Postural-Support Devices

AGENCE D'ÉVALUATION DES TECHNOLOGIES
ET DES MODES D'INTERVENTION EN SANTÉ

Québec

Postural-Support Devices

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by François Pierre Dussault

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MISSION

The mission of the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) is to contribute to improving the Québec health-care system and to participate in the implementation of the Québec government's scientific policy. To accomplish this, the Agency advises and supports the Minister of Health and Social Services as well as the decision-makers in the health-care system, in matters concerning the assessment of health services and technologies. The Agency makes recommendations based on scientific reports assessing the introduction, diffusion and use of health technologies, including technical aids for disabled persons, as well as the modes of providing and organizing services. The assessments take into account many factors, such as efficacy, safety and efficiency, as well as ethical, social, organizational and economic implications.

FOREWORD

POSTURAL-SUPPORT DEVICES

There is a vast range of postural-support devices (PSDs), especially seat cushions and back cushions prescribed to wheelchair users. In 2002, PSDs cost the *Régie de l'assurance maladie du Québec* (RAMQ) close to $10 million. Their unit costs range from around $80 to over $800. Some products cost up to twice as much as similar ones, and certain institutions seem to favour providing upmarket products.

In addressing its request to the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS), the RAMQ wanted 1) to know about the PSDs available on the market, along with their components and methods of construction; and 2) to establish the efficacy, safety and cost of these products.

Close to 500 products were identified in commercial catalogues and organized in spreadsheets. The cross-tabulation capabilities of spreadsheet programs (in particular by product class, cost, selection and eligibility criteria) nevertheless remain limited. Evidence on the efficacy and safety of these products is practically non-existent, although much is being generated in various research projects. Different classification models, four selection models and major evaluation criteria can nevertheless be retained as the starting point for designing an updatable selection grid.

In light of these observations, AETMIS recommends that the RAMQ establish a minimal selection grid and consider forming a consensus group composed of prescribers, users, suppliers and experts to integrate evidence into the grid as it is generated. The RAMQ should also consider implementing relational databases to cross-tabulate all the information relevant to administering its program, particularly current and emerging standards. As to the question of costs, AETMIS recommends that the RAMQ uses the information compiled henceforth to implement billing procedures in association with the institutions and suppliers.

In submitting this report, AETMIS hopes to provide RAMQ with information that will be useful in administering its technical-aids program. This information will also help concerned stakeholders in the Québec health-care system offer services that best meet wheelchair users' needs for postural-support devices.

Dr. Luc Deschênes
President and Chief Executive Officer

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The *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) would especially like to thank **Rachid Aissaoui**, PhD, Associate Professor, *Département de génie de la production automatisée*, *École de technologie supérieure* (ETS), for writing the three-volume report that led to the preparation of this condensed version. We would also like to thank **Yue Li**, who co-signed part of the report and whose doctoral thesis, accepted in June 2003 at the École polytechnique de Montréal, contributed significantly to the Aissaoui Report.

AETMIS thanks **François Pierre Dussault**, PhD, Research Consultant, for his perseverance in seeing this project through to completion.

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The task of compiling the excerpts from the three-volume report and laying them out in this condensed report was greatly facilitated by **Stéphanie Adam**.

AETMIS also thanks **Pierre Vincent**, Librarian at the AETMIS Information Centre, for his assistance during the production of this report.

CONFLICT OF INTEREST

None declared.

SUMMARY

BACKGROUND

Postural-support devices (PSDs) fall under the general concept of technical aids. According to International Standard ISO 9999, a technical aid is "any product, instrument, equipment or technical system used by a disabled person... [for] preventing, compensating, monitoring, relieving or neutralising the impairment, disability or handicap." PSDs are the components of a positioning system, which can include a seat cushion, a back cushion, legrests or footrests, armrests, a headrest or a neckrest.

There is currently a wide variety of PSDs on the market. Some are made by specialized companies; others, by Québec health-care institutions. Sometimes these devices are manufactured in collaboration by a public or private institution and a specialized company. The variety of construction methods used leads to significant variations in the invoices submitted by these institutions. The prices of PSDs billed to the *Régie de l'assurance maladie du Québec* (RAMQ) range from $80 to $800. The RAMQ has noticed that certain institutions most often offer upmarket products to almost all insured individuals. The RAMQ has noticed, moreover, that some products can cost up to twice as much as other similar products. The RAMQ reimburses close to $10 million each year (2002) for the PSDs prescribed to insured individuals.

The RAMQ has no lists of standard components nor references to studies on the qualities and properties of commercially available devices compared with the devices manufactured by the institutions. This situation mainly concerns the seat cushions and back cushions usually prescribed to wheelchair users.

THE RAMQ'S QUESTIONS

In addressing its request to the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS), the RAMQ wanted to know about the different PSDs available on the market, their different methods of construction and details of the components used; and to obtain a comparative study of the efficacy, cost, use and safety level of PSDs.

EVALUATION METHOD

Bearing in mind the RAMQ's questions, AETMIS undertook to identify comparative studies on PSDs by first consulting bibliographic databases. The search for information on the Web led to the Natural Sciences and Engineering Research Council (NSERC) Industrial Research Chair on Wheelchair Seating Aids, whose expertise remained available even though this research group had ceased operating in 2001. To review the current knowledge related to PSDs, AETMIS took the unusual step of approaching professor Rachid Aissaoui, the former principal investigator of that NSERC chair, now at the *École de technologie supérieure* (ETS), and proposed to sponsor him. This sponsorship led to the production of a three-volume report (known as the "Aissaoui Report"), which is summarized in this condensed report.

RESULTS

Currently, no system or process allows for an objective comparison of wheelchair cushions across manufacturers. A working group mandated by the International Organization for Standardization (ISO) to set wheelchair-seating standards has developed draft standards on a) the adoption of uniform terminology; b) the description of body posture and orientation; and c) postural-support devices and tissue-integrity devices. The vali-

dation project for International Standards ISO TC173/SC1 (16840-2, 2001-08-30) that is currently underway will propose methods for verifying the pressure-relief characteristics of wheelchair cushions.

The product survey conducted by professor Aissaoui yielded commercial information on 340 seat units, 79 back units, and 58 seat-and-back modules. Detailed lists and Excel spreadsheets accompany the Aissaoui Report and contain details of all the information on the seat cushions and back cushions found on manufacturers' sites, from which they have been transcribed in their entirety. Also, given that the authors did not have access to the products while drafting their report and that no standardized test has been conducted on these cushions, the manufacturers' claims about their products must be viewed with caution.

To date, few studies have been conducted on PSDs: twenty-two studies were found on seat cushions, and only three on back cushions. These studies nevertheless helped identify the different classification models for PSDs, four selection models, and the principal criteria and the principal methods used in their evaluation. The conclusions drawn in these studies also allowed for a preliminary selection to be made among the cushions based on their main component (e.g., foam, water, gel) or their shape (e.g., flat, contoured), and according to certain specific needs of users.

CONCLUSIONS

- Over 340 seat cushions, 79 back cushions and 58 seat-and-back modules have been identified in the North American market. Although several of these products are not available in Québec, they testify to the breadth of the product range and can serve as indicators for selecting the properties sought in the products considered for the people insured by the RAMQ.
- The cross-tabulating capabilities of the spreadsheets in which these products are compiled remain limited for other parameters such as different suppliers' prices for products in the same category, standards that will become applicable, selection and eligibility criteria, different suppliers' replacement costs, and so forth.
- It will be necessary to consider implementing relational databases to integrate this information and to cross-tabulate it for decision-making purposes. Also, technology-watch mechanisms would help keep these databases up to date and would make it possible to keep track of advances in the field of assistive technology.
- Implementing data-management tools adapted to the nature of PSDs will not be enough on its own to answer all the RAMQ's questions. In fact, much of the knowledge required to provide answers of immediate use to the RAMQ's operations is to a large extent still being generated. It would be advisable to provide for mechanisms to collect this knowledge so that it can be integrated into the decision-making process.
- Several criteria of immediate use can be compiled in a selection grid; they relate in particular to construction materials, quality of pressure distribution, interface shape, comfort, stability, thermal control, and cost. These criteria can be used as the starting point for developing an updatable grid.
- It will also be necessary to begin looking into the question of eligibility criteria, which are to some extent the corollaries of selection criteria.
- The lack of completely validated selection criteria should not prevent the RAMQ from asking suppliers or institutions for justification whenever significant price variations are observed.

RECOMMENDATIONS

Given the needs expressed by the RAMQ and the data that is available to respond to them, AETMIS recommends that the RAMQ:

- adopt the minimal selection grid with the criteria mentioned in the conclusions, namely, construction materials, quality of pressure distribution, interface shape, comfort, stability, thermal control, and cost;
- consider forming a consensus group composed of prescribers, users, suppliers and researchers expert in the field to design a more complete selection grid based on scientific evidence of efficacy and safety that takes into account the RAMQ's operational framework.

ABBREVIATIONS AND ACRONYMS

AETMIS	*Agence d'évaluation des technologies et des modes d'intervention en santé*
ANSI	American National Standards Institute
CCAT	*Conseil consultatif sur les aides techniques*
CONROD	Centre of National Research on Disability and Rehabilitation Medicine (Australia)
CRIQ	*Centre de recherche industrielle du Québec*
CSA/ACNOR	Canadian Standards Association / *Association canadienne de normalisation*
ETS	*École de technologie supérieure*
FIRA	Furniture Industries Research Association
ISO	International Standards Organization
MDA	Medical Devices Agency (Great Britain)
NSERC	Natural Sciences and Engineering Research Council
PSD	Postural-support device
RAMQ	*Régie de l'assurance maladie du Québec*
RESNA	Rehabilitation Engineering and Assistive Technology Society of North America
SSA	Shape-sensing array

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1 CONTEXT

Postural-support devices (PSDs) fall under the general heading of technical aids. According to international standard ISO 9999, a technical aid is "any product, instrument, equipment or technical system used by a disabled person... [for] preventing, compensating, monitoring, relieving or neutralising the impairment, disability or handicap." Le *Conseil consultatif sur les aides techniques* [CCAT, 1992] defines *positioning* as "the procedure aimed at placing a person in a given position by means of a postural-support device" and *postural-support device* as "a device enabling a person to assume or maintain a suitable posture". In this report, *posture* refers to the seated position. A positioning system can include the following components: a seat cushion, a back cushion, a legrest or footrest, an armrest, a headrest or a neckrest.

1.1 MANUFACTURE OF POSTURAL-SUPPORT DEVICES IN QUÉBEC

PSDs figure prominently among the technical aids covered by the *Régie de l'assurance maladie du Québec* (RAMQ) under the physical disability aids program. These aids are manufactured by Québec physical disability rehabilitation facilities or on a subcontracting basis by specialized companies. Sometimes, PSDs are made collaboratively by a public or private facility and a specialized company.

1.2 PROBLEM

The problem facing the RAMQ is twofold. First, the wide variety of construction methods results in significant differences in the bills that the facilities submit. Second, the RAMQ does not have lists of standardized components or references to studies on the characteristics and properties of commercial PSDs compared to those of facility-made PSDs.

1.3 EXTENT OF PSDs IN THE RAMQ EXPENDITURE

In 2002, the RAMQ reimbursed close to $10 million for PSDs prescribed to 6,378 insured individuals, a fifth (20.1%) of whom were under the age of 20 years[1]. These devices are reimbursed on presentation of a medical prescription and a proper bill, without consideration to the fabrication technique chosen by the facility that dispenses the device to the insured.

PSDs cost between $80 and $800. Prices for similar products vary by as much as 100%, depending on the facility.

1.4 NEEDS EXPRESSED BY THE RAMQ

In submitting its request to the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS), first in July 2001, then in a revised form in June 2002 to reflect certain feasibility constraints, the RAMQ wanted to know what PSDs were commercially available and what the different fabrication techniques were, and it wanted information on the components used and a comparative study of the use, efficacy, cost and safety of these PSDs.

1. http://www.ramq.gouv.qc.ca/fr/statistiques/documents/2002/tab6.04.pdf (consulted on 15/01/04).

1.5 SYNOPSIS OF THE CONDENSED REPORT

The following is a section-by-section synopsis of this report.

After providing background information and explaining the RAMQ's request (Section 1), this report sets out the assessment objectives and describes the methodological data search strategies, the particular aspects of the focus of research in this area, and the legal and regulatory framework governing the manufacturing of PSDs (Section 2).

Section 3 contains a condensed version of the three volumes of the Aissaoui Report. It first describes the framework for the use of PSDs, the health problems associated with them, and the contents of the inventories of seat and back cushions that supplement the Aissaoui Report. It then describes the different classifications of PSDs, the ISO standards validation project and four cushion selection models. Lastly, the controlled studies conducted thus far in this area and the avenues proposed by Aissaoui are summarized in this section.

The discussion (Section 4) mainly concerns the following: the limitations of the knowledge necessary for devising immediately applicable answers, the minimal criteria for creating a PSD selection grid, and the creation of relational databases for compiling and managing data.

The conclusions (Section 5) provide partial answers to the RAMQ's questions. To complete the answers, the recommendations (Section 6) suggest that work continue with a view to developing a PSD selection grid.

The following section lists the objectives pursued in order to answer the RAMQ's questions and the means used to arrive at them.

2 ASSESSMENT OBJECTIVES AND DATA SEARCH

2.1 ASSESSMENT OBJECTIVES

The assessment objectives are as follows:

1. To describe the different categories of seat and back cushions on the North American market.

2. To classify seat and back cushions according to their characteristics.

3. To describe the different fabrication techniques.

4. To compare the efficacy, safety and costs of the products with regard to the manufacturer's recommended use or the user's intended use.

The results should enable the RAMQ to modify its PSD coverage policy and to determine what amounts are reimbursable.

The Aissaoui Report and this condensed version of it are intended primarily for the RAMQ, but for other individuals as well (prescribers, suppliers, users, etc.) who might be interested in a knowledge review of PSDs.

2.2 DATA SEARCH

The assessment objectives involved various methods of searching for and processing data. The goal was to identify:

a) <u>The products on the American and Canadian markets</u>

The inventory of these products for the purposes of the report sought to be representative of the diversity rather than to be exhaustive. During this inventory, which was performed in 2002, priority was given to catalogues that were immediately accessible on Web sites. As a result, all the existing products were not necessarily inventoried. The reader will note the absence of a few Québec manufacturers or suppliers, but since they constitute a small proportion in relation to the whole, the representativeness of the number and variety of the products on the North American market is not reduced.

b) <u>Applicable standards</u>

The search in this area seemed to reveal a near-general absence of standards specific to PSDs, although steps currently being taken by standards organizations, such as the International Standards Association (ISO) and the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) will correct this situation. Proposals concerning their acceptability and applicability are presently being developed or are already at the consultation stage.

c) <u>Current selection criteria</u>

The task here was to compile the criteria validated by studies based on suitable scientific methodology that had compared different types of seat and back cushions.

Various information sources were consulted, namely, literature databases, Web sites and resource persons.

2.2.1 Literature databases

The scientific literature search was conducted according to the standard assessment procedure, i.e. querying literature databases, in particular, MEDLINE (PubMed), in order to identify studies that had compared PSDs.

The databases were queried using general terms, such as *wheelchair cushion*, *seat cushion*, *back cushion*, *seat cover*, etc., or simply *cushion* and *cushions*, in order to assess all the current publications concerning both PSDs and related products.

A large number of studies of varying quality were identified. The most relevant and methodologically rigorous studies in terms of objectives were cited. However, steps were not taken to locate unpublished results or results in the process of being published.

2.2.2 Web sites

The manufacturers' and suppliers' Web sites and those of public and private payers were consulted. The sites of numerous research organizations and institutes were consulted as well, in particular, that of the *École polytechnique*'s industrial chair on PSDs, whose two industrial partners were two Québec manufacturers, Promed and Orthofab. The chair was created under a Natural Sciences and Engineering Research Council of Canada (NSERC) grant-in-aid program.

2.2.3 Resource persons and sponsorship proposals

The *École de technologie supérieure* (ETS)

Rachid Aissaoui, an associate professor at the *École de technologie supérieure* (ETS), was consulted for the purpose of scientifically documenting the answers to the RAMQ's questions. Aissaoui was previously the principal investigator in the team attached to the *École polytechnique*'s industrial chair on PSDs, which, in four years (1997 to 2001), received more than $3.5 million in research grants. Numerous scientific publications have attested to the excellence of the research that had been conducted until the influx of funds ceased in February 2001, this because the industrial partners withdrew following an amendment to the clauses concerning the tax deduction for contributions to research. The expertise acquired in the area of PSDs was and still is available.

Realizing that it did not have the necessary human resources to conduct a first knowledge review of PSDs, AETMIS concluded, by way of exception to its mode of operation, that the best way to bring this project to fruition was to have the work performed under a sponsorship arrangement. Aissaoui agreed to conduct such a review and prepared a three-volume report.

Volume 1: Classification of wheelchair seat and back cushions.

Volume 2: Postural-support device standards: Wheelchair seat and back units.

Volume 3: Assessment of postural-support devices.

A descriptive table of the contents (body and appendices) and the table of contents for each of the three volumes in the Aissaoui Report are provided in Appendices 1, 2, 3 and 4 to this condensed report.

Sample spreadsheets supplementing Aissaoui's report (see Section 3.3) are provided in Appendices 5, 6 and 7. These excerpts give an idea of the quantity and quality of the information compiled in that report, which we will refer to as the "Aissaoui Report".

The *Centre de recherche industrielle du Québec* (CRIQ)

CRIQ was asked to submit a proposal for the creation of a relational database capable of incorporating the parameters found in the spreadsheets described below (see Section 3.3) and of including changing classification elements, such as relevant legislation, current and emerging standards, minimal and optional selection criteria, observed product performances (durability, level of satisfaction, etc.), costs and other criteria considered to be relevant. The merits and quality of this proposal could not be assessed, since it was rejected outright because of budget charging issues between AETMIS and the RAMQ.

2.3 PARTICULAR ASPECTS OF THE FOCUS OF RESEARCH ON THIS TOPIC

It will be noted that the approach chosen to answer the RAMQ's questions on the topic differed somewhat from AETMIS's usual procedure for assessing a health technology.

As a rule, this procedure can be summarized as follows: a) internationally recognized evidence regarding a given problem is gathered; b) an analytical grid is used to assess the methodological quality of the studies

identified, which, more often than not, are basically epidemiological, clinical and, occasionally, economic in nature; c) an attempt is made to bring together administrative or clinical/administrative data, if any; d) conclusions are drawn, and recommendations are made to reject, maintain or acquire a new technology or intervention modality. These steps are, for the most part and most often, carried out by AETMIS personnel.

In this case, given the lack of resources specializing in the assessment of technical aids immediately available to AETMIS and the fact that there are experts in the field in Québec's universities, a decision was made to sponsor the drafting of a knowledge review.

However, the fruit of this work, which was carried out at the ETS, consisted of three large volumes. They needed to be condensed in so that the report could be disseminated and made accessible, both to the decision makers and the health professionals concerned, but also for the purpose of rendering it suitable in terms of AETMIS's assessment mandate. This latter task was performed by examining the RAMQ's questions from the perspective of the computer-based tools needed for the future processing of data required for management purposes.

2.4 LEGAL AND REGULATORY FRAMEWORK

2.4.1 Legal framework

Unlike manual and motorized wheelchairs, to which PSDs are often indispensable additions, PSDs are not governed by the federal Food and Drugs Act, specifically, the section dealing with therapeutic products.

2.4.2 Regulatory framework

PSDs are considered consumer products, with no special legislation governing their use for preventive or therapeutic purposes, although it can be argued that they are used mostly as orthoses.

Canadian legislation concerning PSDs amounts to the regulations governing imported tissues considered hazardous products, which must meet different fire resistance specifications.

Provincially, there are criteria governing the quality of the stuffing.

3 CONDENSED VERSION OF THE AISSAOUI REPORT

Although it is generally faithful to the original report, this condensed version does not necessarily follow the order of the contents of the three volumes of that report. Some rearrangements were made for the sake of simplification and conciseness.

3.1 USES OF POSTURAL-SUPPORT DEVICES

Canadian and Québec data on the number of PSD users seem practically nonexistent and were not the subject of a specific and more extensive search for the purpose of this report. Provided below are the data—almost always the same in a number of standard publications—that are usually cited on the situation observed in the United States a few years ago.

Approximately 13.1 million people in the United States use a technical aid to remedy a physical disability [Laplante, 1992]. In 1995, the wheelchair was considered the primary means of ambulation of 1.68 million Americans, with 1.5 million using a manual wheelchair, 155,000 an electric wheelchair and 142,000 a carrier tricycle.

Many wheelchair users have abnormal posture because of their physical handicap and/or years of poor positioning. PSDs can help prevent or counter certain positioning problems. Nearly all wheelchair users use PSDs. For those with more severe disabilities or who are at risk of sustaining musculoskeletal deformations, a more refined maintenance/support system is essential. Table 1 shows a classification of PSDs according to their uses.

This review concerns only two of the PSDs listed in Table 1, namely, seat and back units. We will therefore not discuss legrests, footrests, armrests, headrests or neckrests. It should be noted that most studies concern seat cushions and that the literature on back cushions is sparse, a fact that will be reflected in the information presented here.

For the purposes of this review, the following cushion characteristics were identified: materials and construction; physical characteristics; cover material; mass or weight; dimensions; initial unloaded contour depth; and loaded contour depth.

TABLE 1

Postural-support devices: classification by functional unit

AREA OF THE BODY	FUNCTIONAL UNIT	FUNCTIONS	
		Support component	**Maintenance components**
Pelvis and thighs	Seat	Cushion Rigid interface or seat Anchoring system	Lap belt Straps Trunk control components Support pad Abduction and adduction wedges* Other positioning wedges or supports Foot support Etc.
Pelvis and trunk	Back	Cushion Rigid interface or seat Anchoring system	
Lower limbs	Legrest or footrest	Cushion Stump support Customized support system	
Upper limbs	Armrest	Forearm support Hand support Anchoring system Tray Half-tray	
Head and neck	Headrest or neckrest	Cushion Support	

Source: Bernatchez B., RAMQ, personal communication, June 2003.
* Wedge: A component or device designed to support an axial load.

3.1.1 Current PSD dispensing process

In the current PSD dispensing process, at least five players are involved in choosing a PSD: the consumer, the clinician, the vendor, the manufacturer and the payer. Often considered merely a wheelchair accessory, a PSD is sometimes prescribed without much explanation, often with the simple mention of "seat cushion". Yet, because it plays a crucial role in terms of comfort, stability, postural support and pressure sore prevention, the cushion should be given special attention, especially when prescribed to patients who spend most of their time in a wheelchair.

3.1.2 A broad range of products

Over the past decade, remarkable advances have been made in the field of technical aids, especially those used for wheelchairs. Presently, there are 340 models of wheelchair cushions on the North American market. This broad range of options for the user highlights more than ever the importance of an informed decision for ensuring that a suitable cushion is purchased. However, the large number of different cushions, the frequent lack of objective data on their efficacy, fads and economic constraints are all factors that make the prescriber's and user's choice difficult.

3.2 HEALTH PROBLEMS ASSOCIATED WITH THE USE OF UNSUITABLE PSDs

Many wheelchairs are not designed for long-term sitting posture. They can therefore cause different types of chronic postural problems.

3.2.1 General problems

Although the relationship between poor posture and the costs that it generates is not always immediately perceivable, poor posture can cause the following problems: discomfort, pressure sores, joint contractures, decreased range of motion, spasticity[2], deformation of the spine, internal organ dysfunction, restricted mobility, and increased dependence on the part of the user [Zacharkow, 1988; Engström, 1993; Mayall and Desharnais, 1995].

3.2.2 Pressure sores

Pressure sores are a major problem for people with reduced mobility (wheelchair users, the elderly, the bedridden, etc.) or who have no feeling in certain tissue surfaces. The loss of motor or sensory functions is a major risk factor for the development of pressure sores.

Pressure sores (cutaneous or subcutaneous ischemic necrosis) are ulcers due to the prolonged, continuous pressing of a bony prominence against a hard surface. Also known as bedsores, decubitus ulcers and skin ulcers, they generally occur in the areas of the body with a bony prominence near the skin: sacrum or coccyx (36%), hips (17%), the buttocks around the ischials (15%), heels (12%), ankles (7%) and other areas of the body (13%).

Studies published in Canada, the United States, Europe and South Africa show that 1.5 to 25.7% of hospitalized patients develop pressure sores. In the spinal-cord injured, the incidence of pressure sores varies from 40 to 80% [Cook and Hussey, 1995; Brienza and Karg, 1998], although their prevalence can be as high as 60% in this population [Aissaoui et al., 1997]. Zacharkow [1988] estimated the proportion of pressure sores due to wheelchair use at 36 to 50%.

Pressure sores can cause pain, lead to infections and increase the risk of mortality. Furthermore, treating these lesions is an expensive undertaking. Studies in this regard indicate that treating a single pressure sore can cost between US$5,000 and US$36,000 [Maklebust et al., 1986; Foster et al., 1992; Patterson and Bennett, 1995; Remsburg and Bennett, 1997; Brienza et al., 2001]. Thus, since they occur in a great many wheelchair users, preventing them is a priority when rehabilitating individuals who need a wheelchair and when choosing an appropriate wheelchair and cushion.

Although a number of factors influence the formation of pressure sores, extrinsic factors, such as pressure at the body-seat interface, friction, and skin moisture and temperature, are the most important ones. Cushions are still the most popular and most effective means of prevention. The primary characteristic of a cushion is therefore its ability to help prevent pressure sores. To do this, it must reduce the stresses on the pressure areas. This is why evaluative and comparative studies of seat cushions often examine the physical parameters associated with the pressure exerted on these areas, specifically, the ischials, the sacrococcygeal region, and the back of the thighs.

It should be mentioned at this point that a very inexpensive cushion is not necessarily the most economical. The high cost of treating pressure sores may warrant the purchase of a more expensive cushion. Choosing a cushion that provides adequate support is therefore essential for a person who wishes to achieve an optimal seated position, both from a functional standpoint and from the

2. Spasticity is an increase in muscle tone with rigidity and exaggerated deep reflexes.

standpoint of preventing deformations and pressure sores.

However, certain methods of making and distributing seat and back units are such that their price is exorbitant. Consequently, the importance of having the necessary skills to choose an appropriate cushion cannot be overemphasized.

3.3 INVENTORY OF SEAT AND BACK CUSHIONS

Producing an inventory of the products on the market involved compiling original commercial information on seat and back units and combined modules. Detailed lists and spreadsheets showing a breakdown of all the information gathered on seat and back units are provided in the Aissaoui report.

All the information on seat and back cushions was taken from catalogues provided by the manufacturers and distributors: 60% from the AbleData[3] product database and 40% from the other North American manufacturers listed in Appendix D of Volume 1 of the Aissaoui Report.

The descriptions that were compiled (i.e., the cushion's benefits) come directly from the manufacturer's site. They were copied in their entirety in English. Since Aissaoui did not have access to the products while drafting his report and since no standards testing was performed on the cushions, the manufacturers' claims regarding the quality of their products should be taken with some reservation.

A brief description of the appendices in the Aissaoui Report is provided below. This overview will give the reader an idea of the extent and limitations of the available data. These considerations will be examined later in Section 4 (Discussion) and Section 5 (Conclusions). An excerpt from each of the appendices is provided in this condensed version to illustrate the contents of these lists.

3.3.1 Seat cushions

Appendix A in Volume 1 of the Aissaoui Report contains a detailed list of 340 seat cushions used for positioning purposes. (An excerpt from this list is provided in Appendix 5 below.) The following information is provided in an 8-column table: material, type of cushion, trade name, a product description, the manufacturer's name, the type of user, the manufacturer's suggested price (in U.S. dollars) and an illustration of the PSD.

The appendix also contains an Excel spreadsheet (seatsall.xls) with data on 20 characteristics for each product. The numbers assigned to the cushions are the same in the list and spreadsheet. The following box illustrates how to use the spreadsheet:

3. www.abledata.com.

TRADE NAME	*CONTOURED GEL WHEELCHAIR CUSHION*
Description	*The Contoured Gel Wheelchair Cushion is a gel-and-foam cushion designed for use by individuals who use wheelchairs. This cushion features high resiliency two-density foam construction. Firm base foam provides support while soft top foam provides comfort; the waterfall front increases comfort under the knee.*
Manufacturer	D- Rolyan Foam
Type of cushion	*Gel and foam seat cushion*
Material	*High resiliency two-density foam construction with a built-in four-chamber gel pad.*
Weight or information on transport	*With an attached quick-lock strap.*
Cleaning	*Covered in specially-formulated StaphChek vinyl.*
Dimensions	*20 x 16 x 2 inches, 18 x 16 x 2 inches, or 16 x 16 x 2 inches.*
Shape	*
Structure	*Cushion*
Pressure	*For maximum pressure relief.*
Comfort	*Soft top foam provides comfort; the waterfall front increases comfort under the knee and thigh.*
Posture	*
Stability	*Firm base foam provides support.*
Heat	*
Moisture	*
Safety	*
Durability	*
Reliability	*
Type of user	*

* No data available.

3.3.2 Back cushions

Appendix B in Volume 1 contains a list of 79 back units. (An excerpt from this list is provided in Appendix 6 below.) As is the case with seat cushions, the list is accompanied by an Excel spreadsheet (backsall.xls) containing detailed information provided by the manufacturers, and there is an illustrated list of 20 descriptive features.

3.3.3 Combined seat-and-back modules

Appendix C in Volume 1 contains a list of 58 combined modules. (An excerpt from this list is provided in Appendix 7 below.) Combined modules are PSDs that combine seat and back units. This list is accompanied by an Excel spreadsheet as well (Seat&Back.xls).

3.4 CLASSIFICATION OF POSTURAL-SUPPORT DEVICES

In his report, Aissaoui states that classifications of PSDs for wheelchairs vary according to the resource person or publication. The best-known is the classification by user need. Although not as well known, the other methods of classification provide useful information on construction materials, the different functions of the cushions and their ability to prevent pressure sores.

3.4.1 Classification by user need (Hobson)

This classification was proposed by David A. Hobson, at the University of Pittsburgh Rehabilitation Engineering Center in the United States [Smith and Leslie, 1990]. It divides PSDs into three categories, which are defined mainly on the basis of the needs of the different user populations, namely, those designed to:

a) Provide postural support and compensate for deformations (individuals with cerebral motor impairment).
b) Balance pressure and maintain posture (individuals with spinal cord injury).
c) Improve comfort and posture (individuals with multiple handicaps and the elderly).

3.4.2 Classification by construction material

Most often, seat and back cushions are classified according to their shape and constituent materials (Appendix 8 below shows the different configurations used when making cushions). From the standpoint of materials, cushions can be divided into three categories: a) fluid-filled cushions (air, water, elastomer gels and viscous liquids); b) foam cushions; and c) hybrid models, in which there are two or more types of material.

These cushions can be static or dynamic. Fluid-filled and foam cushions are static devices designed to even out or distribute pressure on the pelvic contact surface. Dynamic cushion models are based on the principle that high local pressure can be tolerated as long as the duration of contact does not exceed certain preestablished limits. A few applications of this principal have been attempted. For example, there is, in essence, a mechanical model and a model consisting of bellows-type air cells.

a) Fluid-filled cushions

Air cushions are generally one of two configurations: compartmentalized or rubber air chambers, or mesh-type structures (e.g., the Roho). The main disadvantage of air cushions is the risk of overinflation or of a loss of pressure.

Less common, water cushions (e.g., the Aqua Seat) have the disadvantage of leaking, of being heavy and of losing their shape (hammock effect), especially if the fluid flotation cushion consists solely of nylon cloth.

Gel cushions (e.g., the Elasto-Gel, 3M's Reston) are made from materials such as silicone elastomer, whose viscosity or consistency is similar to that of the soft human tissues at the body-seat interface. However, the design of the fluid flotation cushion and of the cover material has a considerable effect on pressure distribution characteristics at the body-seat interface. Lately, use has been made of high-viscosity fluids in oversized, supple membranes (e.g., the Jay), which produce an individualized molding effect and promote good heat dissipation. Unfortunately, gel cushions are usually heavy (up to 11 kg), and some models leak.

b) Foam cushions

Polyurethane foam has, for many years, been the main material used when designing and making cushions, especially those intended for people at low to moderate risk of developing pressure sores.

There are three types of polyurethane foam cushions: flat cushions, generically shaped cushions and customized cushions.

The pressure characteristics vary from cushion to cushion and depend on the intrinsic

mechanical properties of the foam, according to whether it consists of a single slab or several layers (flat surface), or shaped to adjust to the pelvic region via generic or customized contouring. It should be noted that some foams lose their mechanical properties after six months of use.

c) Hybrid models

Hybrid models combine two or more of the above-mentioned processes in order to meet the specific user needs. One of these models incorporates several types of fluid materials. Another combines elastomer gels and high-viscosity fluids with polyurethane foam structures (for example, the Jay cushion has a generic structure made of polyurethane foam on which a fluid flotation cushion containing a high-viscosity fluid is placed).

3.4.3 Classification by function (Staarink)

Staarink [1995] developed a function-based classification of seat and back cushion parameters. These functions concern:

a) The seated position (quality of pressure distribution, suppleness of the surface, etc.).
b) Moisture and heat (moisture and heat control properties).
c) The action of sitting in and getting out of the wheelchair (indentation in the sacral, frontal and lateral regions, friction, puckering, etc.).
d) Transport (weight, size, portability, etc.).
e) Maintenance (textile cover washability, nontextile cover cleanability, odor resistance, etc.).
f) Durability (of the cover and cushion, wear resistance).
g) Reliability (fill-ratio sensitivity, sensitivity to positioning, etc.).
h) Safety and fire resistance.

The parameters considered most important after pressure distribution are as follows: surface roughness, stability in the seated position, impact dampening, and moisture and heat control properties.

3.4.4 Classification according to the risk of pressure sores (CONROD)

The authors of a publication on the classification of seat cushions by Australia's Centre of National Research on Disability and Rehabilitation (CONROD) [2001] devised a seat cushion classification based on the principle of preventing pressure sores. The classification was developed for a specific population, namely, victims of injuries to the spinal cord, which is at a risk for pressure sores (see Section 3.2.2).

3.4.5 In brief

There are various systems for classifying cushions and various cushion characteristics and functions. It would be inappropriate for our purposes here to opt for any one of these systems. It also appears that only an informed consensus on the part of prescribers, users, suppliers and payers could lead to the adoption of a standardized classification system that would reflect the perspectives of all those concerned.

3.5 STANDARDIZED TESTS

Less progress has been made with regard to standardized tests for wheelchair cushions than for wheelchairs per se (see the AETMIS report on mid-wheel drive powered wheelchairs). As a result, there is no system or process for objectively comparing cushions between manufacturers. The standards presently being developed are briefly listed below.

3.5.1 ISO standards presently under approval

The International Standards Organization (ISO) has set up a task force charged with establishing wheelchair posture standards, an initiative that the ANSI and RESNA have supported. Preliminary papers concerning or providing the adoption of a common terminology, a description of posture and of the

body's orientation in space, and postural-support and body tissue integrity preservation devices have been drafted.

The validation project for international standards ISO TC173/SCI (16840-2, 2001-08-30), which is presently under way, is proposing methods for checking the pressure reduction properties of wheelchair cushions and test methods developed to evaluate what are considered to be the 12 most important parameters:

1. Interface pressure
2. Load deflection and hysteresis[4]
3. Frictional properties
4. Lateral and forward stiffness
5. Sliding resistance
6. Impact dampening under normal loading conditions
7. Elastic recovery
8. Ability of the cushion to adapt to a given shape
9. Stability
10. Heat and water vapour transfer properties
11. Fluid leakage
12. Biocompatibility

When developing wheelchair cushion standards, use is made of methods for measuring and describing both the characteristics of cushions and their performance. Cushion characteristics can, in general, be defined as its physical properties determined by different mechanical tests (loading, impact, friction, deflection, temperature and humidity). As for the notion of performance, it concerns the cushion's functioning as a support surface. Standards pertaining to characteristics and those pertaining to performance are equally essential. The ISO standards project has emphasized the former and is laying the groundwork for developing the latter.

These mechanical tests will make it possible to control the behaviour of quantitative variables as cushions age, but they will not be able to be used to compare cushions manufactured with different materials.

The development of wheelchair cushion standards should benefit all the parties concerned, above all, the users, for they will get cushions that meet their needs.

3.5.2 Fire resistance considerations

Nonflammability is a very important safety criterion for people with reduced mobility. Although the fire resistance of PSDs is a major concern, improvements that increase fire resistance are usually achieved at the expense of material comfort, pressure distribution and durability. This is why the proposed ISO standard does not recommend test methods or requirements for wheelchair PSD fire resistance. It is therefore up to the manufacturers, consumers and end users to weigh the risk of tissue injury or discomfort against the risk of injuries from a potential fire.

This approach allows for a compromise to be sought between the fire resistance properties and the performance of a product designed to prevent pressure sores in high-risk individuals. On the other hand, it does, in no way, preclude the possibility of developing highly fire-resistant cushions for low-risk users. Efforts are continuing for the purpose of establishing fire resistance standards that will reflect the need to develop relevant tests tailored to different applications. In the meantime, the absence of ISO standards for cushion fire resistance and Canadian legislation governing the importation of products considered to be hazardous because of their inflammability will need to be reconciled.

4. Hysteresis: The property of a physical system that does not return to its initial state when a force is produced which is exactly the opposite of that which deformed the system.

3.6 SEAT AND BACK CUSHION SELECTION MODELS

In his report, Aissaoui presents four seat cushion selection models based on objective selection criteria. The main components of these models are listed in Table 2.

As in the case of the different classification systems, it would not be appropriate to immediately opt for one selection model over another. Some models attempt to examine several parameters, while others focus on one well-defined characteristic.

As a result, the creation of a selection grid tailored to the way Québec's health-care system operates should arise from a consensus among prescribers, suppliers, end users and payers.

TABLE 2

Comparison of the four cushion selection models

SELECTION	BY FUNCTIONALITIES			BY PHYSICAL CHARACTERISTICS
	Several functionalities		**Specific functionality**	
Model	Ferguson-Pell [1990]	Staarink [1995]	MDA [1997]	Sprigle [2001]
Objectives and method	Examines the factors that: • affect comfort • determine stability • minimize the risk of pressure sores	Evaluates cushion performance using an instrumented dummy with sensors on the ischials. Characteristics concerning seat loading conditions, transfer (of weight and of the user), maintenance and durability tested on 5 categories of cushions according to the risk of pressure sore formation: • low • medium • medium with excessive sweating • high with excessive sweating • high with incontinence Comparison of 17 cushions	Measures pressure distribution under the ischials (static measurement). Comparison of 23 seat cushions (19 static and 4 dynamic). Reference cushion: 7-cm flat PVC foam cushion.	Establishes uniform terminology for defining and describing cushions and their covers (materials and components). 225 seat cushions on the North American market were examined.

Results	Determining factors for choosing a cushion:
	• Comfort:
	  • distribution of stresses on soft tissues
	  • buildup of moisture and heat
	  • postural instability
	• Functionality:
	  • degree of stability
	  • weight
	  • frictional properties
	  • thickness
	  • cost
	  • durability and maintenance
	  • appearance
	• Safety
	  • distribution of stresses on soft tissues
	  • degree of stability
	  • frictional properties
	  • buildup of moisture and heat
	  • durability and maintenance requirements
	  • Inflammability
	(These factors are described in Volume 2 of the Aissaoui Report.)
		Classification of parameters according to functions concerning:
		• the seated position
		• moisture and heat
		• getting in and out of a wheelchair
		• transport (weight, size, portability, etc.)
		• maintenance
		• durability
		• reliability
		• safety and fire resistance
		Determining of the minimum levels required for the 5 categories of cushions according to:
		• the quality of pressure distribution
		• the moisture control factor
		(The parameters and their significance are explained in Volume 1 of the Aissaoui Report.)
			Cushions classified into 3 categories:
			A. cushions with no significant difference in relation to the flat PVC reference cushion.
			B. significant reduction in ischial pressure in relation to Class A.
			C. significant reduction in ischial pressure in relation to Class B.
			(The results of this study are presented in Section 3.8.4.1 of this report.)
				Classification according to:
				• the materials used to make the cushion
				• the materials used to cover the cushion
				• weight
				• overall size
				• heights relative to the contour
				• the height of the contour with and without loading
				(The article by Sprigle et al. entitled “Development of uniform terminology and procedures to describe wheelchair cushion characteristics” is provided in an appendix in Volume 2 of the Aissaoui Report.)

3.7 EVALUATION OF SEAT AND BACK SYSTEMS

A complete positioning system includes a cushion and various accessories: a back, a lumbar support, a lateral trunk support, footrests, armrests and a headrest. The total body weight is distributed among these various components in proportions that vary according to the wheelchair model and the user's posture. In assembling the components, one can customize the system on the basis of each user's needs and adapt them to existing wheelchairs.

There are several types of positioning systems. Seat and back cushions can be pre- or custom-made. Some cushions are manufactured for the purpose of facilitating the user's transfer, while others are designed to secure the user in.

The following subsections discuss the objectives of a positioning system and the methods and criteria used to evaluate certain components of such a system, according to the Aissaoui Report.

3.7.1 Objectives of a system

The primary objectives of a positioning system are as follows:

a) To promote comfort.
b) To optimize the user's functional capacities.
c) To prevent secondary complications, such as contractures, postural abnormalities and pressure sores.
d) To be easy to transport.
e) To be esthetically acceptable.

3.7.2 Choosing a system

The decision to use a premade seat/back system, a custom-built system or accessories should be based on a case-by-case analysis of each end user’s objectives. It is possible to write a prescription that adequately meets each user's personal and therapeutic needs.

A systematic approach to positioning consists in analyzing the seated posture, the key to which is the pelvic region. The positioning process in a wheelchair starts with the pelvis and continues with the lower limbs, trunk, head and neck, and ends with the upper limbs, proceeding from the proximal segment to the distal segment [Mayall and Desharnais, 1995].

For about the past 15 years, therapists have been using simulators (Promed, Orthofab's SEM, CRIQ-IRM, Physipro, etc.) to assess user needs in terms of positioning—changing the seat-back angle, varying its spatial position, determining component size and what the necessary accessories are—before recommending a specific positioning system.

In addition to taking numerous user-related factors into account when choosing a positioning system, one should also look at the characteristics of the system itself, specifically, the stability it provides, the frictional properties of the cushion and cover, moisture control, the insulating and thermal dissipation properties, durability, maintenance, weight, cost and fire resistance.

Once the desired function of the supporting surface has been determined, one can devise a method to evaluate the cushion.

3.7.3 Methods and criteria for evaluating a system

A number of clinical methods for evaluating positioning systems can be used to compare their efficacy. Objective evaluation methods determine interface pressure, shear forces (see Section 3.7.3.2) at the body-seat interface, interface shape and cushion cost.

Because there are no objective methods for evaluating the following parameters, one must use subjective methods: comfort, stability and ease of handling, skin reaction, transfer capacity, ease of maintenance, and cost of repairs.

3.7.3.1 INTERFACE PRESSURE

Since pressure sores are due to high pressures on body tissues, it would be desirable to be able to accurately determine these pressures. Determining the interface pressure enables the clinician to determine what supporting surface would give the lowest possible pressures and what the best distribution of these pressures would be. Interface pressure data provide a "portrait" that can be used to determine the relative efficacy of the many different products currently available on the market.

Ferguson-Pell [1990] recommends distributing pressure equally under the region of the ischial tuberosities and that of the greater trochanters (Figure 1). Weight distribution aimed at increasing the support provided by the greater trochanters and the thighs is an important principle in designing cushions, specifically, those with a contoured shape.

Several pressure calculation methods have been devised in order to obtain objective measurements of the pressure reduction at the body-seat interface in wheelchair users. These measures are now the subject of a proposal for integration into future ISO wheelchair seat unit standards [Ferguson-Pell and Parry, 2000].

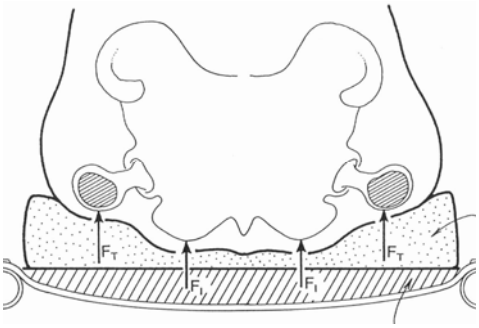
In general, three main types of sensors used to measure body-seat interface pressures were identified in the scientific literature: electronic sensors, pneumatic/hydraulic sensors and electropneumatic sensors.

Advances in electronic technology now permit more accurate measurements than before. The devices used to measure interface pressure and its distribution over the supporting surface range from the single transducer, which is moved over different parts of the body in order to take successive measurements, to transducer networks that make it possible to observe simultaneously the pressures exerted over the entire supporting surface.

New pressure measurement devices have been developed over the past few years. They consist of a detection matrix the size of the seat and a graphic display device for measuring body-seat interface pressure in its entirety, thereby eliminating the need to install a large number of sensors at different locations on the body.

FIGURE 1

Body-seat interface



Shaped cushions share the supporting forces F_I and F_T more equally between the ischial tuberosities (F_I) and the trochanters (F_T). On cushions with no shaping, F_I is considerably larger than F_T, and the ITs have to compress the cushion nearly 5 cm before the trochanters make contact.

Source: Ferguson-Pell, 1990.

However, single-sensor pressure measurement systems have the advantage of being portable and affordable, and they enable the clinician to obtain objective pressure readings on small areas or surfaces.

One cannot predict body tissue deformation by measuring interface pressure distribution alone, since, in addition to the limitrophe conditions (seat or cushion surface), the mechanical properties of the skin, fatty tissue, muscles and bones also contribute to the shape of body tissues.

3.7.3.2 SHEAR FORCES

While so-called normal pressure occurs when the force acts perpendicular to the supporting surface, shear occurs when the forces are parallel to this surface. Local shear is considered one of the main risk factors for pressure sore formation. The supporting surface can also be evaluated by measuring the shear forces. However, the stresses associated with shear are difficult to measure, and the tissue destruction dynamics associated with this phenomenon are not easy to model. Shear evaluation is limited by the lack of reliable sensors suited to the task. The Aissaoui Report presents the different methods for measuring shear forces that different researchers have developed thus far.

3.7.3.3 INTERFACE SHAPE

The fact that there is no exhaustive model for explaining the cause of pressure sores significantly complicates the task of interpreting pressure measurements with a view to identifying undesirable interface conditions.

After Husain [1953] showed the importance of body tissue deformation as a parameter for assessing pressure sore formation, a number of researchers examined this problem. However, using tissue deformation measurements to characterize loading conditions on soft internal tissues is inherently problematic because there is presently no practical clinical method for directly measuring deformations. Imaging techniques such as ultrasound and magnetic resonance imaging hold significant promise but have not yet been perfected specifically for this application. Instead of measuring the deformation of body tissues, some researchers have focused on evaluating shapes that might reduce body-seat interface pressure.

Sprigle et al. [1990b] report that custom-contouring foam cushions further reduces pressure. The contouring of a highly elastic polyurethane foam cushion reduced pressure values from 53 to 45 mm Hg.

Recently, Li [2003] developed an instrument called the shape-sensing array (SSA), a network of fiber optic shape sensors capable of measuring the shape of the body-seat interface with a very high degree of accuracy. The results of tests performed on the new device indicate that the SSA system is capable of making relatively accurate, reproducible measurements. The system can be used to analyze and quantify the complex relationships between seat properties, such as surface shape and cushion and tissue deformation, under different loading and stiffness conditions. This should prove to be very important in research tailored to clinical needs. Once perfected, the SSA might become a useful clinical instrument for designing supporting surfaces and prescribing cushions.

Li et al. [2003b] used the SSA to evaluate the new generic cushion they designed, by comparing it with two standard cushions made in Québec: the cushion made at the *Centre Lucie-Bruneau* and an ISCUS ischial relief cushion. These two studies found that the generic cushion reduced peak pressures under the ischials (see Section 3.8.1.3).

3.7.3.4 COMFORT

Given the large amount of time wheelchair users spend in the seated position each day, comfort is a primary objective in cushion design. An overview of the literature reveals that very few research projects have attempted to measure the well-being of wheel-

chair users. Not only is the problem little known, but the method for evaluating this aspect has yet to be determined.

Even if the notion of comfort is an abstract one, the feeling of well-being can be evaluated using a set of subjective measures performed in standardized conditions [Shackel et al., 1969; Christiansen, 1997]:

a) assessment of overall well-being
b) assessment of well-being with regard to specific areas of the body
c) wheelchair characteristics checklist
d) adjustment mechanisms
e) personal comments

Harms [1990] found that folding manual wheelchairs were uncomfortable both for the physically fit and the handicapped.

While Gross et al. [1994] concluded that there was a close association between pressure values and comfort, Shaw [1991], Lee et al. [1993] and Gyi and Porter [1999] maintain that there is no link between high pressure values and seat discomfort. Pressure data and discomfort data are therefore not sufficiently correlated to constitute a basis for guiding cushion design. According to Aissaoui, these four studies show that even if the pressure exerted on a seat results from a complex relationship between anthropometric and seat geometry factors, the time devoted to product design could be reduced considerably by attempting to optimize, based on pressure intensity and pressure distribution, the comfort provided by the prototypes and to reduce the risk of pressure sore formation.

Fenety et al. [2000] recently developed a method based on the trajectory of the centre of pressure to continuously monitor in-chair movements. Their hypothesis is based on the following observation: seated individuals associate discomfort with the perceptible movements they make in this position. The application of this hypothesis has yielded good results in industrial ergonomics. It would be interesting to see if these movements in the seated position apply to wheelchair users as well.

3.7.3.5 DYNAMIC STABILITY

The actual or perceived effect of a cushion on stability can be a very important determining factor for wheelchair users with little trunk control. Quite often, spinal cord-injured patients are acutely aware of the stability of their trunk and have a much more sensitive and complex perception than what the current image analysis systems can detect. In the clinical setting, a compromise must often be made between cushion's stability and its ability to provide better pressure distribution, which, in practice, translates into accepting a slight increase in pressure under the ischial tuberosities.

Few studies have measured cushion stability quantitatively. In his report, Aissaoui mentions that he developed a technique for objectively measuring dynamic stability, by creating a phase diagram for the behaviour of the centre of pressure at the body-seat interface during reaching movements outside the individual's prehension zone. It was found that the contoured polyurethane foam cushion offers better stability than a flat foam cushion or a Roho air cushion [Aissaoui et al., 2001b]. This objective measure confirms the clinically established fact that the Roho cushion is unstable and can corroborate the user's subjective assessment of his / her stability.

3.7.3.6 THERMAL PROPERTIES AND SKIN REACTION

Once again, very few studies were found that have evaluated the thermal properties of cushions. In addition, some studies did not evaluate all the materials used in making cushions, and others involved just one subject. Furthermore, the manufacturers practically never provide information on cushion characteristics, such as water vapour permeability, water absorption and thermal insulation. The thermal properties of standard

cushions are, however, well known. Polyurethane foam cushions and Roho air cushions are very poor heat conductors, and while gel and water cushions are considered good heat conductors, this can be a disadvantage when the outside ambient temperature is very low, such as in the winter, because cushions are not insulated against the cold.

Lastly, given that an increase in heat indicates a significant increase in tissue metabolism, it is quite possible that a cushion that reduces temperature variations lowers the risk of ischemic lesions to body tissues [Aissaoui et al., 2001b].

3.7.4 Evolution of design and materials

The evolution of seat and back unit design is closely linked to the evolution of the manufacturing materials, such as polyurethane foam and viscoelastic foams (Temperfoam), and to the new uses (e.g., compartmentalization) of fluids, such as gel, water and air. Technological advances have led to the development of new PSDs and to an increase in the number of tools available to clinicians and therapists for prescribing suitable positioning, specifically, seat and back units.

One of the first seat cushion evaluation studies [Garber and Krouskop, 1982] found that it was difficult to classify or compare PSDs solely on the basis of their manufacturing materials. The different materials have evolved in order to adapt to cushion topography at the body-seat interface.

Back units have evolved in relation to the canvas backs found in most manual wheelchair models. Although it has the advantage of being very light and collapsible and therefore transport-friendly, this simple design offers no trunk support and often causes kyphotic posture[5] (frequently observed in the elderly).

There are presently two types of back unit designs: flexible back cushions, which allow a manual wheelchair to be folded, and rigid ones, which cannot be folded but to which one can add components, such as a chest, lumbar or sacral support, for trunk support and stabilization. Flexible back units maintain trunk posture by adjusting to it by means of adjustable tension straps (AT cushion, Orthofab) or stays that adjust to the shape of back lengthwise (DCF, Orthofab).

3.8 CONTROLLED STUDIES

When this condensed report was being prepared, it seemed important to digress on the subject of controlled studies in this area. It will be noted at the outset that the controlled studies mentioned here essentially involved measuring physical properties of a small number of cushions. Some of these studies were conducted with users for the purpose of measuring cushion stability or their level of satisfaction. However, in general, the number of healthy or handicapped volunteers was small.

Measurement or interpretation biases may have occurred but were not analyzed or mentioned for the purposes of this condensed report. However, an overview reveals the characteristics arising from controlled studies and the prevailing conclusions in the field of PSDs at the present time. Within the context of a technology watch on PSDs, a next step should consist in including a critical assessment of this type of trial, whose methodology very frequently differs from that used in conventional epidemiological or clinical studies in the field of health technology assessment.

For example, 22 studies of seat cushions are listed in a table in an appendix in Volume 3 (Appendix 6.1 in the Aissaoui Report), whereas only three exhaustive studies of back cushions are listed in Appendix 6.2. Most of these studies deal with loading conditions at the body-seat interface.

5. Kyphosis: Abnormal curvature of the spine with posterior convexity.

The following subsections summarize, for seat cushions, then for back cushions, the results of the studies listed in the Aissaoui Report.

3.8.1 Seat cushions

Overall, two main concepts have guided seat cushion design: the multilayer hybrid concept and modification of cushion shape.

3.8.1.1 THE MULTILAYER CONCEPT

The multilayer concept was introduced in 1986 after Ferguson-Pell et al. [1986] tested several models of multilayer cushions made of different arrangements of materials of various thicknesses, such as gel, viscoelastic foam (Temperfoam) and foam. In this study, at least 13 multilayer combinations were tested in an able-bodied, not handicapped, population. The authors did not find any relationship between the pressure exerted under the ischials and the mechanical properties of the materials.

3.8.1.2 MODIFICATION OF CUSHION SHAPE

The other concept is that of shape. Seemingly very different materials have evolved towards a common characteristic, namely, interface shape. Experiments have been carried out mainly on three interface shape modifications: 1) the wedge cut-out (made on the lower surface of the cushion); 2) the cut-out (made on the upper part of the cushion); and 3) the custom contoured [Sprigle et al., 1990b; Rosenthal et al., 1996; Brienza and Karg, 1998] or generic [Aissaoui et al., 1998; Li et al., 2000] shape.

1) The wedge cut-out

The wedge cut-out on the lower surface of flat polyurethane foam seat cushions has not helped reduce ischial pressure [Garber and Krouskop, 1984].

2) The cut-out

Lim et al. [1988] introduced the concept of the cut-out by removing the part directly in contact with the ischials and adding a medium-density foam ischial bar. The authors could not make a distinction either between this model and a flat polyurethane cushion with regard to the location, severity and incidence of pressure sores in two similar high-risk groups [Lim et al., 1988]. In addition, the designers indicate that the ischial bar, which is supposed to cause greater pressure under the thighs, can become an additional handicap for individuals who lack trunk stability.

3) The contoured shape

The third type of shape modification is known as the contoured shape, which can be made to measure (custom shape) [Sprigle et al., 1990b; Rosenthal et al., 1996; Brienza and Karg, 1998] or standardized (generic shape) [Aissaoui et al., 1998; Li et al., 2000]. These studies showed that custom or generic shapes yielded better results than flat cushions. However, shapes depend just as much on the density of the polyurethane foam used. And contoured cushions are expensive. It should also be pointed out that even air cushions like the conventional Roho now have a shape that resembles the curvature molded in the foam: the height of the air chambers in the ischial and interischial regions is slightly lower than that of the sides, which creates ischial relief.

3.8.1.3 COMPARISON OF SEAT CUSHIONS

As part of a doctoral thesis done in collaboration with the *École polytechnique de Montréal* and the *École de technologie supérieure*, Li [2003] evaluated the cushion developed by the *Centre de réadaptation Lucie-Bruneau* (LB), whose design was

inspired by the cut-out method, by comparing it to an ISCUS ischial relief contoured cushion (Orthofab) and a generic-shape cushion (GSC) developed by the author. The study involved 16 wheelchair users. Nine subjects participated in designing the generic cushion by allowing measurements to be taken of loaded body-seat interface shapes using a measurement instrument known as a shape-sensing array (SSA) pad. Of the original group of subjects, 10 subsequently participated in a blinded study evaluating the three cushions. The evaluation involved a comparison of the loading condi-tions and dynamic stability, the subjects' perception of stability and postural comfort, and their overall preference.

The results showed that the GSC cushion and the ISCUS provide a larger contact surface and reduce peak pressures under the ischials. The LB cushion objectively provides greater stability. However, this objective measurement of stability was not confirmed by a subjective measurement, since the users perceived the ISCUS cushion to be the most stable.

From the standpoint of comfort, the GSC generic cushion clearly differed from the other two. Seventy percent of the subjects preferred it. This choice may have been conditioned by the comfort factor more than by the load distribution.

It should be pointed out that the subjective parameters were measured during one session. In other words, they only reflected the immediate effect. To assess the comfort and stability of a cushion during the activities of daily living, one must evaluate the long-term effects (follow-up study).

3.8.1.4 COMPARISON OF STATIC AND DYNAMIC CUSHIONS

In 1997, the Medical Devices Agency (MDA) conducted a study of 23 models of seat cushions, 19 static and 4 dynamic. A flat, 7.5-cm-thick PVC foam cushion was used as the reference cushion. The purpose of the study was to evaluate and compare the most widely used seat cushions in the United Kingdom, essentially from the standpoint of pressure distribution. Body-seat interface pressure was measured with the Talley Oxford Pressure Monitor (TPM), which can be used to calculate the pressure under the ischial tuberosities.

The study also provided information on cushion durability. Since, in 1997, there was still no durability test specific to wheelchair seat cushions, the investigators used FIRA (Furniture Industries Research Association) tests—an indentation test[6] that consists in measuring, in newtons, the force required to reduce the thickness of the cushion by 40% of its initial unloaded value, and a fatigue test involving the equivalent of five years of use.

The study involved four groups of subjects:

- Elderly ambulatory individuals (n = 12).
- Elderly nonautonomous individuals (stroke victims) (n = 10).
- Individuals with spastic paraplegia (injury at T[7]1-T11) (n = 23).
- Individuals with nonspastic paraplegia (injury at T12-L[7]3) (n = 12).

By examining only the ischial pressures in each group, the investigators determined, by statistical analysis, three classes of cushions:

- Class A: Cushions with no significant difference in relation to the flat PVC reference cushion.
- Class B: Significant reduction in ischial pressure in relation to Class A.
- Class C: Significant reduction in ischial pressure in relation to Class B.

The greatest reduction in pressure achieved between these three classes was approximately 25%. Naturally, one can increase or

6. Indentation Hardness Index: BS4443: Part 2; method 7; procedure A; 1980.
7. T refers to the thoracic vertebrae, L to the lumbar vertebrae.

reduce the pressure by 50% by modifying footrest height or seat inclination. For example, for elderly ambulatory individuals, three cushions fell in the class where ischial pressure is reduced the most: the STM3, the Roho High Profile and the Jay Cushion.

A parallel can be drawn between the MDA report (United Kingdom) and the CONROD report (Australia). However, a number of cushions listed in the MDA report do not, unfortunately, have an equivalent in the CONROD report. The detailed results of the MDA study and the publication concerning ISO tests entitled "Wheelchair Seating—Part 2: Test methods for devices intended to manage tissue integrity—Seat Cushions" are presented in an appendix in Volume 2 of the Aissaoui Report.

3.8.1.5 STUDIES OF INTERFACE PRESSURE

A number of studies provide interface pressure data on different cushions. One of the first studies dealing with loading conditions at the body-seat interface showed that there is a link between body build (thin, normal or obese) and the pressure exerted under the ischials [Garber et al., 1982]. Thin people have high ischial pressure, regardless of the type of cushion used, and are likely to develop pressure sores [Kernozek et al., 2002].

All research indicates that, of all the cushions, the gel cushion is the one for which the highest pressures are obtained. Foam cushions consistently seem to give the lowest pressures. As for air cushions, the pressures reported in all the studies are in the moderate-to-low range. Custom-contouring foam cushions further reduces pressure (see Section 4.2.1).

3.8.2 Back cushions

Studies evaluating seat cushions abound, but research on back cushions is rather scarce. Aissaoui chose the following three studies to illustrate the current trends in back cushion research.

3.8.2.1 THE PARENT STUDY

The main study of back cushions was conducted by Parent et al. [2000]. It involved the DCF flexible contour backrest (now marketed by Orthofab), which had been developed by the authors and which they compared to the rigid Jay backrest (Jay) and the flexible, adjustable-tension backrest (Orthofab). This study, which involved 15 healthy subjects seated in a positioning simulation wheelchair, evaluated the following three parameters: the anthropometric profile of the trunk, the pressure exerted on the backrest and the subjective evaluation of immediate well-being. In general, the DCF provides increased lumbar comfort and has the important property of evenly distributing pressure on the backrest. In addition, it preserves two features often sought after by wheelchair users, namely, light weight and foldability.

3.8.2.2 THE LACOSTE STUDY

The second study [Lacoste et al., 2003], which involved 15 quadriplegic subjects, compared four wheelchair backrests: the DCF (Orthofab), the adjustable-tension backrest (Orthofab), the rigid J2 Back (Jay) and the Apex cushion (Orthofab). The results will be published shortly. Only a few of them are presented in an appendix in Volume 3 of the Aissaoui Report. They show that, with regard to dynamic stability, the DCF behaves in the same manner as the top-of-the-line rigid backrest. At least 53% of the participants considered the DCF very comfortable. It also had the largest surface during stability testing. It is also important to note that the J2 cushion costs close to CAN$600, while the DCF is usually one-half this price.

3.8.2.3 THE AISSAOUI STUDY

The third study involved three types of backrests [Aissaoui et al., 2002]. It was conducted at the *Centre de réadaptation Marie-Enfant*, *Hôpital Sainte-Justine*. Seven children with cerebral motor impairment took

part in the study. The purpose of the study was to measure the effect of three types of backrests—the DCF (Orthofab), the J2 Back (Jay) and supple canvas—on performance during propulsion. An article is presently being written and will be published shortly in a scientific journal.

The study found that during manual cycling, the lever arm (i.e., the distance between the shoulder as an anatomical landmark and the position of the hand on the handrail) is significantly shortened. This has an important effect on shoulder joint reaction forces and moments, the shoulder being the main power unit for locomotion in a manual wheelchair. The DCF not only provides stability similar to that provided by the rigid cushion (the J2 Back), but also permits positioning of the trunk in such a way as to minimize the amount of stress on the shoulder. Previous studies had found a high incidence of chronic pain in manual wheelchair users.

3.8.3 In brief

Studies show that contoured seat cushions significantly reduce interface pressure.

Li's study showed that it is worth pursuing research on generic contoured cushions, which are less expensive than custom contoured cushions and more promising in terms of efficacy than cut-out cushions, such as that developed by the *Centre Lucie-Bruneau*.

As for backrests, the Parent study showed that the DCF flexible contour cushion offers substantial advantages, namely, even pressure distribution, light weight and flexibility. Upon comparing this cushion with the J2 Back, Lacoste found that the DCF cushion offers the same benefits as the top-of-the-line cushion and costs half as much. In addition, the DCF permits positioning that minimizes shoulder stress, which helps prevent chronic pain in manual wheelchair users.

3.9 AVENUES PROPOSED IN THE AISSAOUI REPORT

In the past few years, several hundred cushions tailored to seat and back units have been developed. In describing their products, the manufacturers use terms such as "increased comfort and stability", "pressure reduction", etc. Most of these new products have never been tested objectively or examined in randomized, blinded studies. Yet, the evaluation of seat and back units can be done only by means of clinical studies and objective measures (postural stability, pressure, posture, comfort).

The data presented above are valid, and the classification proposed by CONROD seems reliable. Unfortunately, it applies only to existing products. Once developed, a battery of tests can be used to evaluate products currently used in Québec or that will be used in Québec in the future. These tests will be based on the ISO standards that are presently under approval (see Volume 2 of the Aissaoui Report) and on the classifications proposed by Staarink and CONROD.

In his report, Aissaoui states that objective pressure, stability and comfort measurements should be made systematically at centres with technical aid services that prescribe custom positioning systems. With these measurements, clinicians will have tools for comparing the different seat and back cushions.

In addition, the ISO standard that is currently under approval (ISO CD 16840-2, 2001-08-30) for wheelchair seat cushion testing should make it possible to measure the mechanical characteristics of cushions subjected to different tests (loading, impact, friction, deformation, temperature and moisture). These tests will enable one to control the behaviour of these quantitative variables during cushion aging, which varies from cushion to cushion, but one will not be able

to use the test to compare different cushions manufactured from different materials.

The criteria proposed by Staarink link the quantitative mechanical variables to pressure sore risk levels for wheelchair users. One should first perform the ISO tests that are currently under approval on existing cushions, then create a look-up table with user needs in terms of: a) preventing the risk of pressure sore formation; b) stability during the tasks of daily living; c) postural comfort; and d) maintaining correct posture in order to slow the progression of musculoskeletal deformations.

It should be noted that the instruments (pressure, shape and posture measurements) used to conduct these tests can, to a large extent, be found in Québec's university network.

In conclusion, Aissaoui states that his report will clarify the current situation regarding the classification and selection of seat and back units. As for future products, a manufacturer-independent approval grid based on objective tests will need to be developed.

4 DISCUSSION

It will be recalled that this assessment stemmed from the fact that the RAMQ had noticed a twofold disparity in the amounts billed by health-care facilities for PSDs:

- It had observed that these amounts can vary by as much as 100% from institution to institution for similar PSDs; and
- It seemed that some facilities automatically offered PSDs at the upper end of the current price range ($80 to $800).

To objectively document the arguments it will use vis-à-vis health-care facilities, the RAMQ asked AETMIS to conduct a review of the existing PSDs that would cover their physical characteristics and fabrication techniques, efficacy, safety, cost, classification and selection criteria.

Two concurrent approaches could have been recommended for the purpose of answering the RAMQ's questions, by taking into account the main components underlying its request: 1) to explain the billing disparity; and 2) to compile evidence on the efficacy, safety and cost of PSDs. The disparity between the amounts billed for seemingly similar products could possibly have been explained by the intrinsic properties of the products resulting from the particular manner in which they are made. And the data compilation regarding classification and selection criteria could have, among other things, helped confirm or call into question the merits of systematically dispensing expensive products.

Only the second aspect, compiling evidence, was acted on for the purpose of this report. Explaining the billing disparity would have required both an administrative and technical inquiry in the facilities, which would have exceeded AETMIS's mandate and responsibilities.

In these circumstances, the discussion will concern the scientific and technical basis of the compiled data and the need to use appropriate computer-based tools to manage the gathered data in a context where the standards, even as they are emerging, are necessary benchmarks for ensuring the quality of the materials that go into designing and manufacturing cushions.

4.1 SCIENTIFIC AND TECHNICAL BASIS

The main observation arising from this report summarizes the current situation well:

> Much of the knowledge needed to provide answers of immediate applicability to the RAMQ's operations are still largely in the process of being acquired by scientific and technical researchers.

For example, of the studies of immediate interest, the most structured comparison of cushions used or usable in Québec was performed as part of a doctoral thesis defended last spring at the *École polytechnique de Montréal* [Li, 2003]. And, once again, this comparison is still preliminary for more than one characteristic of these cushions. Clinically or scientifically supported cushion comparisons are few in number.

Despite these limitations, the findings of this thesis, together with those of the other publications reviewed, do provide some guidelines for creating a PSD selection grid based on the criteria mentioned below.

4.2 SEAT AND BACK CUSHION SELECTION CRITERIA

Based on the sufficiently supported data that were compiled, a PSD selection grid could include at least the following criteria: interface pressure distribution, interface shape, comfort, stability and thermal control.

4.2.1 Interface pressure distribution

All research indicates that gel cushions give the highest pressure readings. Cushions con-

taining other fluid materials (water, air) and foam cushions consistently seem to cause the lowest pressures. However, some foams lose their mechanical properties after six months of use. It will therefore be necessary to be able to distinguish between the different qualities of foam.

As for air cushions, the pressures measured in all the studies are in the moderate-to-low range. The GSC generic cushion designed by Li [2003] and an ISCUS contoured cushion [Orthofab) reduce pressure more than the cushion developed by the *Centre Lucie-Bruneau*. Custom contoured foam cushions further reduce pressure, but they seem to be at the upper end of the price range.

Lastly, regardless of the type of cushion used, thin people have high ischial pressure.

4.2.2 Interface shape

Interface shape refers to the complex relationships between seat properties, surface shape, cushion deformation and user tissue deformation under different loading and stiffness conditions. The shape can now be measured with the SSA system developed by Li [2003], which yields reproducible and relatively accurate measurements. Although the study is of limited validity because of the small number of subjects that participated in it and because the subjective parameters were evaluated during a single session, the SSA could prove to be very useful for research tailored to clinical needs. Once perfected, the SSA could become an extremely important instrument for designing supporting surfaces and prescribing cushions.

4.2.3 Comfort

The four studies that attempted to determine if there is a relationship between high pressure and discomfort did not succeed in sufficiently correlating the data to provide a basis for guiding cushion design. This shows that, even if the pressure exerted on a seat results from a complex relationship between anthropometric factors and seat geometry-related factors, the time devoted to seat design could be reduced substantially by attempting, based on pressure intensity and pressure distribution, to optimize the comfort provided by the prototypes and to reduce the risk of pressure sore formation.

Fenety et al. [2000] recently developed a method based on the trajectory of the centre of pressure to continuously monitor in-chair movements. Their hypothesis is based on the observation that seated individuals associate discomfort with the perceptible movements they make in the seated position. Since this hypothesis has led to good results in the field of industrial ergonomics, it would be interesting to determine if these movements in the seated position apply to wheelchair users as well.

4.2.4 Stability

Few studies have measured cushion stability quantitatively. However, Aissaoui states that he developed an objective dynamic stability measurement technique by creating a phase diagram of the behaviour of the centre of pressure at the body-seat interface during reaching movements outside the individual's prehension zone. It turned out that the contoured polyurethane foam cushion provides better stability than a flat foam cushion or a Roho air cushion.

4.2.5 Thermal control

Since a wheelchair user who sweats excessively or who is incontinent is at higher risk for developing pressure sores, thermal control is one of the parameters that serve as the basis for Staarink's selection model [1995] (see Table 2, page 15).

The thermal properties of standard cushions are relatively well known. Polyurethane foam cushions are very poor heat conductors, followed by air cushions (Roho). On the other hand, gel and water cushions are considered good heat conductors. Nonetheless, when the outside ambient temperature is very low, as in the winter, good heat conduction can be a disadvantage, since cushions are not insulated against the cold.

4.2.6 Costs

A very inexpensive cushion is not necessarily the most economical. The high cost of treating pressure sores may justify the purchase of more expensive seat cushions. Choosing a cushion that provides adequate support is of utmost importance for a person who wishes to achieve an optimal seated position, both from a functional standpoint and to prevent deformations and pressure sores.

4.2.7 In brief

These characteristics could constitute a minimal selection criteria grid, to which other decision elements could be added as they are validated and as their applicability is confirmed, both from a scientific and administrative standpoint.

The review of the existing products, classification systems and selection criteria to be considered revealed that the spreadsheets provided in this assessment, although they do meet the report's immediate objectives, could not be effective without restructuring. There are several reasons for this, which will be examined in the following paragraphs.

4.3 SPREADSHEETS AND RELATIONAL DATABASES

The sample information provided in an appendix in Volume 1 of the Aissaoui report (see Section 3.3) indicates that an ordinary spreadsheet will not be sufficient when the time comes to add and easily link other parameters, such as the prices charged by different suppliers for products in the same category, the applicable standards, the selection and dispensing criteria, durability by supplier and so on.

Relational databases quickly become indispensable in this context. However, it seems that they are not one of the management tools currently available at the RAMQ. To design an appropriate tool, AETMIS contacted the *Centre de recherche industrielle du Québec* (CRIQ) and asked it to create relational databases in parallel with the compilation and evaluation of scientific, technical and normative data, since CRIQ has recognized expertise in this type of work with companies. CRIQ's proposal was turned down at the start of the assessment in June 2002. It will, in fact, be recalled that the merits and quality of this proposal could not be examined, as it was rejected outright because of budget charging issues between AETMIS and the RAMQ.

As a result, a lack of customized computer-based tools will not further optimal integration of the gathered data. The reader will understand that this integration cannot be done for the purposes of this condensed version of the Aissaoui Report. If steps are not taken to create suitable relational databases, the use of the spreadsheets that supplement that report will remain limited and their potential role as decision aids will be diminished accordingly.

4.4 IN BRIEF

An analysis of the costs that health-care facilities bill to the RAMQ will not be avoidable much longer, for as the seat and back cushion selection and dispensing criteria are used, the cost-quality ratio of the products will be easier to determine.

In addition, since the data needed to provide solid answers to the RAMQ have only been partially validated from a scientific standpoint, the *Régie* should initiate a technology watch and adopt mechanisms for examining the possibility of integrating these new dimensions into the selection (and billing) system as soon as they are published.

5 CONCLUSIONS

Going back to the RAMQ's questions, we can review the answers that were provided and their level of applicability. The work involved in carrying out the project included:

- Making an inventory of and classifying postural-support devices; and
- Identifying immediately usable selection criteria.

5.1 INVENTORY AND CLASSIFICATION OF POSTURAL-SUPPORT DEVICES

- More than 340 seat cushions, 79 back cushions and 58 combined seat-and-back modules were identified on the North American market. Although many of these products are not commercially available in Québec, they do give an indication of the current product range and can serve as a guide in selecting the characteristics sought after in the products considered for individuals insured by the RAMQ.
- The cross-tabulation capabilities of the spreadsheets in which these products are listed is still limited for other parameters, such as the prices charged by different suppliers for products in the same category, the applicable standards, the selection and dispensing criteria, durability by supplier and so on.
- Consideration should be given to creating relational databases in order to incorporate these data and cross-tabulate them fordecision-making purposes. As well, technology watch mechanisms would help keep these databases up to date and would make it possible to monitor the evolution of breakthroughs in the field of PSDs.

5.2 POSTURAL-SUPPORT DEVICE SELECTION CRITERIA

- Implementing computer-based management tools tailored to the nature of PSDs would not, by itself, be enough to answer all of the RAMQ's questions, since much of the knowledge needed to provide answers of immediate applicability to the RAMQ’s operations are still largely in the process of being acquired. Mechanisms for gleaning this knowledge should be put in place so that it can be incorporated into the decision-making process.
- A number of immediately usable criteria can serve as the basis of a selection aid grid. These criteria are manufacturing materials, pressure distribution quality, interface shape, comfort, stability, thermal control and cost. They could constitute an initial core for the development of an evolving grid.
- One should start examining the dispensing criteria, which are, in a manner of speaking, the corollary of the selection criteria.
- Notwithstanding the lack of fully validated selection criteria, the issue of cost will require the RAMQ to ask suppliers or health-care facilities for justification when substantial differences are observed.

6 RECOMMENDATIONS

Given the needs expressed by the RAMQ and the data available for meeting them, AETMIS recommends that the RAMQ:

- Adopt the minimal grid consisting of the selection criteria mentioned in the conclusions, i.e., manufacturing materials, pressure distribution quality, interface shape, comfort, stability, thermal control and cost; and
- Consider forming a consensus group consisting of prescribers, users, suppliers and expert researchers in the field for the purpose of devising a more complete selection grid based on scientific efficacy and safety evidence that reflects the way the RAMQ operates.

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APPENDIX 1

Contents of Volumes 1, 2 and 3 of the Aissaoui Report			NUMBER OF PAGES
VOLUME 1 (Classification of wheelchair seat and back cushions)			
Contents	Categorization of seat and back units according to their characteristics in terms of shape and materials. Description of the classification of seat and back units according to the ISO standards under approval and according to the classification model proposed by Staarink [1995].		32
Appendices (4)	A: List of seat cushions		45
	B: List of back cushions		10
	C: List of combined seat-and-back modules		10
	D: List of manufacturers		8
Electronic files (Excel)	sieges.xls	*Number of products and number of parameters per product	340; 22*
	dossiers.xls		81; 21*
	sieges&dossiers.xls		58; 22*
VOLUME 2 (Standards for postural-support devices)			
Contents	Detailed literature review of the current and emerging standards (ANSI/RESNA and ISO) for seat and back units. Presentation of four seat and back unit selection models based on objective criteria.		34
Appendices (3)	A: Article by Sprigle et al. [2001]: "Development of uniform terminology and procedures to describe wheelchair cushion characteristics".		13
	B: Study by the Medical Devices Agency (MDA) [1997b]: "Wheelchair cushions static and dynamic: A comparative evaluation—special issue".		80
	C: ISO standard CD 16840-2: "Wheelchair seating—Part 2: Test methods for devices intended to manage tissue integrity—Seat cushions".		42
VOLUME 3 (Assessment of postural-support devices)			
Contents	Criteria for quantitatively assessing the effect of a functional seat- or back-type PSD. Three specific objectives: 1) Biomechanical analysis of positioning, positioning problems and the solutions provided in the clinical setting. 2) Description of objective and subjective methods for evaluating positioning systems that include seat and back units. 3) A synopsis of the different scientific studies published in the past 30 years, as well as of those conducted and published by the NSERC industrial chair on PSDs. Preliminary list of the more important criteria for evaluating PSDs, specifically, seat and back units.		48
Appendices (4)	Results concerning seat cushions		3
	Results concerning back cushions		1
	Evaluation of the Contour Flexible DCF back cushion		9
	Publication by the Centre of National Research on Disability and Rehabilitation Medicine (CONROD) [2001].		29

APPENDIX 2
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APPENDIX 3
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APPENDIX 5

Seat cushions (excerpt from Appendix A in Volume 1)

	CUSHIONS	BRAND NAME	DESCRIPTION	MANUFACTURER	USERS	PRICE (US$)	
Foam	1. gel and foam seat cushion	ACTION CENTURION FLOTATION CHAIR PAD (MODELS 5200 & 5205)	The Action Centurion Flotation Chair Pad models 5200 ($96.45) and 5205 ($108.85) are polymer flotation seat cushions fabricated of two layers of equal thickness: one made of foam and the other of AKTON, a viscoelastic polymer. These layers are enclosed in an elastic, waterproof cover. The pads come with a washable knit outer cover with a zipper closure and carrying loops. DIMENSIONS: Model 5200 is 16 x 16 x 1.25 inches; model 5205 is 16 x 18 inches. Custom sizes and shapes are available, however. WEIGHT: 6.82 pounds. COLORS: Covers available in blue, brown, black, green, and burgundy. The **CENTURIAN** offers pressure and shear reduction for moderate risk users. Combined 5/8" (1.6cm) AKTON polymer and 5/8" (1.6cm) foam are sealed in a waterproof film barrier to guard against incontinence permeation. Available with the standard Super Lo Shear cover, or the optional Incontinent and Economy covers. Thickness: 1-1/4" (3.2cm)	Action		models 5200 ($96.45) and 5205 ($108.85) DEC 1999	
Foam	2. gel and foam seat cushion	ACTION COMMUTER FLOTATION PAD (MODEL 8500)	The Action Commuter Flotation Pad (model 8500) is a polymer seat cushion fabricated of a 1.75-inch layer of foam and 1/2-inch of AKTON, a viscoelastic polymer. DIMENSIONS: Standard size is 16 x 16 x 2.25 inches, but custom shapes and sizes are available. WEIGHT: 4.7 pounds. COLORS: Covers available in blue, brown, black, green, and burgundy. The **COMMUTER** offers basic pressure and shear reduction for low risk users at an affordable price. Combined 1/2" (1.3cm) Akton polymer and 1-3/4" (4.4cm) foam are sealed in a waterproof film barrier to guard against incontinence permeation. The breathable basic cover offers three sided ring zipper, carrying handle and nonskid base. Thickness: 2-1/4" (5.7cm)	Action		<100	
Gel	3. gel flotation seat cushion	THE PILOT FLOTATION CHAIR PAD (MODELS 9000 & 9005)	The Pilot Flotation Chair Pad, models 9000 ($96.45) and 9005 ($108.85), are polymer flotation seat cushions made of AKTON, a viscoelastic polymer, covered with a soft elastic film material. The pads will not leak if punctured. Features include contoured edges, a washable and sanitizable knit cover that stretches with body movement, a zipper closure on the outer cover and carrying loops. DIMENSIONS: Standard size is 16 x 16 x 1 inches; Pediatric sizes are 12 x 11 x 1 inches, 14 x 11 x 1 inches, and 16 x 13 x 1 inches. Custom shapes and sizes are available. WEIGHT: 8 pounds. COLORS: Available in blue, brown, black, green and burgundy. The **PILOT** provides exceptional pressure relief in a low profile cushion that's ideal for foot propellers and other moderate to high risk users. The 1" (2.5cm) of AKTON polymer provides users with the freedom of no maintenance other than an occasional wipe with antibacterial soap. The BODY SMART Cover is standard with optional Super Lo Shear, Incontinent and Economy covers available to meet the users needs. Thickness: 1" (2.5cm)	Action		models 9000 ($96.45) and 9005 ($108.85) DEC 1999	
Gel	4. gel flotation seat cushion	ACTION PROFESSIONAL FLOTATION CHAIR PAD (MODEL 5100 & 5105)	The Action Professional Flotation Chair Pad, models 5100 and 5105, are polymer flotation seat cushions. The pads are made of AKTON, a viscoelastic polymer that acts like a fluid in gaining support, yet is a soft solid providing resilience. The pads have a waterproof elastic shell and an outer washable knit cover with a zipper and carrying loops. DIMENSIONS: Standard size is 16 x 16 x 1 5/8 for model 5100 and 16 x 18 x 1 5/8 inches for model 5105, but custom shapes and sizes are available. WEIGHT: 14.5 pounds (5100) and 16.31 pounds (5105). COLORS: Available in blue, brown, black, green, and burgundy. The **PROFESSIONAL** is intended for those at high risk of skin breakdown or with a history of ulcers. The 1-5/8" (4.1cm) AKTON polymer provides effective weight distribution on a contour free surface. Individual or multi-client use is appropriate as AKTON polymer does not promote bacterial growth. The BODY SMART Cover is standard with optional Super Lo Shear, Incontinent and Economy covers available to meet the users needs. Thickness: 1-5/8" (4.1cm)	Action		101-500 DEC 1999	

APPENDIX 6

Back cushions (excerpt from Appendix B in Volume 1)

	CUSHIONS	BRAND NAME	DESCRIPTION	MANUFACTURER	GENERIC TERM(S)	PRICE (US$)	
Back Supports	1. back support cushion	BEADEASY BACK	The BeadEasy Back is a back support cushion designed for flexible scholiosis or mild fixed scholiosis, and is suitable for people who use wheelchairs. The cushion is custom made to individual dimensions using a molded system, which can be finished in 15 minutes. The cushion uses a plywood base to hold a platalon bag filled with foam pellets. The bag is molded to fit the individual's dimensions by mixing a special adhesive with the pellets and then creating a vacuum in the bag. The BeadEasy Back allows for use of adjustable thoracic pads.	Allied			
Back Supports	2. solid back insert	ANNA-DOTE	Anna-Dote is a back support cushion and solid back insert designed to aid individuals who use wheelchairs, or straight-back/recliner geriatric chairs to sit upright, allowing for the reduction in stress, discomfort and fatigue that can accompany a slouched to the side position. This positioning supportive aid fits over the backrest of either a wheelchair or a geriatric chair and provides patients with an extended backrest to keep them upright and prevent falling or sliding to the side of the chair. The angled side extensions provide lateral trunk support to the user. Anna-Dote is available in four models: AD100 for straight-back gerichairs; AD100-A for recliner gerichairs (three-position without headrest); AD110 for standard 16 to 18 inch wide wheelchairs; and AD110-A for wider 18 to 20 inch wide wheelchairs. The AD110-A features shorter side bolsters, an additional 3 inches between bolsters, and is designed for the normal to larger framed individual. MATERIALS: Made of fire retardant expanded vinyl with foam n side bolsters. COLORS: AD100, AD100-A and AD110 available in Saddle; AD110-A comes in Light Gray or Dark Blue.	Anna Dote	SPINAL CORD INJURY MOBILITY DISABILITIES	139.50 includes shipping & handling (c.o.d. extra) Aug. 2002 online	
Air	3. inflatable back cushion	VARILITE SINGLE BACK REST & VARILITE SPLIT BACK-REST	Air and foam inflatable lower back cushion for use in wheelchair. Approximately 16 inches wide by 8 inches high, with two loops to attach to wheelchair. Single cushion or split cushion with two compartments. Two cushions can be used together if a complete back support is needed. Varidry stretch covers to wick moisture away from skin.	Cascade		<100	
Air	4. inflatable back cushion	BACK REST, SPORT SEAT, & SEAT REST SELF-INFLATING CUSHIONS	Open cell foam back rest with airtight, waterproof nylon shell. Self inflates; valve to adjust user's comfort. Size 16 by 8 by 2.5 inches; blue, cedar brown covers available. Also available: Seat Rest, similar product for seat of chair, size 12 by 16 by 1.5 inches; price $65.00; Sport Seat, like Seat Rest except heavier duty covering, in navy, rust, or green.	Cascade		<100	
Back Supports	5. back support cushion	BEDLOUNGE	The BedLounge is a back support cushion designed for use by individuals with physical disabilities. Resembling a chair without a seat, this large cushion enables the user to sit upright in bed and provides support for the upper and lower back, arms, shoulders, neck, and head while the user reads or watches television. This padded support has a lightweight internal polypropylene frame and features pivoting armrests and a height- and angle-adjustable headrest pillow. Storage pockets on the armrests can be buttoned closed. The removable slipcover is washable COLOR: Natural, navy, dark green. black, burgundy, denim, blue and white pinstripe, or dark blue and blue pinstripe.	Cequal **D**-vitalityweb		129.95 DEC 2001	

APPENDIX 7

Combined seat-back modules (excerpt from Appendix C in Volume 1)

	CUSHIONS	BRAND NAME	DESCRIPTION	MANUFACTURER	GENERIC TERM(S)	PRICE (US$)	
Seat and Back Supports	1. solid seat and back insert	SOLID SEAT AND BACK	Solid seat and back inserts. Hardwood plywood base with firm foam padding. Naugahyde cover. Various hardware styles and clamps attach units to wheelchair. Customized to fit any wheelchair frame; manual, power drive, travel chair or sport chair. Back insert models: T-back, R- back or with straps.	Adaptive	SPINAL CORD INJURY MOBILITY DISABILITIES	<100	
Seating Systems General	2. foam in place seating system	FOAM & PLYWOOD SEATING SYSTEM	The Foam and Plywood Seating System is a foam in place seating system for people who use wheelchairs. The covering process is custom designed to individual specifications, and emphasizes the comfort properties of the foam.	Allied			
Seating Systems General	3. vacuum seating system	BEADSEAT	Seat and back modules include molded plastic pan with plastic bag filled with pellets. Pans mounted in wheelchair with outriggers and quick release brackets. Interchanging and adjusting offset and straight outriggers allows for adjustment of height and angle. Person is positioned in system and air is evacuated from bags, forming beads into custom molded shape. Resin is injected into bags and sets up within two hours to form permanent shape. Shape can be modified with knives or grinding tools. Units are upholstered with pre-glued foam and stretch fabric. Seats available in 14 inches by 14 inches, 16 inches by 16 inches, 16 inches by 19 inches, 18 inches by 19 inches, and 18 inches by 22 inches. Backs available in 12 inches by 12 inches, 12 inches by 16 inches, 14 inches by 14 inches, 14 inches by 18 inches, and 16 inches by 18 inches. Components may be ordered in kit or separately.	Allied		501-1000	
Air	4. air flotation seat and back cushion	ALLYN AIR SEAT	The Allyn Air Seat is an air flotation seat and back cushion unit for use in cars, trucks, or as wheelchair cushions. The cushion is designed to provide full support including to the lumbar area. Seat and back air pressure adjustable separately. The cushion is portable and washable. The material is 33 gauge vinyl; attachment straps are included. GUARANTEE: One year.	Allyn		<50	
Seating Systems General	5. modular seating system	PIONEER MODULAR SEATING SYSTEM	The Pioneer Modular Seating System was designed for individuals who can adopt symmetrical sitting postures but have problems that relate to postural stability. Trunk and pelvic support can be built into the back section and optimal pressure relief can be achieved with the addition of commercially available pressure relief inserts placed into the base section. Seat length and backrest recline are adjustable to suit the individual. Hip pads are standard. WIDTHS: 38, 43, and 48 cm widths are available. The folding chassis of the seating system is interchangeable with the Pioneer Wheelchair (see separate entry) and the Pioneer Lounge Chair. OPTIONAL ADJUSTABLE COMPONENTS (also available from Bencraft): Headrest, Lateral Pads, Adjustable Hip Pads, and Lumbar-Sacral Pad.	Bencraft			

APPENDIX 8

Materials and shapes of different seat cushions

Vasio – Para

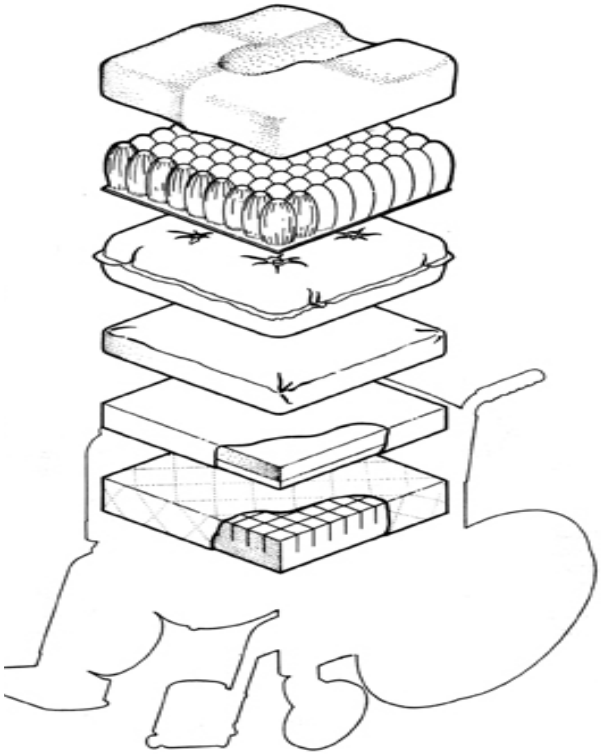
Roho air cushion

Fluid flotation cushion

Gel cushion

Viscoelastic foam cushion

Foam cushion



Source: Smith and Leslie, 1990.

Agence d'évaluation des technologies et des modes d'intervention en santé

Québec