In or out of the Special Medical Procedures Act: made-to-measure guidance

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Executive summary

Health Council of the Netherlands

Medical specialist care includes forms of diagnostics or treatment that have a special status because they are highly complex or expensive, or because the required expertise is scarce. Examples are organ transplantation and proton therapy. It is also possible for procedures to be socially and ethically sensitive, as is the case for instance for clinical genetic counselling and in vitro fertilisation. Such forms of top clinical care are covered by the Special Medical Procedures Act (hereinafter also referred to by its Dutch acronym, the “Wbmv”). Under the Wbmv, carrying out medical procedures that are stated in that regulation is banned unless a permit to do so has been granted. This requirement to have a permit means that performing certain procedures can be concentrated at a limited number of hospitals. The Wbmv outlines when procedures should be made subject to its rules. Because that description leaves a lot of scope for interpretation, the Minister for Medical Care and Sport has asked the Health Council of the Netherlands to formulate more specific criteria. Those criteria must provide guidance for decisions on both the inflow of procedures into the Wbmv and the outflow to regular medical specialist care. The Wbmv Inflow and Outflow Committee has looked into this question.

Added value of the Special Medical Procedures Act

The Committee has examined what the specific function of the Wbmv is within the legislation and regulations that make it possible to monitor the quality and the costs of these forms of top clinical care. After in-depth consultations with those in the field, the Committee has concluded that the Wbmv has an indispensable place. Application of this act should however always be preceded by careful consideration.

This “instrument” should only be deployed if self-regulation by the medical field is failing or threatening to fail and if the intended quality control cannot be achieved through the regular legislation and regulations. In that sense, the act functions as a safety net. The Committee’s opinion is that this function also means that application of the Wbmv will need tailoring to suit every time.

The Wbmv states that the Minister of Health, Welfare and Sport can make a permit mandatory for certain medical procedures “if sufficiently weighty considerations give reason to do so”. It can be seen from the explanatory memorandum to the Wbmv that the requisite weighty considerations are deemed to apply if the quality, costs or ethical and social aspects require special attention. Making a procedure subject to a permit and concentrating where it is carried out into a limited number of centres allows the minister to exert control over

these aspects. Once that special attention is no longer needed, the procedure can, as a rule, flow out of the Wbmv into regular care.

The legal texts only give a broad outline of these aspects. Evaluations of the Wbmv revealed that those elaborations do not provide enough of a grip on the situation; in practice, the assessment criteria have been specified further over the course of time. The Committee has made an inventory of the recurring elements in policy documents, explanations and decisions about the inflow and outflow and the advisory reports of the Health Council of the Netherlands.

Two-part advice

The Committee's advice is in two parts: there is guidance for decision-making, and associated recommendations for its practical application and the roles of the various parties within it.

Guidance for decision-making

The Committee has drawn up a series of questions, with input from the implementation of the Wbmv criteria in practice, that should allow decisions to be made more clearly and unambiguously (see table). That is important in all the phases – inflow, outflow and interim evaluations. The Committee would also like to emphasise that these questions must be weighed up for the specific context and with an eye on their mutual interdependence. Different emphases can then be placed depending on the type of procedure and the circumstances at the time. This is therefore not a rigid decision-making model but something that is always tailored to suit.

Recommendations for the decision-making process

In parallel with this guidance, and focusing on its practical application, the Committee recommends structuring the process of evaluation and decision-making better. It is making various recommendations to that end:

- Reinforce the signalling function, with an eye on the potential inflow
- Specify at the inflow moment what objectives are being targeted
- Involve all the parties from the field in decisions about inflow and outflow and in interim evaluations
- Examine the procedures covered systematically at regular intervals
- Get an independent body to supervise the process
- Encourage the development and application of a targeted methodology and a good dialogue for the evaluation process
- Always ensure a careful transition to regular care upon outflow

Considerations when deciding to move procedures in and out of the Special Medical Procedures Act

Criterion	Inflow	Interim evaluation	Outflow
Effectiveness and safety	Is there insufficient certainty about the effectiveness and safety?	What is known about the effectiveness and safety?	Are the effectiveness and safety sufficiently well assured?
Setting the indications	Is there insufficient certainty about the indications?	What is known about the indications?	Are the indications sufficiently well-founded?
Availability of expertise	Is the requisite expertise scarce?	How much expertise is available?	Is sufficient expertise available?
Multidisciplinary collaboration	Does the procedure require multidisciplinary collaboration?	How does the multidisciplinary collaboration proceed?	Is the requisite multidisciplinary collaboration assured?
Guidelines, care standards and accreditation	Are there current or provisional guidelines, care standards and an accreditation system?	How well-developed are the guidelines, care standards and an accreditation system?	Have the guidelines, care standards and an accreditation system been worked out precisely enough?
Accessibility	Is accessibility an issue to worry about?	What is the status of accessibility?	Does accessibility demand changes to capacity?
Cost-effectiveness	Is cost-effectiveness an issue to worry about?	What is known about the cost-effectiveness?	Is the level of cost-effectiveness acceptable?
Costs	Is it associated with high costs?	How are the costs evolving?	Is the evolution of the costs controllable?
Funding	Is it uncertain whether cost control at the point of purchase can be left to the health insurers?	How is procurement evolving?	Can cost control at the point of purchase be left to the health insurers?
Ethical and social aspects	Are ethical and social problems threatening to become an issue?	What is the status of the ethical and social issues?	Are the ethical and social consequences now of a nature that means regulation by the authorities is no longer needed?

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