INCONTINENCE

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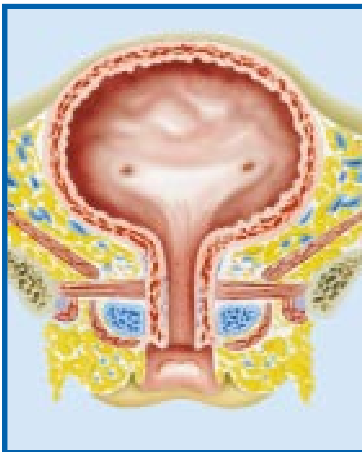

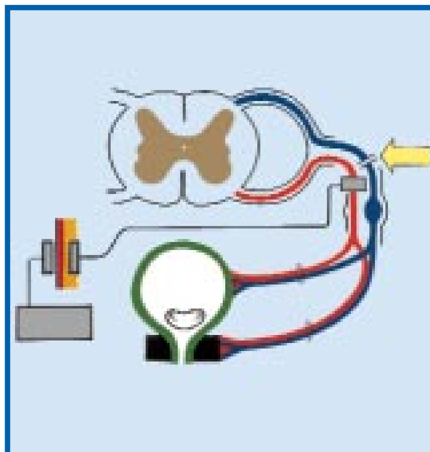

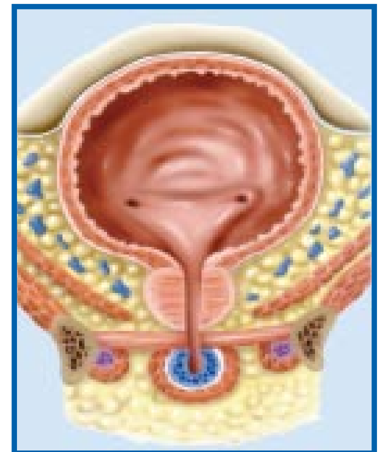

2nd International Consultation on Incontinence Paris, July 1-3, 2001

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FOREWORD

The First International Consultation on Incontinence held in 1998 highlighted the plight of some 200 million sufferers from urinary incontinence worldwide. Urinary incontinence represents a particular and severe problem in certain developing areas of the world, where labour and birth injuries lead to catastrophic leakage. Untreated vesicovaginal fistula, particularly in sub Saharan Africa, affects millions of women causing ostracizism from society. Because of the enormity of this particular problem, the second consultation had a specific committee to highlight the subject, to advance the understanding of the causes of birth injury, to lead to improved treatment for the many untreated women, and most importantly, to begin preventative programmes.

There were three new committees in the 2nd ICI: Pelvic Organ Prolapse, Faecal Incontinence and Incontinence in the Developing World, (mentioned above). The first consultation stressed the importance of a multidisciplinary approach to continence care, and the new committees on pelvic organ prolapse and faecal incontinence recognize that, particularly in women, urinary incontinence coexists with prolapse and faecal incontinence in many instances. This is also true, to a more limited extent, in men with coexisting faecal incontinence. The task of these two committees was very considerable and they had to outline the basic science, and investigation and management techniques within a single chapter.

The report of these two chapters will lay the foundation for a broadening of the multidisciplinary approach to pelvic disorders. Already there are various models of a new ways of working with close collaboration between urologists, gynaecologists and coloproctologists, working within a multidisciplinary team with nurses and physiotherapists. From the research and investigation point of view, we were very dependent on our colleagues from other disciplines such as the basic sciences, epidemiology, social science and engineering.

The 2nd World Health Organisation sponsored consultation on incontinence was held in Paris in July 2001. The structure of the consultation followed the successful formula developed by the ICUD (the International Consultation on Urological Diseases which is recognized as a WHO, Non Governmental Organization) and used for the 1st ICI held in Monaco in 1998 and published the following year. Once again an international faculty of almost 200 individuals from a wide range of professions and specialities were grouped into a series of subcommittees, each with a specific area of responsibility.

The spectrum of subcommittees spanned from Basic Science through to Assessment and Investigation to Therapy. These committees were further divided into specific patient groups for children, women, men, neurological patients and the frail elderly. Subcommittee members were selected according to their academic reputation giving due recognition to the need to provide balance between specialities and geographical regions. A chairperson was selected for each subcommittee and was responsible for the drafting of that committees' chapter. Many committees met at least once before the consultation in Paris, to progress their report.

Each chairperson presented his or her committees' main discussions and recommendations in Paris, their chapter was then modified accordingly, in the light of the consultation.

This book details the evidence reviewed by each committee. Each chapter uses a modification of the Oxford System for evaluating evidence and providing recommendations. The system used during the consultation utilized a simplified system with five levels of evidence (1 to 5) and four grades of recommendation (A to D). This system worked well for the treatment committees but there is, as yet, no system that can be used to evaluate the evidence from the basic science and investigation committees. Nevertheless, the consultation feels that continued efforts to specify the evidence base for the recommendations are of vital importance.

The book's final chapter is the Recommendations of the International Scientific Committee which includes all subcommittee chairs together with the members of the Steering Committee. This chapter has been expanded to include algorithms for the treatment of faecal incontinence and pelvic organ prolapse. Furthermore, the 1998 algorithms have been extensively reconfigured in the light of new evidence and in order to facilitate their use. The algorithms from 1998 were published in the journal "Lancet" and it is the intention of the 2nd ICI to publish the new algorithms in an equally prestigious journal.

The consultation hopes that its' work will begin to help those millions who suffer incontinence and in particular, its' social consequences. We must all work to break down the social taboos that prevent many sufferers from obtaining help for their problem. We must also increase our efforts to prevent incontinence and in particular, the catastrophic birth related fistulae that afflict so many women in the developing world.

Paul Abrams and the Scientific Committee

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WEBER	Ann	USA

Levels of Evidence and Grades of Recommendation

The International Consultation on Urological Diseases (ICUD) is a non-governmental organisation registered with the World Health Organisation (WHO). The ICUD in consultation with WHO advises on the structure of consensus consultations. In the last ten years Consultations have been organised on BPH, Prostate Cancer, Urinary Stone Disease, Nosocomial Infections, Erectile Dysfunction and Incontinence. These consultations have looked at published evidence and produced recommendations at four levels; highly recommended, recommended, optional and not recommended. This method has been useful but the ICUD believes that there should be more explicit statements of the levels of evidence that generate the subsequent grades of recommendations. The ICUD would be delighted if other bodies, such as journals, were to take up the proposed system.

The AHCPR have used specified evidence levels to justify recommendations for the investigation and treatment of a variety of conditions. The Oxford Centre for Evidence Based Medicine have produced a widely accepted adaptation of the work of AHCPR and this has been recently updated. (June 5th 2001 http:// cebm. jr2. ox.ac.uk/)

The ICUD has examined the Oxford guidelines and discussed with the Oxford group, their applicability to the Consultations organised by ICUD. It is highly desirable that the recommendations made by the Consultation follows an accepted grading system backed up by explicit levels of evidence.

The ICUD proposes that future consultations should use a somewhat modified version of the Oxford system which can be directly 'mapped' onto the Oxford system.

A. Therapeutic Interventions

All interventions should be judged by the body of evidence for their efficacy, tolerability and cost effectiveness. It is accepted that at present little data exists on cost effectiveness for most interventions.

Levels of Evidence

Firstly, it should be stated that any level of evidence may be positive (the therapy works) or negative (the therapy doesn't work).

Level 1 evidence (incorporates Oxford 1a, 1b, 1c) usually involves one or more randomised controlled trials or 'all or none' studies in which no treatment is not an option, for example in vesicovaginal fistula.

Level 2 evidence includes good quality prospective 'cohort studies' (and incorporates Oxford 1a, 1b and 1c). These may include a single group when individuals who develop the condition are matched from within the original cohort group. There can be parallel cohorts where those with the condition in the first group are matched by those in the second group.

Level 3 evidence includes good quality retrospective 'case-control studies' where a group of patients who have a condition are matched (for age, sex etc) by control individuals from a general population. (incorporates Oxford 3a and 3b)

Level 4 evidence includes good quality 'case series' where a group of patients all with the same condition/disease/therapeutic intervention, are described, without matching control.

Level 5 evidence includes expert opinion were the opinion is based not on evidence but on 'first principles' (e.g. physiological or anatomical) or bench research. The Delphi process can be used to give 'expert opinion' greater authority. In the Delphi process a series of questions are posed to a panel; the answers are collected into a series of 'options'; the options are serially ranked; if a 75% agreement is reached then a Delphi consensus statement can be made.

Where there is disparity of evidence, for example if there were three well conducted RCT's showing that Drug A was superior to placebo, but one RCT showing no difference, then there has to be an individual judgement as to the level of evidence selected and the rationale explained.

Grades of Recommendation

The ICUD will use the four grades from the Oxford system. As with levels of evidence the grades of evidence may apply either positively (do the procedure) or negatively (don't do the procedure).

Grade A recommendation usually depends on consistent level 1 evidence and often means that the recommendation is effectively mandatory and placed within a clinical care pathway. However, there will be occasions where excellent evidence (level 1) does not lead to a Grade A recommendation, for example, if the therapy is prohibitively expensive, dangerous or unethical.

A grade A recommendation can follow from Level 2 evidence, for example, rectus sheath sling for stress incontinence has never been the subject of RCT's against another procedure such as colposuspension for the same condition.

Grade B recommendation usually depends on consistent level 2 and or 3 studies, or 'majority evidence' from RCT's.

Grade C recommendation usually depends on level 4 studies or 'majority evidence' from level 2/3 studies or Dephi processed expert opinion.

Grade D recommendation is given when the evidence is inconsistent/inconclusive or non-existent for studies that may vary in type from RCT's to case series, or for expert opinion delivered without any analytical process, such as by Dephi.

B. Assessment and Investigation

From initial discussions with the Oxford group it is clear that application of levels of evidence/grades of recommendation to investigate is much more complex than for interventions. The ICUD recommend, that, as a minimum, any test should be subjected to three questions:

does the test have good technical performance, for example, do three aliguots of the same urine sample give the same result when subjected to 'stix' testing?

Does the test have good diagnostic performance, for example, are abdominal leak point pressure measurements significantly different in women with and without urodynamic stress incontinence?

Does the test have clinical relevance that is, does the test alter clinical management, does the test predict outcome?

Where possible the ICUD system (modified from the Oxford system) should be used for assessment or investigation techniques.

C. Basic Science and Epidemiology

The proposed ICUD system does not easily fit into these areas of science. Further research needs to be carried out, in order to develop explicit levels of evidence that can lead to recommendations as to the soundness of data in these important aspects of medicine.

Conclusion

The ICUD believes that it's consultation should follow the ICUD system of levels of evidence and grades of recommendation, were possible. This system can be mapped directly to the Oxford system.

There are aspects to the ICUD system which require further research, particularly to include cost effectiveness, and also factors such as patient preference, for which no evidence exists.

P. Abrams and the Committee

Professor Tage Hald

Honorary President of the 2nd International Consultation on Incontinence

Tage Hald: a pioneering surgeon, great teacher and true European.

I first met Tage Hald in 1975 in the Railway Hotel, a magnificent and majestic Victorian monument to the great days of the railway, in Glasgow during the 6th International Continence Society annual meeting. That encounter summed up Professor Hald's qualities beautifully: he held court to a mixed group of young and older colleagues, showering us with urological wisdom, amusing stories and great hospitality, in equal measures (single malt whisky, I hazily recollect). Then and subsequently, he gave freely of his time to the most junior of us: a sure sign of a great teacher.

Tage Hald is a "country boy" having been born in Jutland, an area that he's now returned to in order to grow his own forest. Even before his medical graduation, he had an international reputation! He had represented Denmark as a freestyle swimmer. He had also spent a good deal of time studying languages to a high level. Indeed his appointment as the Chairman of the Standardisation Committee of the International Continence Society owed much to the fact that he spoke, and certainly wrote, better grammatical English than most native English speakers! After graduation from the University of Copenhagen, he spent a year as a research fellow at New York State University and in 1969 was awarded a Doctorate in Medical Science for his thesis on "Neruogenic Dysfunction of the Urinary Bladder". His collaborations with the late lamented Bill Bradley, an American Neurologist, were recognized worldwide as of the highest quality and culminated in their book on Neurourology. As Chairman of urology, and from 1985 Professor of Surgery, at the University of Copenhagen, he developed a department of exceptional quality and with his collegues put Scandinavian urology in general and Danish urology in particular, 'on the map'.

His early interest in neurourology brought him into the field of incontinence and urodynamics at it's infancy in the late 60's. His knowledge and authority led to he and his co-workers having considerable influence during this important development phase of this new field of investigation and treatment. In urodynamics, he worked with a small Danish company to build the finest urodynamic equipment, now the world leaders. He recognized the fact that a new method of investigation needed to be accompanied by an agreed set of definitions and terminology. As the first chairman of the ICS Standardisation Committee he provided the foundations on which a new method of investigation could develop quickly and become accepted worldwide within a relatively short time. He supervised the publication of the first ????? standardization reports and remained chairman until his protégé Jens Thorup Andersen succeeded him in 1986.

Tage Hald has been honoured many times in his own country and abroad. He has been President of both the Danish Urological Association (1978-1982) and the Danish Surgical Society (1988-1990). His eloquence as a speaker, and his dexterity as a surgeon meant numerous visiting professorships worldwide, awards, and honorary memberships of surgical and scientific societies.

In recent years he took a particular interest in the effects of ageing on the lower urinary tract and chaired a committee on that topic in the successive WHO consultations on "BPH". With the ageing population this topic will assume increasing importance and it is typical of Tage Hald that he had the foresight to appreciate it's significance more than 10 years ago.

It is most appropriate that he is now honoured as the President of the 2nd International Consultation on Incontinence.

Paul Abrams
Chairman of the 2nd ICI, 2001.

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