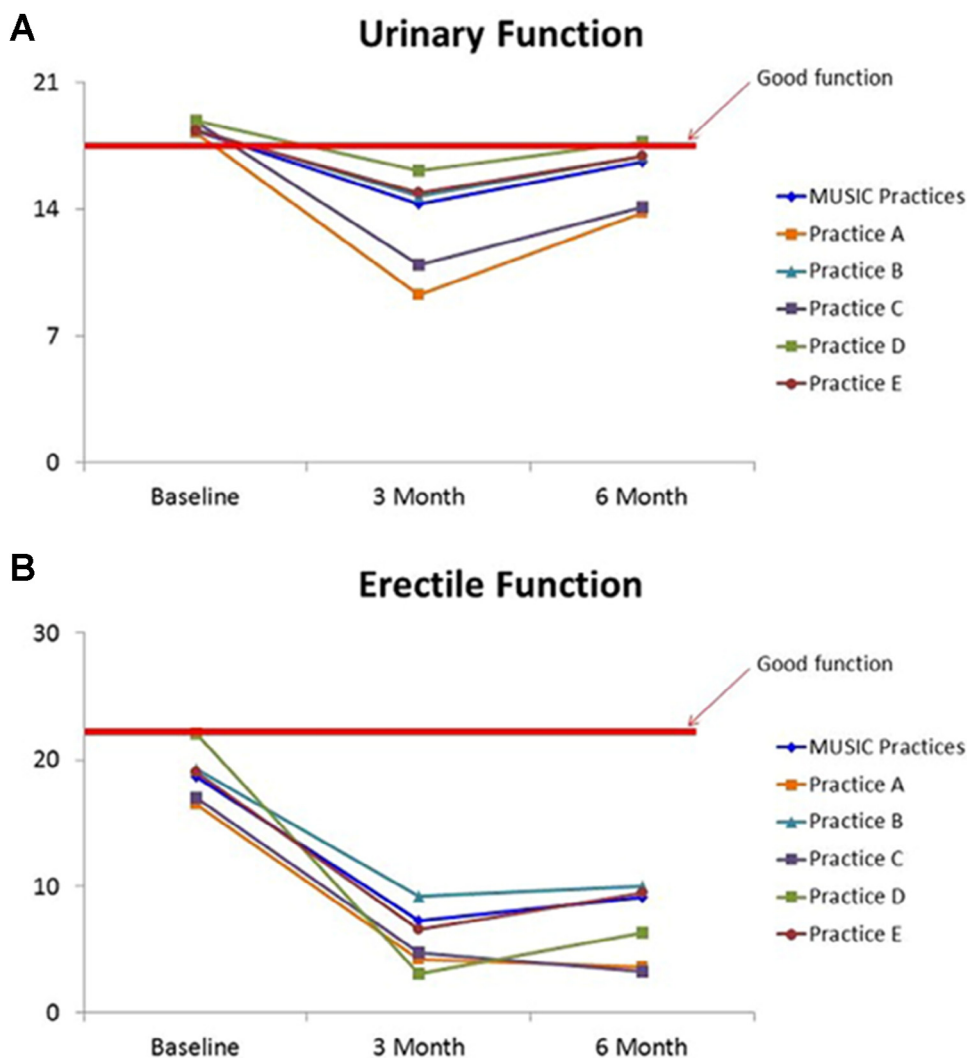


Figure 2. (A) Mean urinary function scores for the 5 pilot practices at baseline, 3 months, and 6 months. (B) Mean erection function scores for the 5 pilot practices at baseline, 3 months, and 6 months.

was structured within the survey process, which resulted in the relatively high response rates. This included automated email reminders to complete the survey 2 weeks before surgery or follow-up visit. More importantly, if the survey remained incomplete, a follow-up telephone call was performed. Additionally, in the study by Parker et al, younger patients (<60 years) and those in urban areas were more likely to complete surveys. In our project, use of paper PRO surveys occurred throughout the states without a geographical trend.

With respect to urinary incontinence, the patient responses in our project demonstrated content validity. The 5 pilot sites reported good mean urinary function preoperatively, decreased function at 3 months, and partial functional recovery at 6 months, consistent with recovery reported in several recent studies.^{5,6,9,10,13} In addition, there was variability in outcome noted among the practice groups, although it was unclear whether patient factors or surgical technique or both account for this variability because we presented unadjusted outcomes. Factors that may ad-

versely affect outcomes include increasing age, comorbidity,¹⁷⁻²⁰ and non-nerve-sparing technique.⁹ Survey results in the Utah Cancer Registry also exhibited an association between surgeon volume and urinary incontinence.¹¹ Additionally, there was still variability within each surgeon volume category, which suggests other operative factors such as skill and technique may influence outcomes.¹¹

Similar to urinary function, erectile function among patients undergoing a nerve-sparing procedure was impacted by time after treatment, which is mirrored in other studies.^{1,5,6,9,10,13} Variation between practice groups was again noted at baseline, 3 months, and 6 months, attributable to patient, tumor, and operative factors. In the literature, age, comorbidity, and preoperative erectile function have been associated with erectile dysfunction following prostate cancer treatment.^{10,17-20} Potency at 1 year was better with bilateral vs unilateral nerve-sparing surgery (69% vs 43%).⁹ In the Utah Cancer Registry, surgeon volume was associated with erection strength, but further variability

within each surgical volume group suggests other factors may influence erection function.¹¹

There were several limitations to the report of this quality-improvement initiative. First, our project was limited by sample size and short-term follow-up. The length of follow-up did not yet allow one to determine the degree of improvement in erectile function after surgery, whereas urinary function improvement was seen. However, the aim of our project was to report the feasibility of a novel statewide collection system and PRO design. Because it was a pilot study, limitations in sample size and follow-up were expected. Nonetheless, the pattern of both early urinary and erection function mimicked those reported in other larger studies, which lent validation to both the data collection process and the survey itself.

An additional limitation arose from using a new survey for collection of functional outcomes. The minimum important clinical difference has not yet been described, thus the meaning of the changes of this survey over time was unclear. With a larger cohort over time, we can estimate this from the standard deviation of pretreatment scores using the Cohen effect size standard of 0.5 standard deviations. A similar process was used in the estimate, the minimum important clinical difference in a modified EPIC, EPIC-CP.²¹

It is recognized that other surveys have been used to assess urinary and erection function. The advantage of the STAR assessment for urinary and erectile dysfunction is that it is shorter than EPIC and simpler to score. It is more pertinent to the post-prostatectomy symptoms than the American Urological Association score. The Patient-Reported Outcomes Measurement Information System questionnaire is helpful in addressing the sexual desire component that may be missed in other questionnaires. Additionally, the STAR assessment has been previously used and validated in a web-based format. It is adaptive to patient responses based on sexual activity.

As our study population grows and matures, we intend to study comprehensively the factors that influence PRO. Patient-level reports contribute to clinical guidance, and physician-level reports of the PROs enhance the understanding of a surgeon's own outcomes, allow self-reflection, and provide opportunities for quality improvement. In addition, the ability to compare outcomes among surgeons and practices will improve after we introduce risk-adjustment techniques that account for patient age or tumor burden. This will be important for better counseling patients who, for instance, have factors that make them at higher risk of declines in erectile function. Additionally, only by risk adjustment analysis can we identify potentially modifiable areas for improvement.

Our study showed that a statewide, electronically based data collection was feasible. The online format provided a degree of automation, which took the burden away from the clinician and the practice to chase down surveys. It also provided ready access during the patient's clinic visit to discuss the issues highlighted in the patient's survey response. Although considerable administrative effort was required to achieve our high completion rates, the

administrative load may be reduced in the future by implementing a telephone interactive voice response symptom that reminds patients to complete the survey. Further, we have now implemented tablet computers for patients completing the survey in clinic with responses synced with the registry. Another possible mechanism to improve electronic response rates would be to use a smartphone application that would remind and allow patients to complete surveys.

CONCLUSION

A web-based system was successful in collecting early PROs for patients undergoing radical prostatectomy among 5 pilot practices in MUSIC. However, despite efforts to encourage electronic completion, 25% of patients still required paper responses. Early outcomes for urinary and erection function were consistent with the literature, suggesting validity for our PRO method. By integrating mature outcome data among more practices in the future and by understanding variations in outcome in relation to surgical technique, MUSIC PRO can be used as a vehicle for quality improvement and improve prostate cancer surgical care throughout the state.

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APPENDIX

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.urology.2017.04.058>.