BUSINESS CASE TEMPLATE

IMPLEMENTATION OF ENDOVASCULAR COIL EMBOLIZATION FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS

Final Report to OHTAC by the JPPC Designated Services Committee

Statement of Principle
In making recommendations concerning financial implications for each party affected by this technology's implementation, a great care was given to the principle of fairness. The proposed business case is based on understanding that a high level of commitment will be required from both Hospitals and the Ministry. The Hospitals interested in and qualified for implementation of the technology should demonstrate maximum efforts in internal reallocation of resources enabling them to absorb maximum operational costs. The Ministry should consider the device, operating, and capital requirements should a need for such additional investments be demonstrated by the analyses of costs associated with implementation of the technology.
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I. BACKGROUND

In March 2006, Ontario Health Technology Advisory Committee (OHTAC), through the Medical Advisory Secretariat (MAS) requested the assistance of the Ontario Joint Policy and Planning Committee (JPPC) in diffusion and uptake of the new technologies recommended by OHTAC.

The Ontario Health Technology Advisory Committee (OHTAC) is the single portal for providing advice to the health care system, including the Ministry of Health and Long-Term Care (MOHLTC), regarding the uptake, diffusion and distribution for new health technologies and the removal of obsolete health technologies. These OHTAC recommendations are based on the assessment of the safety, effectiveness and cost-effectiveness of the new technologies (for the detailed explanation of the role of OHTAC and technologies reviewed by OHTAC, please see the web site http://www.health.gov.on.ca/english/providers/program/mas/ohtac_about.html).

The JPPC’s Designated Service Working Group first technology undertaken is Endovascular Coil Embolization for the treatment of intracranial aneurysm. Endovascular coil embolization is a percutaneous approach to treat an intracranial aneurysm from within the blood vessel without the need of a craniotomy. In March 2004, OHTAC made a series of recommendations aimed at the expansion of this technology compared to the alternative method of treatment currently prevalent in hospitals (i.e. craniotomy). The Medical Advisory Secretariat (MAS) has previously estimated that the incremental device cost is $7,500; and for the purposes of budget estimation, assumed that roughly 60% of patients with aneurysms would be treated with coiling in the fiscal year of 2007 (p. 10 of the OHTAC Report on Coil Embolization).

II. OBJECTIVES

1. To determine whether:
   a) costs associated with the introduction of coil embolization technology for the treatment of intracranial aneurysms can be offset by the cost avoidance of intracranial surgery;
   b) To determine whether the projected increase in coil embolization procedures as envisioned by OHTAC (450 cases with a 60:40 coil to clipping ratio) requires additional funding and if so what is an appropriate funding rate.

2. To identify:
   a) enablers to achieve the diffusion/goal;
   b) the necessary service adjacencies and capital requirements;
   c) performance measures and/or monitoring mechanisms; and
   d) recommendations on implementation strategies;

III. METHODOLOGY

In order to achieve the aforementioned objectives, the JPPC followed its collaborative and evidence based approach. A technical working group consisting of hospital senior executives and Ministry representatives guided the development of a Business Case template. In addition, extensive consultation with clinicians, decision support and medical records from several hospitals was essential in every step of the development of this document.

The following analyses were undertaken to reach the objectives:

A. Analysis of the Current level of uptake was performed on administrative (Discharge Abstract Database) data for FY 2002/03 - FY 2005/06. Cases were identified based on the specified list of procedure and diagnosis codes (please see the legends for the Tables). Additional information on these years, as well as current (FY 2006/07) volumes was obtained from Neuroradiology Departments from several hospitals.
B. A literature review was done to develop the process of care for patients diagnosed with intracranial aneurysms and treated by an intervention. This resulted in a caremap comparing clinical paths of treatment via clipping and/or coiling, which was validated by several clinicians.

C. A cost analysis comparing the unit cost of coiling and clipping was conducted based on administrative data sets (Ontario Case Cost Initiative Data, FY 2004/05). Additionally, several hospitals performed patient chart reviews to enhance data quality and deepen an understanding of the costs of coiling. A literature review was also performed for consistency of the cost analysis results.

IV. RESULTS

A) CURRENT ASSESSMENT OF THE UPTAKE OF THE TECHNOLOGY

Assessment of the Data
In Ontario, based on Discharge Abstract Database (DAD), the number of facilities treating patients with intracranial aneurysms via intervention is limited (table 1). Out of thirteen hospitals identified:

- four centers reported surgical clipping but no coiling procedures for fiscal 2004/05 and 2005/06. All of these centers were outside of the greater Toronto area (Children's Hospital of Eastern Ontario, Kingston, Thunder Bay and Sudbury)
- four other centers reported completing less than 10 coiling procedures annually for fiscal 2004/05 and 2005/06 (Toronto Hospital for Sick Children Hotel Dieu Grace Hospital, Windsor and Sunnybrook Health Sciences Centre, Toronto).
- two centers reported over 50 coiling procedures in 2005/06, and another center reported over 50 coiling procedures for 2004/05 but not for 2005/06 (a drop due to clinical human resources issue).
- In 2004/05 and 2005/06, three centers reported that they used coil over clipping in over 60% of their aneurysms cases
- Of these centers two reported coil rates of 71 and 82% in 2005/06.

Over the four years (from 2002/03 to 05/06), the number of intracranial aneurysms treated with Endovascular Coil Embolization increased by 21% (from 33% to 54%). Given the relative stability in the total number of aneurysm repairs from 2003/04 to 2005/06, the provincial trend is a shift of the coiling to clipping ratio in favor of coiling (Graph 1). However, the breakdown of these trends by hospital (Graph 2), performed for the six centers with relatively high coiling volumes (over 10 annually), reveals two groupings:

- In the first grouping, the total number of aneurysm repairs has been steadily rising. However, this trend has been primarily due to the increase in the number of coiling procedures, as the clipping volumes remained fairly stable from 2002/03 to 2005/06. These facilities, therefore, appear to pick up a new population of coiled patients. Three hospitals fall into this category, namely, St. Michael’s Hospital, UHN, and the Ottawa hospital (Note: TOH reported a loss of a neuro-endovascular specialist that impacted their volumes in 2005/06).
- In the second grouping, the total number of aneurysm repairs has been fairly stable or declining from 2002/03 to 2005/06 (e.g., LHSC, HHSC and Trillium). The rise in the coiling volumes is accompanied with the decrease in the clipping volumes. These facilities shift their patients from clipping to coiling method of treatment, but the intensity of the shift varies across facilities.

Expert Opinion
The future trend of aneurysm treatment, according to the team of clinical experts, will be characterized by an increase in the volumes of both coiling and clipping procedures due to presently increasing discovery of cerebral aneurysms from non-invasive means (CT and MRI). Additional increase in the number of coiled procedures will result from a widening spectrum of treatable aneurysms (formerly not subject to treatment).
Table 1: Volume Trends of Surgical Clipping and Coil Procedures

<table>
<thead>
<tr>
<th>A. Trend of Total Number of Aneurysm Repairs</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>0693 KINGSTON General</td>
<td>19</td>
<td>16</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>0751 OTTAWA CHEO</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>0837 TORONTO Hospital for Sick Children</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>0852 TORONTO St Michael's</td>
<td>38</td>
<td>45</td>
<td>54(69)</td>
<td>57(77)</td>
</tr>
<tr>
<td>0927 WINDSOR Hotel Dieu Grace</td>
<td>12</td>
<td>11</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>0935 THUNDER BAY Regional</td>
<td>1</td>
<td>1</td>
<td>12</td>
<td>7</td>
</tr>
<tr>
<td>0936 LONDON Health Sciences</td>
<td>63</td>
<td>85</td>
<td>63</td>
<td>57</td>
</tr>
<tr>
<td>0942 HAMILTON Health Sciences Corp</td>
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<td>102</td>
<td>122</td>
<td>129</td>
<td>153</td>
</tr>
<tr>
<td>0949 MISSISSAUGA Trillium</td>
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<td>44</td>
<td>30</td>
<td>44</td>
</tr>
<tr>
<td>0953 TORONTO Sunnybrook &amp; Women's</td>
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<td>32</td>
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<td>29</td>
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<tr>
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<td>46</td>
<td>76</td>
<td>93</td>
<td>65</td>
</tr>
<tr>
<td>0959 SUDBURY Regional De Sudbury</td>
<td>10</td>
<td>4</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Provincial</td>
<td>433</td>
<td>490</td>
<td>523</td>
<td>508</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B. Trend of Coiled Cases</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
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<td>0</td>
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<td>9</td>
<td>16</td>
<td>30(45)</td>
<td>35 (55)</td>
</tr>
<tr>
<td>0927 WINDSOR Hotel Dieu Grace</td>
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<td>0</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>0935 THUNDER BAY Regional</td>
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<td>40</td>
<td>45</td>
<td>56</td>
<td>91</td>
</tr>
<tr>
<td>0949 MISSISSAUGA Trillium</td>
<td>18</td>
<td>17</td>
<td>20</td>
<td>36</td>
</tr>
<tr>
<td>0953 TORONTO Sunnybrook &amp; Women's</td>
<td>8</td>
<td>4</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
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<td>10</td>
<td>38</td>
<td>63</td>
<td>32</td>
</tr>
<tr>
<td>0959 SUDBURY Regional De Sudbury</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Provincial</td>
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<td>175</td>
<td>242</td>
<td>275</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>0693 KINGSTON General</td>
<td>63%</td>
<td>81%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>0751 OTTAWA CHEO</td>
<td>50%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0837 TORONTO Hospital for Sick Children</td>
<td>100%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0852 TORONTO St Michael's</td>
<td>24%</td>
<td>36%</td>
<td>65%</td>
<td>71%</td>
</tr>
<tr>
<td>0927 WINDSOR Hotel Dieu Grace</td>
<td>0%</td>
<td>0%</td>
<td>7%</td>
<td>46%</td>
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<tr>
<td>0935 THUNDER BAY Regional</td>
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<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>0936 LONDON Health Sciences</td>
<td>65%</td>
<td>48%</td>
<td>52%</td>
<td>61%</td>
</tr>
<tr>
<td>0942 HAMILTON Health Sciences Corp</td>
<td>3%</td>
<td>2%</td>
<td>27%</td>
<td>27%</td>
</tr>
<tr>
<td>0947 TORONTO UHN</td>
<td>39%</td>
<td>37%</td>
<td>43%</td>
<td>59%</td>
</tr>
<tr>
<td>0949 MISSISSAUGA Trillium</td>
<td>55%</td>
<td>39%</td>
<td>67%</td>
<td>82%</td>
</tr>
<tr>
<td>0953 TORONTO Sunnybrook &amp; Women's</td>
<td>20%</td>
<td>13%</td>
<td>20%</td>
<td>17%</td>
</tr>
<tr>
<td>0958 OTTAWA The Ottawa Hospital</td>
<td>22%</td>
<td>50%</td>
<td>68%</td>
<td>49%</td>
</tr>
<tr>
<td>0959 SUDBURY Regional De Sudbury</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Provincial</td>
<td>33%</td>
<td>36%</td>
<td>46%</td>
<td>54%</td>
</tr>
</tbody>
</table>

Data Legend: (1) Discharge Abstract Data set, FY 2002/03, 2003/04, 2004/05, 2005/06; (2) The volumes refer to the number of aneurysm treatments; therefore, cases with both clipping and coiling volumes were added to both coiling and clipping volumes; (3) Codes (anywhere on patient’s record): Procedure-1.JW.51.SZ-FF (clip), 1.JW.51.GP-GE (coil) Diagnosis - I60.1-I60.7, I60.9, I67.1, Q28.2, Q28.3.

1 Due to data capturing issues the number of coiled procedures for this facility was under-reported in 04/05 and 05/06 DAD data. The corrected number is presented in parenthesis and is used to calculate the percent of coiled procedures. The facility is currently working on correcting all system-level issues to avoid similar problems in the future. Several other facilities were asked to check if their DAD volumes correctly represented the actual volumes, but no major discrepancies were found.
Graph 1
Provincial Trend of Volumes of Coiling and Clipping Cases
DAD 2002/03-2005/06

Graph 2
Trends of Coiling and Clipping Volumes by Hospital
For hospitals with relatively high coiling volumes
DAD 2002/03-2005/06
Discussion on Current Assessment on the Uptake of the Technology

The above analysis suggests that:

- Given the volumes reported and the limited number of centres providing interventional treatment for patients with intracranial aneurysms a regional delivery model for intracranial coil embolization should be developed. Depending on the geographic location, centres with consistently low volumes should increase their levels or refer their cases to the nearest designated coiling centre.  \(^2\)
- While table I reports a 92% increase in the volume of coiled procedures from 143 to 275 over the four years (2002/03-2005/06), only four of the thirteen centres met or exceeded the Medical Advisory Secretariat’s (MAS) estimated 60:40 coiling to clipping ratio in 2004/05-2005/06. On the one hand, this finding may be interpreted as a tendency of the majority of the centres providing aneurysm treatment to offer clipping as the preferred treatment option. However, the administrative data sets do not allow the decision makers to distinguish whether the choice of clipping over coiling is related to availability of trained human resources and technology or the patients’ clinical condition.
- Hospitals that report a substantial growth in coiling procedures while maintaining a stable clipping volume may have a higher number referrals/patients that are not eligible for coiling technology which will impact on their ability to meet of exceed the 60:40 ratio (UHN)
- Those hospitals that report growth in coil procedures and a stable clipping volume may be unable to reallocate resources to coiling due to their surgical population. In fact the growth in coiling may represent a new patient population.
- Some hospitals have started the shift of the coiling to clipping ratio towards coiling, but the intensity of the shift varies across hospitals.
- Given the volumes reported in DAD for the specified list of diagnosis and procedure (ICD10/CCI) codes, the 60% uptake level would constitute 305 cases of coiled aneurysms, and not 450 as projected by the MAS. The MAS estimate of 450 cases for FY 2007 (p. 10 and 59 of OHTAC report) was based on the prediction of the total number of intracranial aneurysm repairs in Ontario to be 750 cases which is not supported by the data presented in this document. Consequently, while at the provincial level, given the current volumes and the growth rate of coiling procedures, the 60% level of uptake of coiling technology is possible, the 450 target is not feasible for 2007/08.

B) UNDERSTANDING THE PROCESS OF CARE

The decision regarding which procedure, coil versus clipping, should be chosen for a patient’s treatment is made by a team of specialists. While there is an increasing trend for cerebral aneurysms to be coiled, the optimal treatment for each individual case is dictated by clinical characteristics of the patient. From the hospital perspective, the pre-requisites for endovascular coiling include the availability of clinical human resources (both endovascular specialists and neurosurgeons), and an operationally sound neuro-angio suite. Given that a patient eligible for coiling may be admitted to a facility any time of the day (especially if a case is urgent), designated neurovascular coiling centers must be able to provide 24/7 coverage for both treatment options. Therefore, a single endovascular specialist is not sufficient to maintain the level of diffusion estimated by the MAS.

The analysis of the clinical path of patients undergoing treatment via endovascular coiling versus surgical clipping (see Appendix A) leads to identifying the following pre-requisites for implementation/further diffusion of coiling as a preferred method of treatment of intracranial aneurysms:

- a neuro-angio suite in good operational condition and physical space to perform procedures. Clinical experts recommend that a designated coiling center should have a biplane neuro-

\(^2\) Such regionalized pattern of care is consistent with the scenario in the Netherlands, where 12 hospitals refer their SAH patients for neurosurgical units to 3 centers. Each of these centers is located within 50 miles from the most remote regional hospital (Roos, Dijkgraaf et al, 2006: 1596)
angiography suite based in the medical imaging department to allow full optimization of the capital resource. Such a room should also have OR ready specifications to allow for more complex vascular cases. In order to maintain operational condition of the equipment of this type, it should be replaced every 5-7 years.

- the existence of an ongoing active neurosurgery program and at least two endovascular specialists (who could be either a neurosurgeon or an interventional neuroradiologist with specialized training);
- expertise in managing complications associated with treatment of aneurysms with coiling and clipping (notably cerebral vasospasm)
- an understanding that the coiling treatment requires an ambulatory component of care as well as an inpatient component of care; and
- an understanding that the coiling method of patients’ treatment will necessitate a resource reallocation in centers already providing surgical clipping method;

C) COST ANALYSIS

The need and/or the specific level of additional funding necessary to expand the utilization of new technologies depends to a great extent on whether, from the hospital perspective (as opposed to the system-level, which is the focus of the OHTAC) the unit-cost of the new technology is more expensive than the alternative one. In order to answer this question, a literature review on comparison of costs of clipping and coiling was conducted alongside with the analysis of Ontario-based cost data.3.

Results of the Literature Review

Based on the existing literature (P. Halkes, M. Wermer, G. Rinkel, and E. Buskens, 2006; M. Javadpour, H. Jain, C. Wallace, R. Willinsky, K. ter Brugge, and M. Tymianski, 2005; Y.B.W.E.M. Roos, M.G.W. Dijkgraaf, K.W. Albrecht, L.F.M. Beenen, R.J.M. Groen, R.J. de Haan and M. Vermeulen, 2002; P. Bairstow, A. Dodgson, J. Linto and M. Khangure, 2002) comparing the unit-cost of coiling and clipping, it is not clear which technology has a higher unit cost. On the one hand, (Bairstow et al,, 2002, study cited in OTHAC report) found that the average costs of treatment via coiling are lower than the costs of clipping. At the same time, one study found no significant difference between the total (i.e., inpatient and ambulatory follow-up) costs of coiling and the costs of clipping  (M. Javadpour, et al, 2005), and another research reported that the costs of coiling outweigh the costs of clipping due to the costs of device (P. Halkes, et al, 2006).

Due to small sample sizes used in these studies, the results are subject to outliers’ influence (except Bairstow et al cited in OTHAC report, which used median values).4 For instance, Halkes, Wermer et al. used 24 patients altogether (12 coiled, and 12 clipped), and Javadpour, Jain, et al used 62 patients (30 of them were coiled). In addition, some of these studies refer to costs incurred by European facilities, and the practice and relative costs used in Ontario hospitals may differ, making extrapolation of the results to the Ontario setting difficult.

It is nevertheless noteworthy that with one exception, all studies converge in their conclusions that the patients undergoing coiling treatment have lower length of stay, as well as lower ICU costs.5 The

3 Although the OHTAC report cites one study comparing the costs of clipping and coiling, the different focus of the report (i.e. clinical effectiveness, safety of new technologies, system-level economic analysis as opposed to hospital-based perspective), as well as development of new research, made it useful to do the aforementioned search for the available literature on hospital-specific costs of coiling versus clipping.

4 It is important to understand, however, that the median value is only a robust estimate of the central tendency when the incremental differences between cases are relatively small and even. In very small samples, median values should also be treated with caution.

5 The aforementioned exception is the research done at the Netherlands (Roos, Dijkgraaf, et all.) which found that the total inpatient length of stay for coiled patients was higher for both ICU and ward, can be subject to two interpretations. On the one hand, the study was conducted at the time when endovascular coiling was a “relatively new treatment method, not yet used on a large scale in the Netherlands.” (p. 1596). As a result, the relative number (sample size) of coiled patients was too small (11 out of 110) to speak of results with high degree of confidence. On the other hand, this result may be indicative of the notion that the failure to achieve the critical mass of coiling treatments may result in high costs, compared to the treatment via clipping.
question remains whether the costs of device (coil, stents, and balloons) outweighs the ICU, nursing and other savings.

**Results of the Comparative Cost Analysis based on Ontario Case Cost Data**

Given that the complexity of the case, and consequently its cost, to a great extent depends on aneurysm condition (i.e. ruptured versus unruptured), the cost analysis separated these two types of cases. The analysis of the average total *inpatient* cost per case for patients with ruptured and unruptured aneurysms based on Ontario Case Cost data (Table 2a) showed that the total costs of inpatient treatment of patients with coiling are on average lower than the respective costs of patients treated with clipping. In line with this conclusion, average total cost per case, median total cost, average RIW, and total length of stay are all higher for clipping cases.

**Table 2a. Comparative profiles for Coiling and Clipping cases**

<table>
<thead>
<tr>
<th></th>
<th>N cases&lt;sup&gt;6&lt;/sup&gt;</th>
<th>Average Total (inpatient) Cost</th>
<th>Median Total (inpatient) Cost</th>
<th>Ave RIW</th>
<th>Ave LOS</th>
<th>Median LOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ruptured Coil</td>
<td>75</td>
<td>$46,661</td>
<td>$36,458</td>
<td>5.87</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>Ruptured Clip</td>
<td>100</td>
<td>$60,461</td>
<td>$46,273</td>
<td>8.39</td>
<td>26</td>
<td>19</td>
</tr>
<tr>
<td>Non Rupt. Coil</td>
<td>50</td>
<td>$16,683</td>
<td>$9,491</td>
<td>3.12</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Non Rupt. Clip</td>
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<td>$28,739</td>
<td>$15,276</td>
<td>5.41</td>
<td>13</td>
<td>6</td>
</tr>
</tbody>
</table>

Legend: see legend for Table 2b.

The breakdown of costs across various departments (Table 2b) is useful to evaluate possibilities for budget reallocation. As can be seen from the department-specific distribution of inpatient costs (Table 2b), the main burden of costs associated with coiling of patients lies with the department of neuroradiology, which incurs the costs of the device. At the same time the nursing, ICU, and operating room costs are higher for patients undergoing craniotomy. These results are consistent with all but one of the aforementioned studies (Note: see footnote 3).

**Table 2b. Breakdown of (Inpatient) Cost by Department**

<table>
<thead>
<tr>
<th></th>
<th>Clinics</th>
<th>DI</th>
<th>Electro</th>
<th>ICU-CCU</th>
<th>Interv</th>
<th>Lab</th>
<th>Nursing</th>
<th>OR_PARR</th>
<th>Other</th>
<th>Pharm</th>
<th>Therapy</th>
<th>Total Ave. (Inpat.) $ per case</th>
<th>Mean LOS</th>
<th>Median LOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rupt. Coil</td>
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<td>$1,534</td>
<td>$47</td>
<td>$17,422</td>
<td>$11,880</td>
<td>$1,643</td>
<td>$7,767</td>
<td>$736</td>
<td>$37</td>
<td>$2,230</td>
<td>$3,359</td>
<td>$46,661</td>
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<tr>
<td>Rupt. Clip</td>
<td>$7</td>
<td>$1,817</td>
<td>$70</td>
<td>$24,705</td>
<td>$6,085</td>
<td>$2,489</td>
<td>$10,015</td>
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<tr>
<td>NonRpt. Coil</td>
<td>$37</td>
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<td>$4,988</td>
<td>$6,304</td>
<td>$557</td>
<td>$2,097</td>
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<td>$598</td>
<td>$645</td>
<td>$16,683</td>
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<tr>
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<td>$1,000</td>
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<td>$854</td>
<td>$1,805</td>
<td>$28,739</td>
<td>13</td>
<td>6</td>
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</table>

Legend for Table 2a and Table 2b: Data: IP (inpatient) OCCI 04/05 (included the following hospitals: St. Michaels, UHH, LHSC, Trillium); Code selection: Diagnosis: I.601-1607, I609 (ruptured intracranial aneurysm), 167.1, Q28.2, Q28.3 (unruptured), Procedure: 1.JW.51.GP-GE (coil), 1.JW.51.SZ-FF(clip). Cases represent inpatient episodes; several cases with both types of treatment were deleted from this analysis as it is impossible to separate the cost for each treatment type.

Yet, close examination of the results in Table 2b, as well as the consultations with hospitals’ decision support and clinical personnel, indicated possible under-reporting of costs for coiling

<sup>6</sup> Some patient data in OCCI data base had missing costs and were excluded from this analysis; however, true volumes, which based upon DAD data, are reported Table 1a.
procedures\(^7\). In order to estimate the extent of under-reporting, four facilities were asked to perform chart reviews and identify the reasons for and the magnitude of the problem. The chart reviews were performed for 115 patients with ruptured and 52 patients with unruptured aneurysms, all procedures performed in FY 2005/06 and 2006/07.

The results of the chart reviews (Appendix B) showed that despite the under-reporting of costs for intervention department (as well as estimated cost of device) in OCCI 04/05, the overall conclusion resulting from the OCCI cost analysis is sustained: the unit cost for coiling does not exceed the cost of clipping.\(^8\)

Based on the cost analysis from OCCI data and the chart reviews, the following comments deserve consideration:

- It is possible, however, that with an increased use of stents for coiling procedures, the average costs of coiled procedures may at some point exceed the cost of clips due to a high ($4,500) cost of stents. The use of stents and their effect on the average costs of coiled procedures, therefore, should be closely monitored by hospitals.

- The present cost analysis is restricted to inpatient component. However, the standard for treatment of patients with intracranial aneurysms via coiling involves ambulatory follow-up (please see Appendix A). The existing administrative data sets, such as DAD and National Ambulatory Care Reporting System or NACRS, do not allow a robust analysis of the ambulatory follow up costs.\(^9\) Based on the estimates provided by the UHN, the average follow up cost of coiled patients (which will be classified as diagnostic imaging costs) is approximately $400 (some variation across hospitals is expected). Yet, the standard for the clinically appropriate number of follow-up visits is evolving, and the number of ambulatory visits (and hence the total ambulatory cost of coiled patients) varies across hospitals. For this reason, the ambulatory cost of coiled patients has not been estimated as part of the cost analysis in this document.

- There is some evidence, that the average number of coils per patient is not constant, as assumed by OHTAC (ten coils per case), but varies across institutions. At the same time, the average costs of device increased since publication of OHTAC report. The team of clinical experts indicated that the future generation of coils will be more expensive, and even though the number of coils per case will decrease, their average cost will rise.

- It is important to remember that patient’s severity can be confounding factor in the OCCI cost analysis, and additional analyses may be required to evaluate if, controlling for the severity of the case, the costs of clipping exceed the costs of coiling.

---

\(^7\) For example, the average cost of coiling of unruptured aneurysms for four facilities reporting costs of coiling in OCCI is $6,475 (Table b, Intervention Department). If the average cost of device is $7,500 as OHTAC estimated, then some facilities under-report the cost of device.

\(^8\) As explained by decision support analysts, there were several major causes for under-reporting of costs for coiled procedures, such as the system-related failure of the medical imaging department to specify the number of coils used in procedures, assigning patients to a different category which does not require the costs of coils (e.g., if embolization is specified as “cerebral” instead of “coil”, it is not clear whether the procedure is used with platinum coils or a different material), or use of an allocation method (as opposed to micro-costing) for neuroradiology division. For example, a switch from a reallocation method to a micro-costing of the angiosuite in one facility resulted in a 4.5-fold (from $2,455 to $11,162) increase in the cost of that branch. This difference, in turn, lead to an increase of the average total cost of (unruptured) coiling procedures from $5,782 to $14,104. The causes varied across hospitals, and the hospitals which have identified these problems, are currently working on improvement of their data and data capturing processes.

\(^9\) Such estimation can only be based on linkage of patient records between DAD and NACRS data sets which is not possible for two reasons. First, reporting of the relevant functional centers in NACRS was not mandatory in 2004/05 (hence, the data quality is unreliable). Second, since patients can go to ambulatory care for reasons other than follow up after a coiling procedure, it may not be feasible to separate the relevant visits from irrelevant ones.
Although the comparative cost analyses based on the OCCI case cost data has a valuable property of a relatively large sample size, compared to the studies identified in the course of the literature review, it also has a disadvantage of patient selection bias. That is, while the estimation of cost conducted in the reported literature was done on patients who were eligible for either coiling or clipping, the current analysis cannot separate such patients from those who are only eligible for one of the two procedures (i.e., the relevant data are not available).

**Discussion on Cost Analysis**

The cost analysis suggests that the reallocation of budget for treatment of patients with intracranial aneurysms leading to a shift towards coiling as a preferred method of treatment is possible in the areas associated with the inpatient length of stay (e.g. ward costs), as well as therapy, lab, and pharmacy costs. The opportunities for reallocation of costs associated with the shift from clipping to coiling are presented below (table2c). For each department identified for reallocation (Clinics, DI, Electro, Lab, Nursing, Other, Pharmacy, and Therapy), the difference is calculated between the average clipping and coiling costs. Based on these cost estimates, hospitals on average can put $6,018 for nonruptured and $6,396 for ruptured towards the cost of the device, if they have reallocation opportunities in the first place.

<table>
<thead>
<tr>
<th>MAS Estimate of Average Device Cost per Case</th>
<th>Clinics</th>
<th>DI</th>
<th>Electro</th>
<th>ICU/CCU*</th>
<th>Interv*</th>
<th>Lab</th>
<th>Nursing</th>
<th>OR_PARR**</th>
<th>Other</th>
<th>Pharm</th>
<th>Therapy</th>
<th>Total $ per case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rupt. Coil $7,500</td>
<td>$6</td>
<td>$1,534</td>
<td>$47</td>
<td>$17,422</td>
<td>$11,880</td>
<td>$1,643</td>
<td>$7,767</td>
<td>$736</td>
<td>$37</td>
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<td>$1,805</td>
<td>$28,739</td>
</tr>
</tbody>
</table>

This analysis assumes 100% delta reallocation (e.g., 100% of difference in nursing costs between clipping and coiling cases can be re-allocated). In reality, however, the re-allocation amount may not be as high as 100%; it may also be different for various departments. Given that the results of the cost re-allocation analysis ($5,749 for ruptured and $7,610 for unruptured) are very close to the MAS estimates for the average cost of the device in the clipping procedures, (i.e. $7,500), as well as the fact that not 100% of costs can be reallocated, some funding recommendations (i.e. II-c) will continue to support the MAS estimate of the $7,500 device cost per case.

At the same time, the opportunities for cost re-allocation will eventually decrease once the facility experiences the growth of coiling cases stemming from the new population of cases subject for coiling. Based on the analysis of volumes, some facilities have reached that level.
V. BARRIERS AND ENABLERS FOR IMPLEMENTATION

1) In order to ensure equitable access of all Ontarians to both methods of aneurysm treatment, the team of clinical experts recommended that the provision of this service be coordinated at the provincial level, and that a Data Registry be established. One of the challenges of the provincial coordination will be to ensure that the characteristics of designated coiling centres are balanced against equal access to care for all patients with similar clinical conditions across the province. The expert opinion is that any designated coiling center should in fact be part of a broader neurovascular center; and as such, should have clinical expertise in a range of procedures (please, see next section).

2) According to the results of cost analysis, some costs associated with inpatient length of stay may be re-allocated from clipping to coiling patients. Yet, as the volume analysis demonstrated, the potential for cost reallocation varies across facilities. Some facilities, which have rigorously implemented the new technology and have absorbed a new patient population, are currently experiencing budget pressures. If their efforts are not recognized, their incentives to continue further implementation of this technology, as well as pursue implementation of other technologies recommended by OHTAC, may be undermined.

3) One of the barriers to further implementation of the technology is availability of the clinical human resources. The volatility of coiling volumes experienced by some facilities is due to the loss (or acquisition) of a single endovascular specialist.

VI. CHARACTERISTICS/ATTRIBUTES OF CENTERS IDENTIFIED AS DESIGNATED COILING CENTERS

1) According to the World Federation of Interventional and Therapeutic Neuroradiology, a designated coiling center for treatment of intracranial aneurysms should perform a minimum of a hundred interventional neuro-radiological procedures per year; at least 50 of these procedures should be coiling procedures for treatment of intracranial aneurysms.\(^\text{10}\) The team of clinical experts felt that, regardless of the specific number attached to the annual requirement for interventional neuro-radiological procedures, it is crucial that the holistic concept of neurovascular care is applied to the center which will receive a coiling designation. This means that clinicians performing coiling procedures should also maintain competence in other interventional procedures, such as carotid angioplasty and stenting, catheter cerebral angiography, central nervous system embolization with embolic materials, devascularization, acute stroke interventions including intra-arterial and mechanical thrombolysis, balloon angioplasty for vasospasms, etc. The annual volume of these procedures should be sufficient not only for maintaining expertise in the centre, but for training of new clinical human resources. Additionally, the clinicians in a centre designated to perform coiling procedures must have expertise to manage the care of aneurysm patients before and after their procedures.

2) In estimating the budget impact of the diffusion of coil embolization in Ontario, the MAS assumed a 60% diffusion rate of coiling across the province. The DSG assigned the 60:40 coiling to clipping ratio on a hospital specific basis with the notion that if all hospitals behaved this way then the provincial target would be met. The position of clinical experts was that while overall such approach was reasonable, the actual coiling to clipping ratio will vary depending on the hospital case mix, since not all patients are eligible for both treatment methods.

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\(^{10}\) Standards of practice in Interventional Neuroradiology or Endovascular Neurosurgery. WFITN. Site conditions and technical operational guidelines. IS Choi, P Lasjaunias, L Picard in Interventional Neuroradiology 12: 7-8, 2006
3) Several other characteristics/attributes of a designated centre for treatment of intracranial aneurysms were identified in the course of the analyses. They can be summarized as follows. A centre designated as coiling centre must:

- Have an ongoing active neurosurgery program;
- Have adequate equipment and clinical human resources to ensure the provision of 24/7 operation of the program;
- Ensure the quality of administrative data sets used to monitor outcomes and utilization of patients diagnosed with intracranial aneurysms and eligible for treatment via any type of intervention.

Consequently, each facility increasing the use of this technology needs to:

- ensure that the communication among various departments is coordinated to enhance data quality;
- ensure proper identification of the numbers of patients and procedures in the Discharge Abstract Database;
- ensure proper capturing of the costs of treatment of each patient diagnosed with intracranial aneurysms;

Any material regarding systemic data issues identified in the course of this communication regarding the adequacy of the ICD10CCI codes should be forwarded to the Ministry, the JPPC, and CIHI.
VII. RECOMMENDATIONS

I. Requirements for Programs/Centers best suited for further implementation of Coil Embolization.

1. In order to ensure equitable access of all Ontarians to this method of treatment of intracranial aneurysms, a regionalized approach to treatment of patients with intracranial aneurysms via coiling should be developed. This would require establishment of designated regional coiling centers. Hospitals seeking designation as a regional intracranial coiling centre would need to meet the following minimum requirements:

a) Demonstrate the existence of an ongoing active neurosurgery program.
b) In order to maintain the clinical expertise, the centre should complete a minimum of 50 coiling procedures for treatment of intracranial aneurysms. In addition, any designated coiling center should maintain competence in a variety of neuroradiological procedures, such as carotid angioplasty and stenting, catheter cerebral angiography, central nervous system embolization with embolic materials, devascularization, acute stroke interventions including intra-arterial and mechanical thrombolysis, balloon angioplasty for vasospasms, etc. The annual volume of these procedures should be sufficient not only for maintaining expertise in the centre, but for training of new clinical human resources. Furthermore, the clinicians in a centre designated to perform coiling procedures must have expertise to manage the care of aneurysm patients before and after their procedures.
c) Commitment to a treatment protocol for intracranial aneurysms that strives for a 60:40 coil-to-clipping ratio (this requirement should be applied with consideration given to hospital case-mix of aneurysm cases treatable via each intervention method).
d) Have on staff a minimum 2 MDs full time qualified (through proper interventional Neuroradiology training) to perform coiling procedures and appropriate plan to increase clinical manpower to sustain provision of 7/24 operation.
e) Capital infrastructure and resources to support the service, including a biplane neuroangiography suite based in the medical imaging department to allow full optimization of the capital resource. In order to maintain operational condition of the equipment of this type, it should be replaced every 5-7 years.
d) Demonstrate continuous commitment to teaching and research

2 New or renovated neuroangiography suites should be constructed so that they have OR ready specifications to allow for more complex vascular cases.

II. Implications for Hospital Funding

a) Only centres approved to provide intracranial coiling services will be qualified for designated funding streams.
b) Hospitals that are below the 60:40 ratio and do not report a substantial increase in combined clipping/coiling volumes should be encouraged to move towards the 60:40 ratio using resource re-allocation opportunities.
c) Recognition should be provided to those hospitals that have demonstrated an increase in the coiling volumes accompanied by stable or rising clipping volumes. The level of recognition will be based on an assessment of the hospitals opportunity to reallocate funds as determined by the ministry and will not exceed the $7,500 per procedure as estimated by the Medical Advisory Secretariat. The possible scenarios for hospital funding implications are outlined in Appendix C.
d) New funding will be required to support incremental volumes above each designated hospital’s specific base volumes. The funding methodology for new coiled incremental cases will be consistent with the funding methodology used for other Priority Services. This includes
specification of funding scope and assumptions, identification of cases at the level of ICD10 CCI codes, application of the methodology used to fund indirect variable costs, as outlined in Appendix C.

e) As a provincial resource, the designated coiling center may experience exceptional growth in coiling and clipping services. This growth will need to be addressed on a center-specific basis.

f) That the funding conditions for coiling services be reviewed 1 year and 3 years after implementation.

IV. Other:

1 There is a need for establishment of a standardized Neurovascular Registry that would be responsible for province-wide Standardization of Data collection to monitor outcome, utilization, and support research to assess the long term benefits of this technology. Hospitals designated an intracranial coiling center should ensure the quality of administrative data sets used to monitor outcomes and utilization.

2 That the Ministry’s health human resource strategy recognize the need to retain and train physicians skilled in neuro endovascular services to meet the current and future demand for intracranial coiling services.

3 That policymakers, providers and other stakeholders encourage the development of practices/programs that promote the early identification of risk factors and warning signs of intracranial aneurysms.

V. Provincial coordination of aneurysm treatment

a) That the ministry develop a provincial operational framework for coiling treatment of intracranial aneurysms. The framework should identify at a minimum service criteria, referral population, funding rate, and data collection process.

b) Centres designated as provincial coiling centres to should work with other centers to develop formal relationships with referring sites.

c) Hospitals that do not have the resources and expertise to provide coiling of intracranial aneurysm services should refer patients to the identified designated centers. Provincial referral patterns should be developed for each designated center.
REFERENCES


4. Comparison of Cost and Outcome of Endovascular and Neurosurgical Procedures in the Treatment of Ruptured Intracranial Aneurysms; Phillip Bairstow, Andrew Dodgson, Jennie Linto and Mark Khangure; *Australasian Radiology* 2002, 46: 249–251
APPENDIX A: Clinical Path of Patients Undergoing Treatment for Intracranial Aneurysms

**Intake, Assessment, Diagnosis, Treatment Decision**
- ER time (urgent) or Referral (elective)
- PREREQUISITE OF ASSESSMENT
  - Patient clinical grading
  - Transfer to the Coiling Center (capable of both coiling and clipping)
  - (from the most common to least common) CTA, CT, MRA, Intra-arterial catheter angiography, Lumbar puncture
- Laboratory investigations
- Clinical grading of the patient (WFNS Scale, etc)
- Patient age, co-morbidities, etc.
- Size, morphology and location of aneurysm (determine the procedure)
- Clinical feasibility of coil / clip / both
- Multi-disciplinary forum (incl. neurosurgeon and interventional neuroradiologist) plus patient consent

**Treatment (Urgent for Ruptured, Elective for Unruptured)**

**INTERVENTION**

**Required technology**
- Clipping: neurosurgery OR neuroangiosuite
- Coiling: neuroangiosuite

**Required human resources**
- Neurosurgeon
- Neurosurgeon and endovascular specialist
- Nurses with special training

**Devices and Supplies**
- Clips
- coils, stents, balloons

**RECOVERY**
- ICU LOS
- Neurosurgical Acute LOS
- ALC LOS

**EVALUATION OF OUTCOMES AND DISCHARGE**
- Rankin Score
- Glasgow Outcome Score
- Post operative Angiography (clipping only, but in some facilities for coiled patients as well)
- Discharge planning, discharge and transfer to appropriate settings

**Follow up and post-acute care**
- General Acute LOS (if transferred to a community hospital)
- Rehabilitation LOS
- Complex Continuing Care LOS
- Long-term care LOS

**For coiled patients only:**
- Angiographic follow up (CTA, MRA) (1 or 2, depending on facility)
- Antifibrinolytic drugs

**Complications and their management**

Common to clipped and coiled patients:
- Hemiparesis, hemiplegia, cerebral infarction, ischemic deficit, parent artery occlusion, intraoperative rupture

Coil: re-rupture or re-occurrence of the aneurysm due to collapsed, migrated, malpositioned coils

- Need for additional procedure (coil or clipping)
### Appendix B: Chart Review Results

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean LOS</td>
<td>5</td>
<td>Median LOS</td>
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<tr>
<td>$17,109</td>
<td>5.8</td>
<td>2</td>
<td>$45,251</td>
</tr>
</tbody>
</table>

The Average total costs are estimated with Trillium data. However, since Trillium does not micro-cost their allied health the average costs would be higher if the data of this facility are excluded: $23,677 for unruptured and $51,091 for ruptured aneurysms.

### Comparison of OCCI 04/05 and Chart Review Results: (Total) Cost Breakdown by Department

<table>
<thead>
<tr>
<th></th>
<th></th>
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<tr>
<td>DI</td>
<td>$6</td>
<td>$9,538 (n=55)</td>
<td>$7</td>
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<td>$70</td>
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<td>$235</td>
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<td>$17,422</td>
<td>$16,220</td>
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<td>Interv*</td>
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<td>$30</td>
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<td>Nursing</td>
<td>$7,767</td>
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<td>OR_PARR*</td>
<td>$736</td>
<td>$719</td>
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<td>Other</td>
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<td>$677</td>
<td>$3,094</td>
<td>$591</td>
<td>$327</td>
<td>$677</td>
<td>$261</td>
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<tr>
<td>Therapy</td>
<td>$3,359</td>
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<td>$60,461</td>
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<td>$46,691</td>
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<td>Total</td>
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<td>$60,461</td>
<td>$28,739</td>
<td>$60,461</td>
<td>$645</td>
<td>$28,739</td>
<td>$28,739</td>
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</table>

### Conclusion from Chart Review:

- There is no evidence that the costs in the departments targeted for re-allocation are under-reported in OCCI. While the cost in the intervention department (as well as estimated cost of device) are higher for chart reviews than for OCCI, the difference is offset by delta in Nursing, Therapy, etc.

### Notes on the Chart Review Methodology

1. Chart review data represent 05/06 and 06/07 costs.
2. Because of the different reporting format (i.e. reporting of indirect costs), adjustment for indirect cost was made for UHN (22% for ruptured, 15% for unruptured) and for St. Mikes (33% for ruptured and 20% for unruptured), based on their data.
3. Device cost was estimated based on UHN data only (55 cases for ruptured, and 14 unruptured), the other incorporated the device cost in the Intervention department.
4. Trillium does not micro-cost allied health, so the average for therapy department was estimated without it.
5. DI department costs are based on London and Trillium data, because in other hospitals they include interventional costs.
### RECOMMENDATION II c

**POSSIBLE SCENARIOS FOR RECOGNITION OF HOSPITALS PRESENT ATTEMPTS TO IMPLEMENT THE NEW TECHNOLOGY**

<table>
<thead>
<tr>
<th></th>
<th>FY 2005/06</th>
<th>FY 2006/07</th>
<th>Funding Implications (recognition for current uptake)</th>
<th>Logic</th>
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<tr>
<td><strong>Hospital A</strong></td>
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<td></td>
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<tr>
<td>Coiling Volume</td>
<td>50</td>
<td>60</td>
<td></td>
<td>No additional funding</td>
</tr>
<tr>
<td>Clipping Volume</td>
<td>50</td>
<td>40</td>
<td></td>
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</tr>
<tr>
<td>Total Volume</td>
<td>100</td>
<td>100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### RECOMMENDATION II d

**FUNDING FOR NEW COILED INCREMENTAL CASES**

<table>
<thead>
<tr>
<th></th>
<th>FY 2007/08</th>
<th>FY 2008/09 and onwards</th>
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</thead>
<tbody>
<tr>
<td>Base Volume</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incremental Volumes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Determined by the Ministry**

- New Funding rate consistent with funding methodology for other Priority Service Programs (direct cost+30% indirect, etc.)

**Funding for 10 incremental coiling cases at a maximum amount of $7,500**

- Since increase in coiling volumes was not accompanied by decreasing clipping volumes, hospitals could not re-allocated dollars, but used resources for uptake of the technology.
| Hospital D | 50 | 50 | 100 | 80 | 40 | 120 | Funding for 20 incremental coiling cases at a maximum amount of $7,500 | Reallocation opportunities were limited to 10 cases shifted from clipping to coiling, the remaining 20 coiling cases were due to new population | New Funding rate consistent with funding methodology for other Priority Service Programs (direct cost+30% indirect, etc.) | New Funding rate consistent with funding methodology for other Priority Service Programs (direct cost+30% indirect, etc.) | Determined by the Ministry | Determined by the Ministry | Determined by the Ministry |