Project Title: 
Extension Study: Prospective randomised control trial of management strategies for patients with multiple sclerosis and significant urinary problems

Full Business Name of Administering Organisation: 
The University of Melbourne

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Full Street Address: 
Parkville, Victoria 3052 Australia

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Ethical approval: 
The Royal Melbourne Hospital Ethics Committee

Contact Person: Dr Helen E O’Connell

Position Title: Urologist and Senior Lecturer

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Research Team at RMH:

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Dr. John King, MBBS, MD, FRACP  Neurologist, Co-investigator
Professor Trevor Kilpatrick, MBBS, FRACP, PhD  Neurologist, Co-investigator
Dr Mike Whishaw, MBBS, FRACP  Geriatrician
Dr Ramin Samali, BSc (Med), MBBS (Hon)  Urology Fellow (2003)
Dr Caroline Dowling, BSc (Med), MBBS (Hon  Urology Fellow (2004)
Dr Kalavampara Sanjeevan MBBS, MS, MCh (Urol)  Urology Fellow (2005)
Mrs. Louise Kurczycki, RN, BAppScN, GradDipN  CNC (Continence), Unit Manager
Ms Kerry Poole, RN  CNA
Mrs Kathy Myles, BSc (Hons)  Research Assistant
Dr Lachlan MacGregor, MBBS, MMedSc, DRANZCOG  Statistician

Acknowledgements:

Professor Steven Davis  Neurologist, Director of Neurology
Dr Samantha Pillay  Urologist
Dr Catherine Temelcos  Urologist
Dr Niall Tubridy  Neurologist
Dr Mark Marriott  Neurologist
Dr Helmut Butzkueven  Neurologist
Mr John Carey  MS Research Nurse Neurology
Ms Josephine Baker  MS Research Nurse Neurology
Ms Ann Duncan  Clinical Research Nurse Urology
Dr Elizabeth McDonald,  Medical Director MS Society (Vic)
Ms Janet Francis and staff  MS Nerve Centre Blackburn
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BACKGROUND

There is a dearth of prospective controlled trials to support clinical strategies for patients who have MS and significant urinary problems. The only randomised control trials for people with MS who have urinary problems are relatively recent and involve the administration of new medications. However there are very few of these. Clinical decision making for people with MS who have urinary problems appears ad hoc and based on the available facilities of the practitioner rather than on the basis of identified need and effectiveness data.

Moreover, there are no prospective studies that have evaluated the merit of performing sophisticated urodynamics in this patient group, though most repeated studies have involved such a test. Some prospective studies have been performed in the spinal cord injury (SCI) patients who have many similar problems to people with MS. In the SCI population there appears to be a significant benefit from providing urinary treatment guided by a Urodynamic (or bladder pressure) diagnosis. Even in the SCI group of patients there are few randomised control trials.

This Randomised Control Trial sponsored by an earlier NCMS grant comparing two treatment strategies is almost complete. The two treatment arms differ in a few respects. Patients in the **Control arm** have their management plan determined by the Urologist using Fluoroscopic Urodynamics, and subsequent, planned regular medical and nursing review in the outpatient’s clinic. The progress with therapy is determined by standardised methods as per the protocol. The **Trial arm** involves a management strategy evolved with the intent of assessing the efficacy of the management strategy outlined in an algorithm, suggested by the US National MS Society web site. In this case, an experienced Continence Nurse Advisor (CNA) systematically recognises and treats problems as per the algorithm drives this second strategy. These patients are similarly reviewed in the outpatient’s clinic. Patients who are not responding to treatment in this latter group are referred to the Control group.
STUDY DESIGN

This study uses a randomised, controlled, repeated-measures design. The RCT compares bladder pressure management with management based on a history of symptoms and presenting problems and residual volumes in patients with established Multiple Sclerosis. The two strategies being compared by the RCT are summarized in Fig 1 and Fig 2. Patients are stratified according to their MS severity (Fig 3).

**Fig 1 ALGORITHM 1: ANALYSIS & MANAGEMENT OF BLADDER SYMPTOMS**

- **UTI**  Urinary Tract Infection

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Department of Health and Aged Care – 2003 Grant Program Round 4 No. 2
**Fig 2 ALGORITHM 2: BLADDER PRESSURE MANAGEMENT (BPM)**

**URODYNAMICS**
- VOIDING FLOW RATE
- POST-VOID RESIDUAL VOLUME CHECK

**POOR CONTRACTILITY**

**DETRUSOR HYPERREFLEXIA & DETRUSOR SPHINCTER DYSSYNERGIA**

- ISC +/- prophylactic
- Antibiotics

- Anticholinergic medication & ISC

- If ongoing severe bladder symptoms

- If severe bladder symptoms continue
  - Repeat Urodynamics

- Check bladder pressures with CMG to ensure safe bladder pressure achieved

- Ensure resolution of symptoms

- Add treatment as required to achieve Low bladder pressure storage and drainage

**OPTIONS:**
- Intravesical oxybutynin
- Detrusor myectomy
- Augmentation cystoplasty
- Ileovesicostomy
- Ileal conduit
- Other

- If ongoing severe bladder continue

- Repeat Urodynamics

**PVR** Post Void residual
PROJECT OBJECTIVES AND OUTCOMES

OBJECTIVE 1
Evaluate by randomised control trial (RCT) design, two different management strategies and assess their relative effect on quality of life as well as their short and long-term efficacy.

OUTCOME
The RCT has progressed and it is envisaged that recruitment will cease this year. The rate of recruitment has escalated as knowledge of the Unit has grown in the general community and within Urology, Continence and Neurology circles. It is clear from the data outlined in the results section of the report that quality of life and urinary symptoms improve with appropriate intervention and support provided by our specialist medical and nursing team.

PATIENT NUMBERS
Patients who have been randomised 92
Patients with MS who are ineligible, & receiving treatment 40
Patients waiting to be randomised or seen 30
Total patients with MS treated by the Unit 160
Overall number of patients (with or without MS) treated by the Unit 400

Table 1: Patient Numbers

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<th>Recruitment Status</th>
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<td>Treatment Group</td>
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</table>
**Fig 3** Randomised patients categorised into Sex and MS/Urological Status

![Bar chart showing patient status by sex and MS/Urological symptoms]

- **HMHU** = High MS High Urinary symptoms
- **LMHU** = Low MS High Urinary symptoms
- **HMLU** = High MS Low Urinary symptoms
- **LMLU** = Low MS Low Urinary symptoms

**OBJECTIVE 2**
Support the necessary staff, infrastructure, systems and networks to carry out the study including the fluoroscopic and other Urodynamic studies, questionnaires, urological and neurological clinical care, community links for ongoing care, administration of the clinic, investigations, database, reporting and fund raising.

**OUTCOME**
The Innovative Grants from the National Continence Management Strategy (NCMS) provided the initial funding required to operationalise the NeuroUrology and Continence Unit (NUCU) that now provides an important management and clinical research function in the State of Victoria. An additional NCMS grant helped to employ a Continence Nurse Advisor to assist the Continence Nurse Consultant, including the delivery of education sessions to a broad range of nursing staff.

The Grants have enabled the Unit to develop a model of service to meet the needs of patients whose urological problems have a neurological basis, and to carry out a study which investigates two accepted and different treatment regimens for significant bladder problems in patients with MS. The infrastructure and systems including a comprehensive database and networks required to provide this service,
carry out this primary research and embark upon other projects are in place. The unit now provides a substantial clinical service, which requires ongoing, recurrent funding. This ongoing fundraising challenge is labour and resource intensive and has put the long-term survival of the Unit at risk of survival.

**OBJECTIVE 3**

**Determine whether questionnaires used in other patient populations are suited to use for studies of people with MS related urinary dysfunction and which of these is suitable as the primary outcome measure for the RCT.**

**OUTCOME:**

The UGDI appears to be a highly responsive and simple tool and appropriate as a primary outcome measure. Its short form contains domains that evaluate voiding dysfunction, incontinence, and recurrent infections thereby broadly serving to evaluate the spectrum of urinary problems in people with MS. We are currently preparing these findings for publication. To date, there appears to be little or no difference between the two treatment arms. Identification of which patients would benefit more from Urodynamically-driven treatment is not currently possible. None of the outcome measures adequately evaluate the effect of intermittent self-catheterisation on urinary quality of life. This appears to be a significant shortcoming that is currently be addressed by a further study.

Accordingly Dr Lachlan Macgregor, our Biostatistician will be performing a re-analysis of the data after excluding this item from analysis in both groups. It is not expected that this deletion will alter the overall findings. The Incontinence Impact Questionnaire (IIQ) will be analysed for suitability as a primary outcome measure.

**OBJECTIVE 4**

**Develop a service in the Public environment to provide a prospectively valuated service to people with significant urinary distress due to MS and other neurological disorders.**

**OUTCOME:**

The Unit has strengthened many collegial networks that have increased the referral base from key providers such as the MS Nerve Centre (formerly MS Society), Neurologists and the MS database. Many Continence and MS nurses use the staff
of the Unit as a resource, particularly in relation to management of bladder dysfunction in people with MS.

**OBJECTIVE 5**
Develop an education program for health professionals and the general community.

**OUTCOME:**
The Continence Nurses and Medical Staff of NUCU have been proactive in providing tailored education to a broad range of nursing staff in a variety of settings, to peak nursing bodies such as the Nurses for Continence, MS nurses special interest group, Urological Nursing Society, Continence Foundation of Australia (CFA) and General Practitioners.

Since the educational requirements of Health Professionals, particularly nurses varies, we have produced a number of generic and specific Power Point presentations. We also adapt these to the audience or develop new ones as required. Appendix-A lists all of the MS-specific education sessions provided. Feedback in all sessions has been positive. Participants rated all responses as either very good or excellent. All respondents have generally appreciated learning about the work of the NeuroUrology and Continence Unit and the study results. The attendees have been keen to participate in general discussion.

Evaluation parameters measured whether the session:
- Met expectations
- Was Clear and logical
- Was pitched at right level
- Improved practice
- Allowed adequate time for discussion
- Had a suitable venue
RCT PROGRESS REPORT

The RCT has progressed well and it is envisaged that recruitment will cease this year. The rate of recruitment has escalated as knowledge of the Unit has grown in the general community and within Urology, Continence and Neurology circles. It is clear from the data outlined below that quality of life and urinary symptoms improve with appropriate intervention and support provided by our specialist medical and nursing team.

RESULTS

Preliminary results to date appear promising (Fig 4 - 8). Patient outcomes in both groups are associated with improved continence and reduced impact of incontinence as well as improved quality of life. It is clear at this early stage of analysis, that both treatment arms have had significant improvement in both urinary symptoms and urinary quality of life. The improvement becomes evident at one, three and six months of review, and has been sustained in the majority of cases out to the period of observation, some cases now being greater than 12 months. To date, there appears to be little or no difference between the two treatment arms. Identification of which patients would benefit more from Urodynamically-driven treatment is not currently possible. To date the CNA has moved two patients from the treatment group to the control group due to poor progress.

Long-term data are needed to demonstrate the durability of the improvements observed, to determine whether a distinction between treatment groups would develop and also to possibly demonstrate differences in MS progression due to a reduction in urinary morbidity, especially a reduction in febrile UTI. This is expected to take time. The Unit will continue to evaluate patients on a long-term basis. Moreover there is no current data to guide us about the expected time-course of such an impact.

The UGDI appears to be a highly responsive and simple tool and appropriate as a primary outcome measure. Its short form contains domains that evaluate voiding dysfunction, incontinence, and recurrent infections thereby broadly serving to evaluate the spectrum of urinary problems in people with MS. We are currently preparing these findings for publication. However, the initial analysis included a
question from the UGDI that proves to be invalid for most patients after they have commenced intermittent self-catheterisation (ISC). Furthermore, the outcome measure tools do not evaluate the perceptions or effect of intermittent self-catheterisation on urinary quality of life. This appears to be a significant shortcoming that is currently being addressed by a further study.

Accordingly Dr Lachlan Macgregor, our Biostatistician will be performing a re-analysis of the data after excluding this item from analysis in both groups. It is not expected that this deletion will alter the overall findings.

**Fig 4**   **PATIENT GLOBAL IMPRESSION OF IMPROVEMENT**

![Graph showing Patient Global Impression of Improvement](image1)

**Fig 5**   **AMERICAN UROLOGICAL ASSOCIATION – SYMPTOM SCORE**

![Graph showing American Urological Association – Symptom Score](image2)
Fig 6  UROLOGICAL QUALITY OF LIFE

Patient Visit

Fig 7  INCONTINENCE IMPACT QUESTIONNAIRE (Short Form)

7 items (score 0-3)

- Ability to do daily chores
- Physical recreation
- Entertainment
- Travel > 30 min
- Social activities
- Emotional health
- Frustration

IIQ-7

Control  Trial

Patient Visit
**Fig 8  UROGENITAL DISTRESS INVENTORY**

6 items (score 0-3)
- Frequent urination
- Leakage related to urgency
- Leakage related to exertion
- Volume of leakage
- Difficulty emptying
- Associated pain

![Graph of UGDI %](image)

**TREATMENTS USED**

- The treatments have included Anticholinergic medication supplemented by alpha-blockade and low dose tri-cyclic anti-depressant medication where required. A few patients have required prophylactic or suppressive antibiotic treatment, particularly if commencing intermittent self-catheterisation.

- Intermittent self-catheterisation has been used in over 30% of MS patients and has been associated with a reduction in febrile urinary infection in several patients including those previously on constant antibiotics prior to the strategy being introduced. It is associated with reduction in bothersome urinary symptoms and improved quality of life. An extension study examining pre and post ISC outcome measures is currently underway.

- Conservative interventions such as regulation of fluid intake, prevention and resolution of bowel problems like constipation, pelvic floor muscle strengthening or biofeedback, use of cranberry tablets, and bladder retraining have also proven to be some of the beneficial adjunctive strategies used.
The review and appropriate ordering of aids and appliances has reduced the cost burden for the patient, particularly for those requiring intermittent self-catheterisation.

Some of the those patients refractory to the usual treatment methods as per the stated Algorithms have benefited from some intravesical Anticholinergic therapy and intraurethral / intravesical Botox. The latter treatment is offered as part of a further research study.

PATIENT ADHERENCE TO TREATMENT
There are many factors that contribute to treatment adherence and therefore serve as constant challenges for the staff of the Unit. As much as possible, these difficulties have been addressed and/or procedures put in place to minimize their impact. Providing the support and education required is time intensive. The patients have found it necessary and invaluable to access the CNA but this has increased the workload considerably over the staffing time available. The nursing and administrative staff do not work on a full-time basis, so the challenges to meet patient needs continues.

For the individual with MS, the impact of urinary incontinence is usually far greater and more devastating than the impact of bladder emptying difficulties. There is greater drive and impetus for the patient to deal with incontinence, than there is to deal with the latter problem that often requires intermittent self-catheterisation. It is often emotionally and psychologically difficult for the MS patient to accept doing ISC. Another of the Unit’s research projects has demonstrated this. It is understood that adherence to ISC can be difficult to maintain where cognitive changes impact upon learning, judgment and decision-making, and where there are gross motor deficits, necessitating the need for carer involvement or alternative interventions.

Some patients whose cognitive and executive functioning has been impaired find it difficult to remember appointment dates. It has not always been evident on first contact that this could present as an issue, and so remains a challenge. Furthermore, some patients feel better after treatment has been initiated and do not see the need to remain on the trial.
CONCLUSIONS

Accurate assessment and appropriate management can improve bladder symptoms and quality of life in both Control and Trial groups. Intervention is making a significant difference in both groups despite the refractory and severe nature of the urinary problem at presentation. Preliminary analysis does not show any significant benefit in the Control group i.e. the value of Urodynamic studies is not apparent. The primary outcome measure (UGDI) although useful has limitations because three of its questions become obsolete once patients commence ISC. Modification of questionnaires required for the ISC group. This is being addressed by our research group with the commencement of a trial of a new ISC specific questionnaire.

This is a diverse patient population, difficult to follow up (multiple other appointments, mobility) & interventions are time consuming, teaching ISC in particular. Additional data will enable the discrimination of MS patient sub-groups who may require a Urodynamically determined intervention from the outset. The results will also be transferable to other neurological groups of patients.

DISCUSSION AND IMPLICATIONS

Generally the work related to the randomised control trial has highlighted how resource and labour-intensive the work is. The process of recruitment, randomisation, Urodynamics and patient assessment along with patient follow-up including the instruction of intermittent self-catheterisation and other treatments requires a great deal of nursing, medical and research assistant time. The workload escalates exponentially as the number of patients to the study increases and meeting the demands becomes an ever-increasing issue with the current resources.

It is clear that MS patients with complex urological and continence problems respond well to treatment. Many times these patients have not had any treatment prior to coming to the unit. Considering a model of care which combines the expertise of a Urologist specialising in NeuroUrology with an experienced Continence Nurse Consultant appears to generate very good outcomes for people with MS despite the severity of their urinary problem and their overall disability.
From a resource standpoint the important take-home message is that initial assessment by an experienced and medically supported CNA appears to be safe and at least as efficacious to provide initial management of these patients. This is a highly significant finding. To arrange fluoroscopic urodynamics for each of these clients is a significant resource-intense undertaking. Although Urodynamics clarify the underlying pathophysiology, grade the severity of the problem and reveal complications of the bladder problem such as vesico-ureteric reflux and high bladder pressures that are known to predispose to serious urinary infection or renal scarring. These tests may not appear to be necessary at the outset for all patients. Ongoing evaluation of the data will indicate in the long term whether there are sub-sets of MS patients in whom a prospective urodynamic diagnosis would be useful and whether there are predictors of a worse outcome if a urodynamic diagnosis is not available. Access to a medically supported, salaried experienced CNA appears to make an enormous difference to the delivery of timely and efficacious care in the early phases of tertiary referral for this client group of people with significant urinary dysfunction due to MS.

Specialist nursing is necessary and provides the education and ongoing support for carers to enable some patients to live independently at home who would otherwise require nursing home support. The team at Royal Melbourne Hospital in association with community-based resources, RDNS, MS Society and other links that become established affect this support. However many external continence services do not tend to review patients on a long-term basis. Our ISC study particularly demonstrates the need to maintain ongoing contact with patients to ensure positive outcomes.

We will continue to compare the two arms of management, to determine the long-term distinctions between the two groups. Long-term data will determine whether particular patient characteristics e.g. MS severity, recurrent infections, high residual volumes, presence of Detrusor Sphincter Dyssynergia predict a worse outcome if Urodynamic studies are not performed prospectively or as early as possible. Such findings would enable NeuroUrology services to appropriately direct relatively scarce and logistically costly resources.
A well supported CNA who has the ability to order simple investigations and able to prescribe some medication lends itself in this situation. It is believed that the measure of difference comes from having an experienced Continence Nurse Consultant in this role. This model of service would be akin to the Nurse Practitioner model that is well in the development phase in Victoria and one that should be pursued in this case. It is unclear however; whether a suitably trained, RN working independently in the community, as distinct from a tertiary referral centre would achieve the same outcomes. Given the level of disability of the affected MS clients and their carers, travel to our health facility can be both inconvenient and difficult. The possibility that an RN working in the community could provide the same efficacy is a matter worthy of further investigation. We hope to be able to establish a study comparing our model to a CNA working in a more typical community-based role.

Due to the sequellae of MS, the impact of urinary symptoms compared with other MS related symptoms can vary in impact and significance for the individual. This is an important area in which there is limited research. The unit has commenced a project related to the perceptions of using ISC and measurement of urological symptoms quality of life before and after ISC instruction. The unit is undergoing further research that includes other novel treatments such as Intravesical Ditropan, Botox, Neuromodulation, and is also measuring the economic impact and cost burden associated with having MS and bladder problems.

We have also found that ISC is well tolerated by all of the patients who have required this intervention. Anecdotally this would not reflect the intervention of choice in the community. Many patients with MS and voiding difficulty would have permanent catheterisation. The long term health impact is mooted to be deleterious to the patient, so this area needs extensive education of health practitioners and further research.
# LIST OF PUBLICATIONS


# RESEARCH IN PROGRESS

**2002- Current**

Randomised control trial of Bladder Pressure Management (BPM) versus management based on symptoms and residual volumes in patients with established Multiple Sclerosis (MS). Principal Investigator – Dr Helen O'Connell, Co-Investigators: Costello A J, King J, Kilpatrick T J.

Double blind placebo controlled, randomised control trial (Eli Lilly) Duloxetine for sensory urgency and detrusor instability. Principal Investigator – Dr Helen O'Connell. Co-Investigator: Costello A J

Open label Duloxetine (long term safety evaluation) for stress incontinence. Principal Investigator – Dr Helen O’Connell, Co-Investigators: Costello A J, King J, Kilpatrick T J.

**1996-2003**

Development of smooth muscle sphincteric stimulator. Collaborative project with Departments of Anatomy and Zoology.

1. Pharmacological studies of smooth muscle sources for Sphincteric substitution
2. Rabbit studies of stress incontinence model and treatment with a stimulated smooth muscle graft. Co-investigator– Helen O’Connell

**2004**

Urinary symptoms and quality of life following Intermittent Self Catheterisation in MS Patients. Principal Investigator Louise Kurczycki. Co-Investigators Helen O’Connell, Caroline Dowling, Kerry Poole, Kathy Myles.

A prospective study of patient perceived urinary and bowel problems versus those of health practitioners in an acute care and rehabilitation setting. Principal Investigator Louise Kurczycki, Co-Investigators Helen O’Connell, Kerry Poole
## APPENDIX-A

### PROFILE OF EDUCATION SESSIONS DELIVERED

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<td>▪ Assessment and treatment options</td>
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<td>04/06/04</td>
<td>Consortium of MS Centres Toronto, Canada Multidisciplinary Conference attended by Louise Kurczycki where two posters on ISC study and RCT were presented</td>
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<td>Melbourne Health Research Week Royal Melbourne Hospital, Parkville Podium Presentation at the Nursing Forum ISC study – This presentation won the award for best nursing paper</td>
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<tr>
<td></td>
<td>- NeuroUrology and Continence Unit</td>
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<tr>
<td></td>
<td>- Results of ISC study and RCT</td>
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<tr>
<td>19/08/04</td>
<td>Medical nurses</td>
<td>4</td>
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<tr>
<td></td>
<td>- Neuro-Urology &amp; Continence Unit</td>
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<tr>
<td></td>
<td>- General principles of urinary anatomy and physiology</td>
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<tr>
<td></td>
<td>- Bladder dysfunction</td>
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<tr>
<td></td>
<td>- Assessment and treatment options</td>
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<tr>
<td>13/09/04</td>
<td>All staff invited. Bethlehem Hospital, Caulfield</td>
<td>12</td>
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<td></td>
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<td></td>
<td>- Results of ISC study and RCT</td>
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<tr>
<td></td>
<td>- Discussion on long term efficacy of IDC in MS patients</td>
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<tr>
<td>Date</td>
<td>Organisation/Location</td>
<td>Content Included</td>
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<tr>
<td>17/02/05</td>
<td>MS Society Watsonia</td>
<td>- NeuroUrology and Continence Unit&lt;br&gt;- General principles of urinary anatomy and physiology&lt;br&gt;- Bladder dysfunction&lt;br&gt;- Assessment and treatment options&lt;br&gt;- Principles related to bladder pressure management</td>
</tr>
<tr>
<td>24/02/05</td>
<td>MS Society Williamstown</td>
<td>- NeuroUrology and Continence Unit&lt;br&gt;- General principles of urinary anatomy and physiology&lt;br&gt;- Bladder dysfunction&lt;br&gt;- Assessment and treatment options&lt;br&gt;- Principles related to bladder pressure management</td>
</tr>
<tr>
<td>3/02/05</td>
<td>Royal District Nursing Service (RN Div 1)</td>
<td>- NeuroUrology and Continence Unit&lt;br&gt;- Principles related to bladder pressure management&lt;br&gt;- Catheterisation (intermittent and indwelling)</td>
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<tr>
<td>9/03/05</td>
<td>Royal Melbourne Hospital (Royal Park campus). Grand Round Presentation</td>
<td>- RCT bladder pressure management (current trial results)</td>
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<td>10/03/05</td>
<td>MS Society Watsonia</td>
<td>- NeuroUrology and Continence Unit&lt;br&gt;- General principles of urinary anatomy and physiology&lt;br&gt;- Bladder dysfunction&lt;br&gt;- Assessment and treatment options&lt;br&gt;- Principles related to bladder pressure management</td>
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<tr>
<td>19/03/05</td>
<td>Nurses for Continence (Cabrini Hospital)– general membership study day including:</td>
<td>- Trial of Void associated with Neurological conditions&lt;br&gt;- Update on use of catheters for “single use”</td>
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<tr>
<td>Date</td>
<td>Organization</td>
<td>Content to be included</td>
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<tr>
<td>28/04/05</td>
<td>MS Society Williamstown</td>
<td>- NeuroUrology and Continence Unit</td>
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