

## Moving Beyond the “1 Size Fits All” Paradigm

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**H**istorically, treatment for localized prostate cancer followed an assembly line algorithm in which, once diagnosed with cancer, the patient is either scheduled for surgery or radiotherapy. This has been characterized as the “1 size fits all” paradigm. Over the past 10 years, validated measures for the assessment of health-related quality of life (HRQOL) have been promulgated as relevant and critical endpoints for prostate cancer care.<sup>1</sup> As we have learned more regarding complications, particularly those involving HRQOL, refinements in techniques have been made and new therapies have been developed. An important goal of measuring pretreatment HRQOL is to aid decision-making before therapy because pretreatment HRQOL status is reported to be an important predictor of post-therapy HRQOL.<sup>2</sup> In theory, men with better function before therapy should be given the opportunity to undergo specific techniques that are known to be associated with better functional outcomes, albeit with somewhat greater risks. For example, the use of nerve-sparing radical prostatectomy (NSRP), which carries a risk for more positive surgical margins, has been shown to result in better sexual function after surgery.<sup>3</sup> Although it may be intuitive to some that pretreatment HRQOL is linked to post-therapy HRQOL based on physiologic principles, is this the only pathway? As suggested by Chen et al.,<sup>4</sup> another mechanism by which recovery may be correlated is how therapies are aligned or misaligned with an individual's pretreatment HRQOL.

In the study by Chen et al.,<sup>4</sup> the possibility of mismatch as a mechanism for worse outcomes was examined in a group of 438 men. Among men with a mismatch, which is defined as an instance in which the patient receives a primary therapy that would likely worsen the patient's baseline function or be unlikely to result in the intended functional benefit, HRQOL, particularly sexual functioning, was found to be worse compared with men who were better matched. What was also remarkable among the authors' observations was the high frequency of mismatch using an admittedly liberal definition. Take for example the finding that 40% of men with poor baseline sexual function underwent NSRP. Although at face value this appears trivial, the fact remains that there is a finite increased risk for positive surgical margins with NSRP. Other equally compelling examples of mismatch with high frequencies are highlighted in the article by Chen et al.<sup>4</sup> The reasons behind such egregious mismatches defy obvious explanation but several possibilities exist.

See referenced original article in *Cancer*. 2008; 112:61–68.

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Received September 5, 2007; accepted September 6, 2007.

Mismatch between pretreatment HRQOL and the actual treatment received may be attributed to the poor dissemination of high-quality evidence to patients. A review of educational materials designed for patients with prostate cancer found that many are outdated, incomplete, or biased.<sup>5</sup> Moreover, many of these materials failed to meet literacy requirements for lay persons.<sup>5</sup> However, in the age of Google searches and iPhones, there is little doubt that the Internet is now a common source of health information regarding prostate cancer for men. A recent review of Internet sites by Black and Penson<sup>6</sup> found that 94% of the data reviewed on websites were correct; however, many websites also were found to be limited in content and lacked references to substantiate their claims. Time-consuming as it may be, it remains the purview of the physician to appropriately counsel patients regarding the likely risks, benefits, and alternatives before treatment of prostate cancer.

A fundamental tenet of the field of outcomes research is that measures be reliable and validated before use. This suggests another possible explanation for the mismatch, which may be the failure to use a validated HRQOL measure before treatment. Outside of the research setting, the use of validated HRQOL measures among prostate cancer patients remains uncommon. Many clinicians opt for simpler, generic queries regarding urinary, sexual, and bowel function that are prone to subjective interpretation and bias. Mild urinary leakage for one person may in fact be devastating urinary incontinence to another. For these reasons, validated measures need to become more universally applied in practice.

In a preference-sensitive decision, as is the case for localized prostate cancer therapy, it is imperative that all relevant information be presented to those who are making the decision. There is evidence that treatment decisions are highly influenced by the specialty of the consulting physician.<sup>7</sup> The conclusion reached by Chen et al. that baseline QOL is not considered during decision making is plausible but inconclusive because the authors did not actually measure the physician-patient communication.<sup>4</sup> Hypothetically, the results may have been skewed in the opposite direction had there been no patient-physician communication regarding pretreatment HRQOL. Nevertheless, their findings are consistent with the "1 size fits all" mentality observed so often in today's society.

Decision-making for the treatment of patients with localized prostate cancer is an important and yet infrequently studied aspect of quality of care. Observations made by Chen et al.<sup>4</sup> should prompt all

clinicians to pause and question the quality of their patient counseling processes. Do they routinely incorporate pretreatment HRQOL measures into practice? Do they use validated measures that are now available? The National Cancer Institute's 2006 Cancer Research plan emphasizes quality cancer care, which it defines as evidence-based care that is patient centered, timely, and technically accurate, and is administered by physicians who use appropriate levels of communication, share decision making, and demonstrate cultural sensitivity.<sup>8</sup> Qualifying descriptors such as "technically accurate," "appropriate levels of communication," and "shared decision making" are more than mere criteria for a quality of care assessment. Rather, they exist as the building blocks for good quality care. Consequently, it is at the core of quality cancer care that all patients are provided evidence-based, patient-centered information that is timely and administered with easily understood and accurate communication. A better appreciation of how much of the treatment variation in care is due to informed patient discretion is necessary to improve care. To our knowledge to date, the determinants of the quality of decision making are largely unknown and a conceptual model does not exist. A patient-centered conceptual model is necessary to aid clinicians and researchers in identifying areas of deficiency in the decision-making process for patients with early prostate cancer, and to establish the framework for designing effective decision-support interventions that will improve the cancer survivorship experience.

Although the findings by Chen et al.<sup>4</sup> are thought-provoking, there are several limitations to keep in mind. First and foremost is that the authors actually did not measure physician-patient communication. Second, generalizable data outside of this single-institution series are needed as a validation of their findings. A population-based approach that assesses the association between the quality of decision making and HRQOL outcomes would be necessary to prompt global policy changes. Such a study could then establish the framework for interventions to improve "mismatch" as an outcome onto itself. Last, it is important to point out that few men in the study by Chen et al. actually underwent active surveillance, suggesting a potential for selection bias.<sup>4</sup>

It is conceivable that "mismatch" as described by Chen et al.<sup>4</sup> may someday be applied as a quality of care metric, although much more development is still necessary. Currently, pretreatment HRQOL is already an indicator in the RAND Corporation prostate cancer set of measures.<sup>9</sup> One can foresee a not-so-distant future in which "mismatch" will be overcome

by better-quality decision-making processes. Ideally, each patient will have a tailored educational intervention as he participates in the treatment decision-making process, because although the “the 1 size fits all” mentality works well for fast-food chains, it clearly works less well in medical care.<sup>10</sup>

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