Estimated Cost-effectiveness of Growth Hormone Therapy for Idiopathic Short Stature

Joyce M. Lee, MD; Matthew M. Davis, MD, MAPP; Sarah J. Clark, MPH; Timothy P. Hofer, MD; Alex R. Kemper, MD, MPH, MS

Objective: To estimate the cost-effectiveness of growth hormone (GH) therapy for idiopathic short stature (ISS).

Design: Cost-effectiveness analysis.

Setting: Decision model.

Patients: A cohort of 10-year-old prepubertal boys with ISS treated with GH.

Interventions: Comparison of children treated for 5 years with GH therapy vs children receiving no intervention.

Main Outcome Measures: Incremental cost per child, incremental growth per child, and incremental cost per inch of final height gain.

Results: The estimated incremental cost-effectiveness ratio of GH therapy for ISS in the base case analysis compared with no therapy was $52,634 per inch (per 2.54 cm), or $99,959 per child, reflecting an incremental growth of 1.9 in (4.8 cm). Alternate treatment strategies such as increased duration of GH treatment and high pubertal dosing of GH did not substantially improve the cost-effectiveness ratio. Probabilistic sensitivity analyses showed that growth variability in response to GH had the greatest impact on the cost-effectiveness of GH therapy.

Conclusions: Targeted treatment of children with ISS with the greatest potential for growth appears critical for maximizing cost-effectiveness of GH treatment. However, the significance of the cost per inch is difficult to judge until the utility gains associated with height gain after GH therapy for ISS can be ascertained.

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In July 2003, the US Food and Drug Administration (FDA) approved the use of recombinant growth hormone (GH) for the long-term treatment of idiopathic short stature (ISS)—also called non-growth hormone-deficient short stature—defined by height SDs ≤ −2.25 and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means.

With this indication, it is estimated that 400,000 children in the United States now qualify for GH therapy. While endocrinologists are the most likely prescribers of GH, general pediatricians will likely encounter patients with this new indication for GH and may be asked by parents for guidance about its effectiveness and cost.

The FDA approval was based on evidence from 2 clinical trials: the only randomized, double-blind, placebo-controlled study to final height conducted at the National Institutes of Health (NIH), Bethesda, Md, and an uncontrolled European dose-response study. In the placebo study, children treated with GH had a final adult height approximately 3.7 cm (1.5 in) taller than that of the placebo group. The dose-response study suggested that the amount of height gained is dose dependent, with higher doses leading to increased growth.

Considerable debate exists about the benefits of a 1- to 2-in (2.5- to 5.1-cm) height gain from GH therapy in otherwise healthy short children. Although some studies suggest that ISS can be associated with psychosocial impairment, it is not associated with physical disability. In addition, GH therapy has not been shown to improve quality of life in children with short stature. Furthermore, GH therapy is expensive: at current prices, it may cost $20,000 or more per year for a 30-kg child, and because GH therapy is usually continued until final adult height is reached, treatment can last 5 years or more.

Rising pharmaceutical costs are a prominent concern for the US health care system. Cost-effectiveness studies of pharmaceutical interventions can serve as a useful decision-making tool for both clinicians and payers. Two studies published in 2002 evaluated the cost-effectiveness of GH therapy for ISS, but both were performed before the availability of the most recent GH efficacy data. Given that a much larger cohort of children is now eligible for GH therapy, the long-term cost-effectiveness of GH therapy for ISS needs to be reevaluated.
therapy, a reassessment of its cost-effectiveness with respect to the recent efficacy data is warranted.

The objectives of this study were to estimate the cost-effectiveness of GH therapy for ISS based on the efficacy data used for FDA approval of this indication, and to evaluate the cost-effectiveness of alternate GH treatment strategies for ISS.

**METHODS**

**DECISION ANALYSIS MODEL**

We constructed a deterministic decision tree to compare GH treatment of ISS with the strategy of height monitoring for ISS, given the lack of alternate treatment options for ISS. Growth hormone efficacy was measured in terms of final adult height gain (final adult height minus baseline predicted adult height at the start of treatment). Given that GH treatment has not yet been proven to improve psychosocial adjustment or quality of life in children with ISS, this aspect of GH therapy was not considered in the model. The analysis was conducted from the perspective of the health care payer.

**ASSUMPTIONS FOR THE BASE CASE SCENARIO**

Because most GH trials for ISS predominantly enrolled male children, our base case scenario consisted of a hypothetical cohort of 10-year-old prepubertal male children with ISS (height 2.25 SDs below the mean, no evidence of GH deficiency based on GH stimulation tests, and no comorbid conditions that compromise growth). Assumptions regarding duration of treatment, drug dosing, patient weight, treatment dropout, and GH efficacy were based on the 2 clinical trials used for FDA approval (a randomized, double-blind, placebo-controlled NIH study and an uncontrolled European dose-response study) and other published studies where appropriate (Table 1).

**FINAL HEIGHT GAIN**

Final height gain for the no-intervention group was derived from the placebo-treated group of the NIH randomized controlled trial. Although mean final height gain for this group was approximately −0.3 in (−0.8 cm), the 95% confidence interval for this figure overlapped 0 in. Therefore, we assumed a height gain of 0 in for the no-intervention group. Final height gain for the GH intervention cohort was assumed to be 2.8 in (7.1 cm), which was the mean adult height gain of children in the arm of the dose-response study that used 0.37 mg/kg per week.

Given that a number of clinical trials of GH for ISS have shown that growth velocity in the first year of treatment is double the pretreatment growth velocity and declines with each successive year of treatment, the model assumed a height gain for each year that was proportional to the increase in growth velocity for each successive year of treatment.

An overall discontinuation rate of 30% in the first year of treatment was assumed, based on rates from observational studies. Given that one recent study of children with ISS showed that children who discontinued treatment had growth rates similar to those of children who continued with treatment, children with early discontinuation of GH treatment were assumed to accumulate a height gain calculated pro rata for the number of years of treatment. Finally, GH was not assumed to accelerate puberty in this model, as recent studies have shown that GH treatment does not appear to accelerate bone age or induce an earlier onset of puberty in children.

**COSTS**

Direct medical costs, including pharmacy costs, physician costs, and laboratory and radiologic costs, for both the GH-treated group and the no-intervention group, were estimated as follows (in 2004 US dollars): GH cost per milligram, $52; cost of physician visit, $58; bone-age radiograph, $17; free thyroxine and thyrotropin measurement, $74; and insulin-like growth factor I determination, $27.

Indirect costs such as transportation costs and parental wages lost because of physicians’ visits were not included.

Regardless of the potential for GH treatment, an initial evaluation is necessary for all children to identify possible organic causes of poor growth. Therefore, the costs associated with the initial evaluation for short stature, including possible laboratory studies, GH stimulation testing, and imaging studies, were not included in this model, because they would be identical for children in the GH treatment and no-intervention groups.

Growth hormone is regarded as a safe medication with frequent and rare adverse events. Given that studies of GH

<table>
<thead>
<tr>
<th>Variable</th>
<th>Assumption</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at initiation</td>
<td>10 y</td>
<td>9, 10</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>3, 4, 10</td>
</tr>
<tr>
<td>Duration of treatment</td>
<td>5 y</td>
<td>3, 4</td>
</tr>
<tr>
<td>Drug dosage</td>
<td>0.37 mg/kg per wk†</td>
<td>4, 11</td>
</tr>
<tr>
<td>Weight</td>
<td>5th Percentile adjusted for chronologic age</td>
<td>12</td>
</tr>
<tr>
<td>Discontinuation rate</td>
<td>30% in first year of treatment</td>
<td>13</td>
</tr>
<tr>
<td>Health care events associated with height monitoring</td>
<td>Annual visit with pediatric endocrinologist</td>
<td></td>
</tr>
<tr>
<td>Health care events associated with GH treatment</td>
<td>GH therapy</td>
<td>14</td>
</tr>
<tr>
<td>Height gain for height monitoring</td>
<td>0 in</td>
<td>3</td>
</tr>
<tr>
<td>Height gain for standard GH treatment (0.37 mg/kg per wk)</td>
<td>2.8 in</td>
<td>4</td>
</tr>
</tbody>
</table>

Abbreviation: GH, growth hormone.

Conversion factor: To convert inches to centimeters, multiply by 2.54.

*Height 2.25 SDs below the mean, no evidence of GH deficiency based on GH stimulation tests, and no comorbid conditions that compromise growth.

†Drug dosage for the baseline case was derived from the dosing approved by the US Food and Drug Administration for GH treatment of idiopathic short stature.
side effects in ISS are currently underpowered to assess the frequency of more serious rare adverse events, the costs of side effects of GH therapy were not considered in the model.

Charge data from our hospital were converted to costs by multiplying charges by 0.5. Retail GH prices obtained from a survey of several US pharmacies were averaged and then verified with another drug reference publication. Costs are expressed in 2004 US dollars.

All modeling was conducted with @RISK software (version 4.5; Palisade Corp, Newfield, NY). We applied a 3% yearly discount rate to both costs and height gain on the basis of consensus guidelines for conducting cost-effectiveness analyses published by the Panel on Cost-effectiveness in Health and Medicine.

COST-EFFECTIVENESS CALCULATIONS

The incremental cost-effectiveness ratio for GH treatment of ISS was defined as the incremental cost of GH treatment divided by its incremental clinical benefit in dollars per inch.

DETERMINISTIC SENSITIVITY ANALYSES

Key assumptions were varied over plausible ranges to examine several parameter effects on the model estimates of GH cost-effectiveness. One-way sensitivity analyses were performed, including (1) final height gain ranging from 1.8 to 3.9 in (4.6-9.9 cm), based on the confidence intervals from the dose-response study; (2) a discontinuation rate ranging from 10% to 40%; (3) age at initiation of 8 or 12 years, with 5 years of treatment; (4) the use of a low dosage (0.24 mg/kg per week) or high dosing of GH at puberty (0.7 mg/kg per week for the last 3 or 4 years of therapy); and (5) a prolonged treatment duration of 7 years (from ages 8-15 years) and 10 years (from ages 5-15 years).

Growth assumptions for the sensitivity analyses are shown in Table 2. Assumptions of height gain for the sensitivity analyses of discontinuation rate and age at initiation were the same as the base case analysis. An increased duration of treatment has been shown to be positively associated with height gain and growth velocity plateaus at a stable rate into the fifth and sixth years of treatment. Therefore, the model assumed total baseline growth for the first 5 years of treatment (2.8 in), and for years 6 to 10 of treatment, incremental growth was assumed to be similar to that in the fifth year of treatment.

PROBABILISTIC SENSITIVITY ANALYSES

We also performed probabilistic sensitivity analyses to assess the impact of growth variability on the cost-effectiveness of this therapy. Rather than using fixed estimates of height gain, we constructed a probabilistic Monte Carlo simulation for the base case analysis. Mean height gain was varied over a normal distribution using variance estimates from the dose-response study. Variance in height gain with GH has 2 determinants: growth variability and error in estimating the predicted adult height. The relative contribution of these 2 determinants to the variance in height gain is unknown. However, one plausible estimate is that growth variability represents 50% of the variance, as the variance of height gain of the 0.37-mg/kg per week arm of the dose-response study was 3.43, compared with the variance of height gain of the placebo group in the placebo-controlled trial, which was 2.37. Therefore, we modeled scenarios in which growth variability represented 30%, 30%, and 10% of the variance of height gain from the dose-response study (Table 2) and limited the distribution to a minimum height gain of 0 in and a maximum height gain of 12 in (30.5 cm). Cost-effectiveness ratios were calculated for 10,000 iterations and the distributions of the ratios were examined.

The estimated incremental cost-effectiveness ratio of GH treatment for the base case analysis compared with no treatment was $52,634 per inch (per 2.54 cm), with an incremental height gain of 1.9 in (4.8 cm) during 5 years and an incremental cost per child of $99,959 (Table 3). Although mean growth per child was assumed to be 2.8 in (7.1 cm) for children who completed 5 years of GH treatment, the mean incremental height gain for the entire cohort was lower (1.9 in) because of early discontinuation of GH treatment in 30% of the cohort, who accumulated a
the incremental cost per inch (data not shown).

Alternate treatment strategies, including high-dose GH at puberty and increased duration of treatment, resulted in increases in the incremental growth per child, but also resulted in marked increases in the incremental cost per child because of the use of more drug overall. There were no substantive improvements in the cost per inch, even when generous assumptions of GH efficacy were used.

Analyses using hospital charge rather than cost data were also conducted, with no appreciable differences in the incremental cost per inch (data not shown).

The results of the deterministic sensitivity analyses are shown in Table 4. The incremental cost-effectiveness of GH for ISS was most sensitive to estimates of drug efficacy. With higher estimates of efficacy, the incremental cost per inch was more favorable ($38 783), and with lower estimates of efficacy, the incremental cost per inch was less favorable ($81 875).

Because of weight-based dosing and increases in weight with increasing age, GH cost per inch was somewhat sensitive to the age at initiation ($42 792 for earlier initiation by 2 years; $66 411 for later initiation by 2 years). The discontinuation rate did not appreciably affect the cost per inch.

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Analyses using hospital charge rather than cost data were also conducted, with no appreciable differences in the incremental cost per inch (data not shown).

When plausible estimates of growth variability in response to GH were used in our model, the mean incremental cost-effectiveness ratio was significantly higher in the probabilistic analyses compared with our deterministic analyses, with wide 95% confidence intervals (Table 5). Only when growth variability represented 10% of the variance of height gain did the cost per inch approximate the figure calculated from the base case analysis, with a significant narrowing of the confidence intervals.
spond to GH, rather than universal treatment of all eligible children, represents an important treatment strategy for improving the cost-effectiveness of this therapy.

The chief challenge in implementing such a strategy, however, is that ISS represents a heterogeneous group of children with short stature of various causes. Diagnoses such as insulin-like growth factor I deficiency, partial GH insensitivity, genetic short stature, familial short stature, and constitutional delay of puberty all fit the classification of ISS,25 no doubt contributing to significant growth variability among children with ISS. Further studies are needed to determine which subsets of children with ISS will have the greatest therapeutic response; the subset of patients who have insulin-like growth factor I deficiency may be one such candidate group.26

The impact of GH therapy on quality of life is uncertain, and quality-adjusted life-years or other utility measures for incremental height gains have not been formally generated from primary data.8 Therefore, future studies to assess the quality-adjusted life-years gained with additional height gain due to GH therapy are required to understand the significance of a cost per inch of $52 000. One threshold for cost-effectiveness frequently cited in the literature is $50 000 to $100 000 per quality-adjusted life-year gained, but whether such a range is appropriate for judging gains in height is not known.27

**LIMITATIONS**

A limitation of this analysis is that it was based largely on 2 clinical trials,3,4 each with a small number of enrolled patients. Assumptions from the studies may not be entirely generalizable because of the small sample sizes. However, to date they represent the best available data and were the basis for FDA approval and for determination of the FDA-approved GH dosing for ISS. Although we did not perform a systematic review of the literature, we are unaware of other data that would change these assumptions.

Growth assumptions for the base case analysis were based on an open-label dose-response study, which did not include an untreated group and was not blinded. Ideally, cost-effectiveness studies are based on the results of randomized controlled trials; the NIH trial3 was the first and only randomized, double-blind, placebo-controlled trial of GH therapy for ISS, and it included intent-to-treat analyses. However, in that study GH was administered at a dose and dosing frequency now considered suboptimal (0.22 mg/kg per week given subcutaneously 3 times per week).3,28

Because of the lack of definitive GH trials for ISS regarding alternate treatment strategies, height gains associated with a longer duration and high-pubertal-dose treatment had to be extrapolated on the basis of studies in the literature. However, we used growth assumptions that favored GH therapy. For example, one study15 of GH-treated children with ISS showed that GH treatment in patients treated for anywhere from 2 to 10 years led to a height gain of greater than 5 cm (1.9 in) above their predicted height.

**Table 4. Estimated Incremental Cost per Child, Incremental Growth per Child, and Cost per Inch for Deterministic Sensitivity Analyses**

<table>
<thead>
<tr>
<th>Sensitivity Analyses</th>
<th>Incremental Cost per Child, $</th>
<th>Incremental Growth per Child, in</th>
<th>Cost per Inch, $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>99 959</td>
<td>1.2</td>
<td>81 875</td>
</tr>
<tr>
<td>Lower (1.8 in)</td>
<td>99 959</td>
<td>2.6</td>
<td>38 783</td>
</tr>
<tr>
<td>Higher (3.9 in)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at initiation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment from ages 8-13 y</td>
<td>81 268</td>
<td>1.9</td>
<td>42 792</td>
</tr>
<tr>
<td>Treatment from ages 12-16 y</td>
<td>126 123</td>
<td>1.9</td>
<td>66 411</td>
</tr>
<tr>
<td>Discontinuation rate, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>137 779</td>
<td>2.6</td>
<td>53 531</td>
</tr>
<tr>
<td>40</td>
<td>87 352</td>
<td>1.7</td>
<td>52 174</td>
</tr>
<tr>
<td>Dosing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low-dosage GH (0.24 mg/kg per wk)</td>
<td>65 092</td>
<td>1.4</td>
<td>45 700</td>
</tr>
<tr>
<td>Standard-dosage GH (0.37 mg/kg per wk) × 2 y followed by high-dosage GH at puberty</td>
<td>155 440</td>
<td>3.1</td>
<td>49 821</td>
</tr>
<tr>
<td>Standard-dosage GH (0.37 mg/kg per wk) × 1 y followed by high-dosage GH at puberty</td>
<td>170 866</td>
<td>3.4</td>
<td>50 384</td>
</tr>
<tr>
<td>Treatment duration, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 (Ages 8-13 y)</td>
<td>122 513</td>
<td>2.5</td>
<td>49 396</td>
</tr>
<tr>
<td>10 (Ages 5-15 y)</td>
<td>145 550</td>
<td>3.2</td>
<td>45 156</td>
</tr>
</tbody>
</table>

Abbreviation: GH, growth hormone.

Conversion factor: To convert inches to centimeters, multiply by 2.54.

**Table 5. Estimated Incremental Cost per Inch for Probabilistic Sensitivity Analyses**

<table>
<thead>
<tr>
<th>% of Variance Due to Growth Variability</th>
<th>Cost-effectiveness Ratio (95% CI), $</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>125 416 (24 369-417 154)</td>
</tr>
<tr>
<td>30</td>
<td>93 820 (27 716-270 616)</td>
</tr>
<tr>
<td>10</td>
<td>57 482 (34 830-107 518)</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval.
height, which is substantially lower than our assumptions for a longer duration of treatment. Furthermore, growth assumptions for high pubertal dosing were derived from studies performed on GH-deficient children and not children with ISS. Studies have shown that children with GH deficiency tend to have better catch-up growth and a greater final height gain than children with ISS.\(^{2,20,30}\) Therefore, our high-dose growth assumptions were likely generous estimates of growth for children with ISS.

Growth assumptions may also be optimistic in that we assumed 100% adherence until discontinuation or completion. Nonadherent children will likely have less overall growth as they discontinue taking their shots, but they may continue to incur standard GH drug costs if their nonadherence is unrecognized, resulting in a higher incremental cost per inch.

Our model was based on charge data from our institution, so it may not be generalizable to other health care settings. Our model may also underestimate the costs of GH therapy, as it does not account for mild potential side effects associated with GH therapy or rare complications. Safety studies of GH-treated patients with ISS thus far have not shown a significant rate of adverse effects, but longer-term safety data are currently unavailable.\(^{19}\) Given that growth assumptions favored GH therapy and costs may have been underestimated, our estimate of the incremental cost per inch is likely a conservative figure.

Finally, this study was performed from the health care payer perspective. Further studies looking at the cost-effectiveness from a societal perspective may yield different results, as some studies have shown in males that greater heights in adolescence are associated with greater financial and career success.\(^{31}\)

**IMPLICATIONS**

With the ISS indication, it has been estimated that more than 400,000 children aged 4 to 15 years are now eligible for GH therapy. At an average incremental cost per child of approximately $100,000, the potential cost of treating all eligible children with ISS is approximately $40 billion dollars. Not all patients with ISS will be treated with GH, but if just one tenth of all eligible children are treated, the cost will still be considerable.

Since the licensure of GH therapy for ISS, a number of commentaries have highlighted the cost of GH therapy as an important issue for the health care system and society.\(^{2,22}\) There is debate about whether GH for ISS constitutes a medical treatment or an enhancement therapy. Some authors have referred to GH as a “lifestyle drug,” a drug that improves quality of life rather than alleviates illness.\(^{33}\) Certainly lifestyle drugs and their costs have been a frequent topic of interest in the adult literature, but to our knowledge GH therapy represents the first costly lifestyle medication to emerge in the field of pediatrics. Given that the rising cost of prescription drug therapies is a frequent topic of interest in the adult literature, but to our knowledge GH therapy represents the first costly lifestyle medication to emerge in the field of pediatrics, this study was performed from the health care payer perspective. Further studies looking at the cost-effectiveness from a societal perspective may yield different results, as some studies have shown in males that greater heights in adolescence are associated with greater financial and career success.\(^{31}\)

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**Correction**

Incorrect Author Byline and Corresponding Author Ad-
dress: In the online version only of the January issue of 
the ARCHIVES, the editorial by Curry and Mermelstein 
titled, “Do As I Say, Not As I Do: Does It Work for 
Tobacco Use Prevention?” (2006;160:102-103) had the 
wrong author listed at the end of the editorial and in the 
Table of Contents. The authors should have been Susan 
J. Curry, PhD, and Robin J. Mermelstein, PhD. The 
ARCHIVES regrets the error. This correction was made 
previously to online versions of this article. In addition, 
the address for the corresponding author changed and should 
read: Dr Curry, Health Policy and Administration, Institu-
tute for Health Research and Policy, University of Illinois 
at Chicago, 1747 W Roosevelt Rd, Room 538, M/C 275, 
Chicago, IL 60608 (suecurry@uic.edu).