BrightOutcome
COLLABORATIVE SYMPTOM MANAGEMENT

Descriptions of clinical studies

Several clinical studies have supported the positive impact of Patient-Reported Outcomes (PRO) in clinical settings. This report includes descriptions of recent studies as well as studies prior to 1997.

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Summary

Recent findings

Several recent clinical studies have supported the positive impact of the routine monitoring of and responses to patient-reported outcomes (PRO) in clinical practice (e.g., Chumbler et al.[1], Velikova et al.[2], Detmar et al.[3], Castro[4], and Rubenstein et al.[5]) Main benefits of this type of patient care solutions include:

- Better patient physical, functional, and emotional well-being[2].
- Better utilization of healthcare resources and services, such as fewer "preventable services" and bed days of care (BDOC) for hospitalizations[1].
- Better detection of more moderate-to-severe issues in several less observable (e.g., social and emotional) or subjective (e.g., pain and fatigue) PRO domains[3].
- Improved provider-patient communication as reported by providers[4].

Findings before 1997

However, these successes are mostly recent findings. Prior to 1997, a number of studies have also evaluated the impact of using PROs and found no significant differences in health status and/or care process variables[6, 7]. Several researchers have addressed the question of why earlier studies of the use of PROs in clinical practice have failed to consistently find the expected positive impacts. Greenhalgh et al. [8] have argued for the use of "patient-centered" measures, provision of PRO results to the entire health care team, monitoring patients longitudinally, attention to barriers to the use of PRO by clinicians, and careful design of the report interface including provision of PRO score interpretation.

Clinical findings incorporated into BrightOutcome products

Other researchers have emphasized the importance of linking PRO scores with meaningful clinical information. Rubenstein et al.[5] emphasized the need to pair resource and patient management guidelines with PRO scores to make it easier for physicians to make patient management changes based on PRO results. Rosenbloom et al.[9] conjectured that failure to supplement PRO results with specific clinical suggestions may have accounted for their failure to find differences in health status or treatment satisfaction between a PRO assessment intervention and control groups.

Collectively, the lessons learned from these earlier studies contributed to the success of the more recent studies. Our products are designed with these lessons in mind and leveraged many ideas from the recent successes.

RCTs for cancer published after 1997

Benefits:
Fewer "preventable services"
Few hospitalization bed days of care

1) Chumbler et al.[1] reported a matched case-control trial conducted between July 2003 and February 2004 to study the effect of a PRO-based telehealth program on healthcare utilization for veterans undergoing chemotherapy treatment. For each patient in the intervention group, up to two control patients were selected to match tumor type and cancer stage. A total of 43 patients were in the intervention group and 82 in control. Patients in the intervention group used a palm-sized messaging device to provide daily reports of five common symptoms experienced by chemotherapy patients, including fatigue, pain, nausea, functional limitations, and emotional distress. A care coordination nurse received alerts when reported symptom severity was above predetermined thresholds and called the patient to triage and follow-up. The trial results showed significantly fewer "preventable services" (determined via medical record reviews), bed days of care (BDOC) for all-cause hospitalizations, chemo-related hospitalizations, and BDOC for chemo-related hospitalizations for the intervention group compared to the control group, implying a more successful management of symptoms.

Benefits:
Better overall QoL
Better physical, functional, and emotional well-being

2) Velikova et al.[2] conducted a prospective RCT between January 2000 and July 2001 involving 28 oncologists and 286 cancer patients commencing active treatment (mostly metastatic patients with chemotherapy) to study whether routine use of PRO data could improve communication and patient outcomes. Patients were randomized into 3 groups: completion of PRO assessments ***with*** feedback given to physicians (Physician-Patient intervention), completion of PRO assessments ***without*** feedback given to physician (Patient Only intervention), and control with a 2:1:1 ratio favoring Physician-Patient intervention. Physicians were not randomized. For both intervention groups, patients completed QLQ-C30 and HADS on touch-screen computers prior to each visit. Physicians for patients in the Physician-Patient intervention group received graphical charts of the assessment results, while physicians for those in the Patient Only intervention did not. Outcomes of the interventions were measured using a different instrument, the FACT-G. Significant improvements in FACT-G scores were obtained in both intervention arms compared to control. The following table summarizes the results.

	Physician-Patient Arm Compared to Control	Patient Only Arm Compared to Control
FACT-G Total Scores	p=.006*	p=.01*
FACT-G Physical Well-being	p=.006*	p=.003*
FACT-G Functional Well-being	p=.03*	p=.08
FACT-G Emotional Well-being	p=.008*	p=.12
FACT-G Social Family Well-being	p=.69	p=.56

No significant differences were found between the two intervention arms. Statistically significant differences (alpha=0.05) were obtained between the Physician-Patient group

and control on every measure except the FACT-G Social Family Well-Being scores. Interestingly, significant results also were obtained between the Patient Only group and Control group scores on the FACT-G Total and Physical Well-being measures. This is particularly notable since the Physician-Patient group had twice as many participants and, therefore, was substantially more powered for finding significance. In addition, they found that for the Physician-Patient group compared to control, there was more frequent discussion of PRO concerns (p=.03), and 64% specifically referred to PRO data during the clinical encounter. The discussion of PRO concerns did not prolong the clinical encounter. Explaining the contrast between these results and those of studies in which significant benefit for patients had not been found, Velikova et al. highlighted their use of repeated measurements, a cancer-specific outcome measure, the inclusion of feedback, and training of the physicians with a request that they use the PRO information in the clinical encounter.

Benefits:
Less depression

3) McLachlan et al.[10] conducted an RCT between March 1999 and February 2000 with 450 cancer outpatients (only 38% were receiving anticancer therapy) to study whether making PRO data available to the healthcare team would improve the psychosocial functioning of cancer patients. Patients were randomized to either intervention or control using a 2:1 ratio. Patients in the intervention group completed QLQ C-30, CNQ, and BDI-SF on a touch-screen computer before a visit. A one-page summary of the assessment results was immediately available during consultation with the physician and the care coordination nurse. The trial results showed no significant between-group difference in changes in cancer needs, health status, psychosocial functioning, or satisfaction with care. However, in the intervention group compared to control, significant improvement in BDI scores (measuring depression) were observed for patients who reported moderate to severe depression at the baseline.

Benefits:
Improved patient-provider communication

4) Taenzer et al.[11] conducted an RCT roughly around 1997-1998 (inferred from the article) with 53 cancer outpatients (unclear if the patients were on active treatment or not). Patients were assigned 'sequentially' to the control group first, and then assigned to the intervention group. The choice of this design instead of full randomization was to avoid contamination that could occur if the same physician was seeing patients from both the control and the intervention groups. Each patient in the intervention group completed computerized QLQ C-30 before a visit and the report was made available during the visit, while those in the control completed the paper QLQ C-30 after visit. Based on an exit interview, the authors found significantly more issues were endorsed on QLQ C-30 as having been discussed during the clinic visit in the intervention group compared to control. Also marginally more QLQ C-30 items were acted upon based on medical record audit in the intervention group. No difference in patient satisfaction as measured by PDIS was observed.

Benefits:
NA

5) Jordhoy et al.[12] conducted a clustered RCT between March 1995 and November 1997 with 434 palliative cancer patients with life expectancy between 2 and 9 months. Patients were randomized into either the intervention or the control group. Patients in the intervention group completed QLQ-C30, IES, and other PRO instruments each month. A comprehensive palliative care program involving both inpatient staff and community staff was provided based on patient-reported needs and priorities. The trial results failed to show significant improvement on any PRO dimensions. The authors suggested various reasons for the results; including ceiling effect, the early stage of the new palliative care program, and the involvement of community service personnel who lacked experience in palliative care.

Benefits:
Better detection of less-observable or subjective PRO issues.

6) Detmar et al.[3] conducted a crossover RCT between June 1996 and June 1998 with 10 physicians (5:5 crossover) and 214 cancer patients (114 intervention, 100 control) undergoing palliative chemotherapy (recruited after two cycles of chemotherapy) in an outpatient setting to study the effect of PRO assessment on patient-physician communication. Patients in the intervention group completed EORTC QLQ-C30 in the waiting room immediately before the visit. The assessment results in graphical charts were made available during the visit. Patients in the control group received usual care without completing the QLQ-C30 questionnaire. All encounters were audio-recorded and content analyzed. The content analysis revealed significantly more frequent discussion of PRO concerns in the intervention group. The intervention also helped physicians identify more moderate-to-severe issues in several PRO domains, judged by level of agreement between patient's own health status assessment and the physician's assessment. The improvements were associated mostly with less observable (e.g., social, emotional) or subjective domains (e.g., pain, fatigue). No significant improvement in patient satisfaction scores was observed (likely due to ceiling effect of satisfaction measures), except for perceived emotional support from the physician. Only modest improvement on patient health status as assessed by SF-36 was observed. The use of SF-36 may be one reason that no significant outcome improvement was observed.

Benefits:
NA

7) Rosenbloom et al.[9] reported an RCT conducted between 1990 and 1992 (however the article was published in 2007) with 213 patients with metastatic cancer undergoing chemotherapy treatment. Patients were randomized to intervention, attention-control, and control groups. Patients in the intervention group completed FACT-G and associated disease-specific modules before each clinic visit, and were interviewed by a research nurse in a 20-to-30-minute structured interview to further explore details of reported concerns. Interview results were passed on to a treating nurse for clinical consideration. Patients in the attention-control group also completed the FACT-G instrument before each visit but did not receive the structure interview. Patients in the control group did not complete the FACT-G. Trial results showed no significant between-group differences in changes in overall PRO status (measured by FLIC) or

patient satisfaction (measured by PSQ-III) over time and no difference in clinical treatment changes. Several reasons were suggested by the authors for the failure to find significant differences including ceiling effects, the involvement of nurses instead of physicians in the trial, instrument limitations, and the limitations of the structured interview.

RCTs for other diseases published after 1997

Benefits:
Better provider-patient communication.

Castro[4] conducted a large-scale RCT (n=1079) to evaluate the effect of PRO data on patient satisfaction and provider-patient communication for rheumatoid arthritis patients. The RCT was to follow each patient for one year. For the first 6 months, no intervention was given. At 6 months, all patients completed a suite of PRO instruments (including HAQ, SF-12 Mental, pain joint count, a questionnaire on medication compliance, and a VAS on disease activity) before each visit. Two-thirds of the patients were randomized to view their PRO result charts with their physicians and the rest did not view the results. The primary endpoint for patients was a single question on satisfaction with medical care. Endpoint for physicians included six questions on provider-patient communication. Viewing PRO result charts did not improve patient satisfaction (perhaps due to ceiling effect and/or insensitivity in the one-item satisfaction measure) but did result in significant improvement in provider-patient communication as reported by the providers.

Benefits:
Fewer ER visits
Fewer admissions for hospitals and nursing homes
Shorter length of hospital/nursing home stay.

Meyer et al.[13] reported a prospective quasi-experimental design as part of a VHA-funded two-year project (1998-2000) to test "disease management principles, the care coordinator role, and the effective use of technology to maintain veterans in their homes." The study enrolled 791 veterans from a "high use, high risk, and high cost population" with various clinical conditions including CHF, COPD, hypertension, and diabetes. These patients completed SF36 daily on a messaging device, which implemented a custom-designed care algorithm on symptom self-management and disease knowledge areas. Compared to a population with clinically similar conditions, the intervention group had significantly fewer emergency room visits, hospital admissions, hospital bed days of care, nursing home admissions, and nursing home bed days of care. The same concept was later applied to cancer patients (see above).

RCTs published before 1997

Greenhalgh and Meadows[6] conducted a systematic review of literature between 1987 and 1997 and identified 13 RCTs that studied the effects of routine use of PROs in clinical practice in terms of care process and patient outcomes. None of these studies focused on cancer patients. Most of these studies were general/family practice for patients with disability or psychological distress.

With respect to the care process, the review found evidence that the use of PROs helped clinicians detect more psychological issues and, to some degree, functional issues as well. Some studies showed increased referral rates and more changes to treatment, but most studies did not find such differences. Most studies also did not find significant improvement in patient outcomes, although one study reported improved mental functioning and another found better functional status despite similar anxiety scores. No study reported improved patient satisfaction and only one reported better patient-physician communication.

Espallaagues et al.[7] conducted a similar systematic review based on publications between 1976 and 1997 and 21 RCTs. 10 of these 21 studies were also reviewed in Greenhalgh and Meadows' report. Again, no study was cancer-specific and most were conducted in primary care settings or with patients who had mental health issues.

The general conclusions are unsurprisingly similar to those of Greenhalgh and Meadow. More than half (11 of 20) of the studies showed positive effects of providing PRO data to clinicians on process of care; most notably diagnosis rate and health service utilization, followed by treatment. The effects were more prominent when mental health PROs were used, but less when the PRO data were limited to only general health status. Improvements in patient outcomes were reported in 4 of 11 studies. Improvements in patient satisfaction were reported in 3 of 7 studies.

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