outcomes and the scientific basis of clinical care

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Health care is undergoing increasing scrutiny by consumers and other interested parties. The quality of treatments, services, and delivery systems, as well as their efficiency, are subjects for public discussion and political agendas. In order to systematically evaluate dental health to address these concerns, objective measures of benefits and costs associated with treatment are needed. Criteria are necessary to quantify costs, benefits, and risks, and thereby make judgments on how well providers are meeting the health needs of society. "Clinical outcomes" refer to the products or consequences of health interventions. They can be used to evaluate clinical performance on both a case-by-case basis or over a broader population level.

All treatments have multiple outcomes, even though the goal may be to address a single clinical sign or symptom, or a specific disease entity. To be useful, clinical outcomes need to address both the desired and the undesired sequelae of treatment, and must do so both for the short and long term. Unlike medicine, where survival or death are obvious alternate consequences of the management of certain conditions, there are as yet no universally accepted outcome measures for the majority of treatments provided in dentistry.

Examples of outcomes may be the survival of a tooth, the longevity of a restoration, or the absence of pain following a procedure. Cost, both the financial and the "burden" of care, are also outcomes, in this case with negative value to the patient. Given that both negative and positive attributes exist for any clinical intervention, outcomes assessment provides a means for estimating the tradeoffs that patients must make in establishing their preferences, thus providing informed consent.

The outcomes movement, which is closely tied to the evidence-based and patient-centered care profiled in the Institute of Medicine report, is only just beginning to receive general attention within dentistry. As a step toward formulating useful outcome measures, we have recently adopted the following criteria at the Ohio State University College of Dentistry. An outcome measure should:

1. Be unambiguously definable and mutually exclusive with alternative outcomes
2. Be quantifiable
3. Have known reliability
4. Have clearly established validity
5. Be directly associated with a tangible benefit to the patient.

Becoming involved in this process is the best way to ensure that the focus remains on oral health and not just the bottom line.

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References

It may be argued that some important outcomes with benefit to patients, such as improved esthetics, are disqualified by these stringent criteria. While that may be the present case, if these outcomes are deemed to be of sufficient importance as to require treatment, we must establish suitable psychometric instruments to quantify both the extent of esthetic handicap and the improvement associated with treatment. There are already several methods used to assess patient satisfaction, impacts of oral conditions on the quality of life, and other issues that may be regarded as value-based rather than physical aspects of the clinical equation. The main point is that for meaningful evaluation, we need the utmost in rigor and precision in what we are measuring. The fact that it is not easy at present to come up with all of the needed outcome measures does not argue for adopting definitions of criteria that, because of their imprecision, yield meaningless and equivocal results.

Once we have good data available for outcomes based on representative samples of patients and providers, it is also possible to establish the probabilities for the results of alternative clinical decisions. This data is important for helping patients make better choices based on their own values and preferences or "utility systems." Such information will be even more useful in predicting outcomes if odds can be stratified by demographic variables that render prediction more specific for a patient or class of patients, such as age, gender, socioeconomic factors, or other pertinent risk indicators.

An example of information that can be obtained from a systematic study of treatment and outcomes is illustrated by a retrospective assessment of patients treated in the graduate orthodontic clinic at the University of Pittsburgh. This study was based on a retrospective database of cases treated at the University of Pittsburgh between 1977 and 1991, and consisted of a large sample of Class I and II Division 1 malocclusions in the permanent and mixed dentitions treated in both the mixed and permanent dentition. All cases for which complete records were available were included in the sample (Table 1).

Variables measured included duration of treatment in months, and pre- and post-treatment Peer Assessment Rating (PAR) index scores. The PAR index is a well-established measure of malocclusion severity, and was developed for and is now also widely used as an outcome measure for orthodontic treatment.

### Table 1. Comparison of Clinical Outcomes for Orthodontic Treatment Begun in the Mixed and Permanent Dentition Stages

<table>
<thead>
<tr>
<th>Malocclusion Class</th>
<th>Dentition at Start of Treatment</th>
<th>Number of Subjects</th>
<th>Mean % Reduction (SD)</th>
<th>Mean Treatment Duration in mo (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Mixed</td>
<td>129</td>
<td>58.9 (23.2)</td>
<td>30.1 (13.7)*</td>
</tr>
<tr>
<td></td>
<td>Permanent</td>
<td>265</td>
<td>55.9 (27.1)</td>
<td>21.5 (9.0)*</td>
</tr>
<tr>
<td>II Div 1</td>
<td>Mixed</td>
<td>172</td>
<td>65.4 (22.8)</td>
<td>33.1 (12.1)*</td>
</tr>
<tr>
<td></td>
<td>Permanent</td>
<td>340</td>
<td>64.3 (20.3)</td>
<td>26.8 (10.1)*</td>
</tr>
</tbody>
</table>

*P < 0.0001, †P < 0.0001

### Table 2. Comparison of Cost Outcomes for Orthodontic Treatment Begun in the Mixed and Permanent Dentition Stages

<table>
<thead>
<tr>
<th>Malocclusion Class</th>
<th>Dentition at Start of Treatment</th>
<th>National Average Cost (SD)</th>
<th>Calculated Cost/ mo of Treatment</th>
<th>Calculated Cost/% PAR Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Mixed</td>
<td>$2497 (818)</td>
<td>$83</td>
<td>$42</td>
</tr>
<tr>
<td></td>
<td>Permanent</td>
<td>$3182 (546)</td>
<td>$148</td>
<td>$57</td>
</tr>
<tr>
<td>II Div 1</td>
<td>Mixed</td>
<td>$2640 (815)</td>
<td>$80</td>
<td>$40</td>
</tr>
<tr>
<td></td>
<td>Permanent</td>
<td>$3340 (571)</td>
<td>$125</td>
<td>$52</td>
</tr>
</tbody>
</table>

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The validity of the PAR score has been demonstrated by comparing the ranking of malocclusions scored for the index with the rating of malocclusion severity as determined by a panel of expert orthodontists. A high degree of agreement between the clinicians' ranking of severity and the severity determined by the index indicates that the PAR rating is a valid estimate of severity.\(^6\)

In the study discussed here, the duration of treatment was determined and the percent reduction in PAR scores attributable to treatment was calculated for each case. Both of the variables measured, treatment duration and percent PAR index reduction, represent outcomes of orthodontic treatment. The main findings from this study are included in Table 1, and indicate that:

1. Treatment duration on average was considerably less for cases begun in the permanent dentition than for the mixed dentition cases.
2. The amount of improvement was similar at both ages for the same malocclusion.
3. These outcomes may have varying degrees of utility, or value, to the consumer and to the health care provider.

As reported in the American Dental Association (ADA) 1993 Survey of Dental Fees,\(^7\) considerable differences in the fees charged for orthodontic care exist between treatment in the mixed dentition and permanent dentition, even for the same type of malocclusion (Table 2). The rationale for such differences is not clear, nor is it self-evident, according to the data shown above, that one strategy provides substantially different benefits which could either justify or account for the difference in costs. Whether we are considering the benefits to consumers or the profitability for the provider, or a necessary compromise between these factors, it would seem important to know what differences in economic outcomes are to be expected from the two different timing options for orthodontic services.

Based on the average reported fees for treatment, we can calculate the cost per month of treatment and the cost per unit improvement (Table 2). These outcomes can then be compared to guide both informed consent by patients and practice-management decisions by health care providers. These comparisons show us that the average cost per month of treatment is substantially higher in the permanent dentition than in the mixed dentition, and that the cost per unit of improvement, as measured by the PAR index, is also higher in the permanent dentition.

It may be concluded that the decision concerning the timing of orthodontic treatment, early in the mixed dentition versus later in the permanent dentition, involves a tradeoff. Earlier treatment is likely to cost less, but take longer, than later treatment. Given that the average quality of results assessed by the relative reduction in PAR scores is comparable and that mixed dentition treatment is less expensive both in absolute and relative terms, under what conditions would the preferred option for a patient or parent be treatment in the permanent dentition?

Clearly, such issues will be subject to the factors that enter into the patient's value system or constraints imposed by their individual circumstances. The decision is the consumer's. The provider's obligation is merely to provide the information and give guidance in interpreting the consequences of choices.

From the perspective of the provider, there is some justification for basing fees on the costs of providing care, and after examination of this outcome data, reassessment of fee structures might be in order.

**Discussion**

Clinical outcomes assessment represents the only means of answering the question of how good dentistry is and how much value it provides for the consumer. It also is a way for dentistry to examine its performance and for improving the services it provides. This could be seen as potentially undermining professional autonomy, because the existence of yardsticks means that others could measure our performance. Fears have been voiced that once such objective monitoring is possible, organizations such as insurance companies may use the information in ways that would have a negative impact on health care professions. Although it may not be possible to totally dismiss such anxiety, we are given little choice as to the future role of outcomes and their application to the evaluation of dentistry. If we do not take the initiative and determine the objective measures used to evaluate our performance, then others certainly will. It is probable that if outcome measures devised by dentistry are done scientifically and in good faith, with our patients' interests at heart, such measures will be preferable to those devised strictly for cost containment with no consideration of the benefits to patients. Careful evaluation of the outcomes of our treatments provides us with the information we need to continue to improve the care we provide, and to demonstrate the value of our treatments to patients and payers.
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References

Pediatric dental treatment outcomes: the importance of multiple perspectives
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Edelstein, Vig et al., and White have highlighted the importance of outcomes assessment in pediatric dentistry, and called for further development of pediatric dental outcome measures. Although similar views are commonly expressed within the health services research and health policy communities, outcomes research and assessment have not attracted broad levels of support within the dental profession. Many practitioners continue to view outcomes measurement and assessment as burdensome—and a threat to professional judgment. However, as Seale has pointed out, data derived from outcomes research and assessments are becoming increasingly valuable, if not essential, in situations where pediatric dentists and other health professionals are called upon to defend treatment decisions and substantiate treatment recommendations.

Enhancing the quantity and quality of available outcomes measures is an important prerequisite to developing improved outcomes assessment activities that will further the scientific basis of clinical practice and quality patient care. Outcomes measurement as an isolated activity, however, is of limited value. In order for outcomes measurement to be meaningful and allow us to better understand those factors that influence outcomes, direct measures or indirect indicators of outcomes must be linked to measures of structural elements or processes of care. Fundamental to this emphasis on structure-process-outcome linkages is the premise that good structure increases the likelihood of, but does not guarantee, good processes and that good processes in turn increase the likelihood of, but do not guarantee, good outcomes. This more comprehensive approach provides a rationale for gathering information on outcomes that practitioners and policy makers can readily appreciate.

Because outcomes are influenced by a variety of factors over which practitioners frequently have limited control, such as patients’ lifestyles, presenting disease status, inherent resistance to disease, and compliance with professional recommendations, outcomes measures also need to be adjusted for factors known to influence outcomes. Appropriate risk adjustments not only increase the validity of outcomes assessments, but also help overcome practitioners’ concerns about being judged unfairly because of the baseline characteristics and behaviors of the patients they treat.

Much has been made of the relative paucity of outcome measures in health care in general, and in dentistry in particular. While few would argue with that concern, we also should not overlook the fact that countless data-collection opportunities on important aspects of care that could be used to examine treatment processes and outcomes are missed because of the primitive state of most existing clinical information systems. Were efficient systems such as computer-based patient records widely available, practitioners could readily retrieve information linking patient conditions, treatment choices, and patterns of care to selected outcomes that are of interest to practitioners and patients alike. Ongoing, systematic data collection of this nature is essential to understanding what works best under different circumstances for which patients, as well as to meaningful quality improvement.