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Mater Research Support Centre

Mater Misericordiae Health Services

MRSC Newsletter

Welcome to the second edition of the MRSC newsletter. We intend that an edition will be produced quarterly and circulated electronically to those on our mailing list.

This second edition is an introduction to what the Centre can do for you. Feel free to contact us should you wish to join our mailing list, if there is any information you would like to include in the newsletter, should you have any comments you would like to give us or you wish to contact any of our staff by emailing: Anne-Maree at [Anne-Maree Stout@mater.org.au](mailto:Anne-Maree.Stout@mater.org.au) or phone 3840 1591.

What's New

John P Kelly Funding

The John P Kelly Research Committee (JPKRC) has been established to allocate funds from the John P Kelly Foundation. To assist in the process MRSC has agreed to act as the Secretariat. MRSC will therefore deal with the administration of the allocation process, and prepare the papers for the committee meetings. To facilitate communication a website has been established which can be accessed on the Mater Intranet, Departments, John P Kelly Research Committee.

New Equipment at the MRSC

The MRSC has recently purchased a thermal binding machine and an A3 laminator. This equipment is available for use by Mater staff for any research related project at cost price.

Smoking Cessation in Pregnancy Project

Through a service agreement with Queensland Health, staff at the Centre for Clinical Studies have developed clinical practice guidelines for Smoking Cessation in Pregnancy. For more details see inside article.

RESEARCH GRANTS SOON TO CLOSE

John P Kelly Research Foundation - The 2004 allocation exercise of the John P Kelly Research Committee has now commenced. **\$100,000** has been made available for allocation to those interested in funding support for research related needs. Closing Date **5.00 pm Monday, 31 May 2004**

Birth Issues Inaugural Scholarship for Best Original Paper - Two scholarships of **\$500** each. The aim of the scholarship is to encourage writing for publication and to acknowledge excellence in scholarship. Closing Date **Wednesday, 30 June 2004**

HOW MRSC CAN HELP YOU

The Mater Research Support Centre (MRSC) builds on the previous initiatives and the work of the Mater Perinatal Epidemiology Unit (MPEU) and the Centre for Clinical Studies (CCS) that has resulted in a national and international reputation with respect to Clinical Trials, Cochrane Reviews and Perinatal Epidemiology. Following this framework the MRSC has emerged and now offers assistance with clinical trials, literature searching, statistical advice, research design and other support complex wide. Please see our website for full details on what we can offer. Following are examples of how the MRSC has assisted clinicians with projects.

The Induction of Labour Trials:

These are two local randomised controlled trials comparing methods of induction of labour at term. These trials were instigated by Dr Paul Devenish-Meares and Jocelyn Toohill, (MMH) as Chief Investigators, who were concerned at escalating caesarean section (CS) rates.

Current practice at the Mater Mothers' Hospital (MMH) for induction of labour is to use prostaglandins or balloon catheters (when prostaglandins fail to induce labour). Failed induction of labour results in CS rates of between 20 to 50%.

Literature Search:

With the assistance of the MRSC the investigators conducted an extensive literature search and systematic review for best practice for induction of labour. The results of the search suggested the use of balloon catheters appeared to result in a better outcome, with a CS rate of 15 to 25%. However the results of the RCTs were inconclusive due to small sample sizes and other methodological flaws and properly conducted RCT's were recommended. These recommendations led to the development of the two induction of labour trials.

Staff at the MRSC also assisted with the writing of the protocol. Closely following the required steps in a standard approach to planning a large scale controlled trial there were few problems or criticisms, ensuring a smooth passage through HREC, requiring only minor amendments.

Sample Size calculations:

MRSC staff provided assistance with the power and sample size calculations for the primary outcome of Caesarean Section Rate. A sample size calculation tool can be found on the MRSC website (Mater Intranet). Go to 'Departments', Mater Research Support Centre or contact us in person by phoning

Anne-Maree Stout on 3840 1591. We are only too happy to help. Remember when calculating sample size, the difference needs to be clinically meaningful.

Model to be Used: Fixed Sample Size? Sequential Analysis?

Not sure? The MRSC can help!

Until recently most randomised controlled trials used a fixed sample size model. However, the use of sequential analysis is becoming more popular. Sequential analysis evaluates the study as the data accumulates, and a decision can be made to terminate the study when the results allow a conclusion to be drawn. Using this design, multiple interim analyses are conducted, analysing both efficacy and safety.

The Induction of Labour trial investigators consulted with MRSC staff and the decision was made to use the sequential analysis model.

Assistance with Co-ordination:

In collaboration with the trial investigators the MRSC staff have provided in-service sessions to MMH staff, held regular meetings with the investigators, prepared the monthly CONSORT reports, assisted with recruitment of eligible women, data collection and data entry.

How Can You Help the MRSC help You?

The MRSC is happy to assist with individual research projects, however we ask that you try to clearly identify your research question and undertake a literature search before approaching the MRSC. We can however, offer assistance in helping you define your research question and give advice on literature searching. We are hoping that in the near future we may be able to offer a literature searching service. However due to financial constraints we are presently unable to do so.

Likewise we are presently unable to offer assistance with manpower requirements such as recruitment and data collection unless funding is available. If funding is available the MRSC has a wide range of experience in running clinical trials and can provide total coordination of the study including budget management, identification and employment of suitable staff for recruiting, data collection and data entry.

DEVELOPMENTS AT THE MRSC

The MRSC has had to address two major challenges. The first was the need to communicate effectively with the Mater community. The second was to cope with the many and varied technical tasks related to research, when manpower was constrained both numerically and in some areas technically.

The development of the website therefore was a major effort of the MRSC, containing a wealth of research, statistical, teaching, and communication resources. The web allows easy communication, bypassing the constraints of time and space, and computing.

automates a great proportion of the intellectual functions and provides resources that researchers need. The volume of requests increased, and the type of enquiries and requests diversified, after the launch of the website in November 2003, and this compelled MRSC to reorganise its consultation services.

A consultation service is now well established, reaching the stage where auditing progress and quality control can be implemented. Software for quality improvement has been developed, and initial implementation appears successful.

EVIDENCE BASED CLINICAL PRACTICE GUIDELINES: *What and where are they?*

A recent series of papers in the Medical Journal of Australia from the National Institute of Clinical Studies (NICS) has highlighted the concerning level of non evidence based practice and the ways in which this problem can be addressed¹. **In the paper by Heather Buchan (CEO NICS), it is estimated that 30-40% of patients do not receive treatments of proven effectiveness and a further 20-25% have treatments that are unnecessary or potentially harmful².** NICS has identified a number of areas where care can be improved in Australia including: *Smoking advice for pregnant women; Use of Angiotensin-converting enzyme inhibitors for heart failure; and measures to prevent DVT in hospitalised patients²*

Although insufficient as a single strategy, the development of Evidence Based Clinical Practice Guidelines (EBCPG) are widely accepted as the starting point to address gaps between evidence and practice.

What are EBCPG? Clinical Practice Guidelines (CPG) are variously defined but widely accepted as documents which provide recommendations and options on a course of action for clinicians and consumers faced with a specific clinical problem. CPG's are intended to inform the decision making process and may not suit every situation after consideration of individual circumstances including patient preference.

However, not all CPG are **EBCPG's**. EBCPG's should include, as a minimum, evidence of systematic literature search and review of the information obtained according to accepted criteria. Unfortunately, the quality of many CPG's is sub-optimal. A recent review of the quality of 431 guidelines showed the majority were unsatisfactory³. A validated instrument, the AGREE (Appraisal of Guidelines for Research and Evaluation), is available for assessing the quality and applicability of guidelines³

Where are EBCPGs? The MRSC is compiling a listing of guidelines websites which will be available on the MRSC website. Also, at the Mater best practice recommendations are included in the clinical practice protocols which are available on the Mater Intranet under Manuals.

Where to start in developing an EBCPG? Don't re-invent the wheel! The first step is to identify all existing guidelines and assess for quality and local applicability using the AGREE instrument. For more information or assistance please contact the MRSC.

1. National Institute of Clinical Studies. Adopting best evidence in practice. Med J Aust 2004;180(6 Suppl):S41-S72.
www.mja.com.au/public/issues/180_06_150304/suppl_contents_150304.html
2. Buchan H, Sewell JR, Sweet M. Translating evidence into practice. Med J Aust 2004;180(6 Suppl):S43-S44.
3. Eccles MP, Grimshaw JM. Selecting, presenting and delivering clinical guidelines: are there any "magic bullets"? Med J Aust 2004;180(6 Suppl):S52-S54.

MRSC CONSULTATIONS NOV 2003-MAR 2004

This gives you an overview of the type of consultation performed and the profession of our clients. Please note that a unit of consultation is a project. Each project focussed on a particular purpose of the consultation. Please note that the statistics are from current data, and data may not be complete in projects that are pending.

Number of projects:	126
Registered and pending consultation	31
Ongoing	56
Suspended (no progress)	02
Converted to long term collaboration	02
Completed	35
Type of consultation:	98
Statistics and other technical advice	28
Research planning	19
Systematic review (Cochrane)	23
Research teaching	11
Data analysis	11
Database development	03
Manuscript support	03
Profession of clients:	91 (some not recorded)
Doctors	37
Nurses	29
Researchers	07
Allied Health	06
Management	10
Others	02

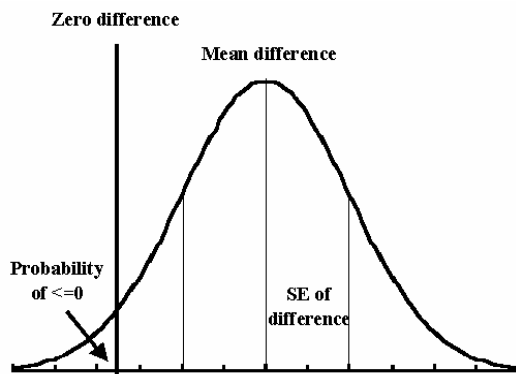
SAMPLE SIZE CALCULATIONS – PART 1

This is the first article in a series of three articles looking at sample size calculations. The other two articles will be produced in the next two MRSC newsletters.

Type I Error

It was Gauss who first described the Normal distribution curve, where repeated measurements from the same phenomenon produce different results, clustered around a central tendency, but distributed in a predictable manner. He termed this the Normal Distribution. De Moivre derived the mathematical model that produces the Normal Distribution curve and the Standard Deviation, from which the probability of having a value that deviates from the central tendency can be estimated.

If the difference and the Standard Error of that difference between two groups of measurements are calculated, the number of Standard Deviations from zero can be estimated. From this, the probability that this difference is zero (the null hypothesis) can be estimated. The lower the probability, the less likely is the difference zero, the more likely that a significant difference exists.



This is the basis of the probability of Type I error (Alpha), which is formally defined **as the probability of erroneously rejecting the null hypothesis**. It is however easier to think of this as the probability that the difference is zero. Conventionally the value of 0.05 is used. If the Type I error is less than 0.05, then the difference is said to be significant.

The use of the Type I Error allows the statistical decision where measurements from groups are different. This allows factors that are related to differences in outcome to be identified, thus forming the basis of much of the scientific advances of the 20th century.

Type II Error

Although a decision that measurements from groups are different can be made if the Type I error is small, a decision that the groups are the same cannot be made if the Type I error is large.

The problem here is that sameness needs to be defined. A difference of absolute zero hardly exists in reality, as measurement error alone will result in an observed difference. Sameness therefore has to be defined in terms of a difference that is of no practical importance, and below which we will accept that sameness exists. Once this is defined, the probability that an observed difference is smaller can be determined.

Type II error (Beta) is therefore the probability that the difference between groups is smaller than the defined minimum. Formally stated, it is **the probability of erroneously accepting the null hypothesis**. It is important to note that null is a defined difference that can be accepted as "null", and not a zero value. By convention, the probability of 0.2 is used for decision making. For most researchers, Type II error is expressed as power (Power = (1 - Beta) x 100 %). A Type II error of 0.2 is equivalent to a power of 80%.

Power analysis

Given any set of data divided into groups, one is able to calculate Alpha and Beta, from which confident conclusions can be drawn whether the groups are different, same to a defined extent, or that a statistical decision is inappropriate.

If both probabilities of Alpha and Beta are higher than the accepted level, the statistical conclusion should be that whether a difference exists or not remains unknown.

Planning a research project, Effect Size and Sample Size

In planning a research project, one needs to decide whether the research model is sufficiently robust and powerful.

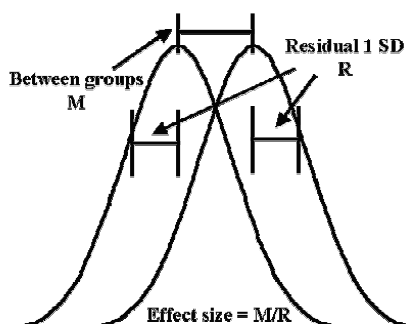
Robustness is a concept representing the reliability of the conclusion that a difference exists, and this is associated with the probability of Type I error (Alpha) chosen to decide that the null hypothesis should be rejected. Conventionally an Alpha less than 0.05 is accepted.

Power is a concept representing the reliability of the conclusion that a difference does not exist, and this is associated with the probability of type II error (Beta) chosen to decide that the null hypothesis should be accepted. Conventionally a Beta less than 0.2 is accepted.

Both power and robustness improves as the number of observations increase. **Sample size calculation** is therefore required to ensure that the required level of robustness and power can be reached in a research study.

The sample size needed depends on the Type I and Type II error that is defined (by convention 0.05 and 0.2), and on the **Effect Size**. The Effect Size is the minimum difference that is of practical importance, measured as a ratio of the background variation. A simple example of the Effect Size is that for comparing the means of 2 groups, where Effect Size = difference between the groups / Standard Deviation within each group (assuming that the 2 groups have similar SDs).

To detect an obvious difference (large difference in relationship to background variation) will need less observations (smaller sample size) than to detect a subtle difference (small difference in relationship to background variation). The following figure demonstrates the relationship that goes to make up the Effect Size.



Why Reviewers and Editors consider Sample Size Calculations to be so important

Research projects with inadequate sample size indicate poor design, and may produce results that mislead. Reviewers therefore rightfully view them with suspicion.

Similar research projects that use inadequate sample size tend to produce much wider variation in results. Small samples therefore often result in unstable results that may mislead.

Without sample size calculation or power analysis, no conclusion can be drawn if the Type I error is greater than the decision level (0.05). Inadequately small studies are therefore at a greater risk of wastefully using research resources.

Unscrupulous researchers may frequently evaluate their data, and rush to publish when a spurious significant finding is obtained. This leads to a misleading bias towards positive findings in the literature.

On the other hand, unnecessarily large studies are wasteful, and inconsiderate of risks to patients. Reviewers tend to view these also indicating poor design, and ethically questionable.

Research, particularly clinical research, uses up valuable resources in the health care sector. It places patients at risk, and inconveniences colleagues. Research that uses samples larger than are required to arrive at a confident conclusion are therefore unethical.

Excessively large sample size may also produce results that are statistically significant, but practically meaningless, such as finding a statistically significant difference that is smaller than the measurement error.

The estimation and use of correct sample size in a study is therefore essential, and the lack of which is commonly taken as a shortfall in the quality of research design, lack of ethical considerations, or both.

Part 2 of this article in the next newsletter will address topics such as comparison of means between groups and sample size calculations for estimating population parameters.

MRSC Support for Cochrane Reviews

For any staff members wishing to start a Cochrane systematic review or those with one underway, keep in mind that the MRSC is an invaluable source of support for Cochrane reviewers. The MRSC retains a wealth of knowledge, skill and contacts where Cochrane is concerned. We can provide assistance with Cochrane methodology; associated Cochrane software (Review Manager); courses to improve research skills including analysing and interpreting data; liaison with Cochrane Review Groups; and review of protocols and reviews etc.

Upcoming Course: Introductory and Advanced Cochrane Workshop

The Acute Respiratory Infections Cochrane Collaborative Review Group in collaboration with the Mater Health Services, Centre for Clinical Studies will be holding a Cochrane Reviewer Workshop on Saturday 15 May 2004.

New Cochrane Reviewers Software (RevMan) version

RevMan 4.2.4 is now available from www.cc-ims.net/RevMan, both as full installation and as a patch (www.cc-ims.net/download/revman/revman42patch.exe) to upgrade from a previous version of RevMan 4.2.

Need assistance navigating the Cochrane Library?

- The National Institute of Clinical Studies has developed a user guide to help people effectively navigate the Cochrane Library and associated databases. The user guide can be found at: <http://www.nicsl.com.au/cochrane/guide.asp>
- Vicki Flenady, presenter at Friday Lunchtime Meeting – 7 May 2004 'How to get the most out of the Cochrane Library' (12.15-1.30pm, New Life Centre, Level 4, Mater Mothers' Hospital)

For further information, please refer to the Mater Research Support Centre intranet site (<http://intranet.mater.org.au/webdoc/ccs/www/htmls/RSCsite/RSCHome.html>) or alternatively contact: Vicki Flenady ext 1592 or Katie Welsh ext 2197.

SMOKING CESSATION IN PREGNANCY: DEVELOPMENT, IMPLEMENTATION AND EVALUATION OF GUIDELINES MATER MOTHERS' HOSPITAL

Through a service agreement with Queensland Health, staff at the Centre for Clinical Studies, have developed clinical practice guidelines for smoking cessation in pregnancy. These guidelines were prepared according to the National Health and Medical Research Council's (NHMRC) Guidelines for the Development of Guidelines, which included the establishment of a state wide Working Party. These guidelines have been endorsed by the Southern Zone Maternal Neonatal and Gynaecological Network Expert Panel to be piloted at the Mater Mothers' Hospital.

The key recommendations of the guidelines are for the utilisation of the 5As approach to smoking cessation. All women at **every antenatal visit** who have been identified as smokers or recent quitters should be **Asked, Advised, Assessed, Assisted**, and have **Support Arranged**, and the appropriate documentation made in regard to their current smoking status and assistance and support offered. The guidelines recommend using support agencies ie Quitline to assist women in quitting.

For quality assurance purposes a prospective quasi-experimental before-and-after study design will be used to evaluate the clinical practice guidelines. The implementation program consists of a multifaceted "locally owned" package including the following key components: establishment of a project team comprising of antenatal clinic staff who will

oversee and facilitate the implementation of the guidelines and tools and will undertake a training session offered by the Queensland Cancer Fund. These staff will then provide education to all staff on an ongoing basis. An audit and feedback mechanism will be established and run by the local project team on smoking rates and uptake of the guidelines into practice.

The evaluation will include an audit of practice and surveys of staff and women attending the MMH. Staff will be asked for their feedback in respect to the sufficiency, content, clarity and quality of the guidelines and tools. Women will be surveyed for their feedback regarding satisfaction with the support, information and advice given regarding smoking cessation in pregnancy.

Primary outcomes:

Practice Compliance: recall by women on receiving the 5A's by survey at 34-36 weeks gestation or prior to discharge following birth by survey of women and audit of hand held record; Clinician knowledge and views of the guidelines and implementation program.

Secondary outcome: Pregnancy smoking quit rate at 34-36 weeks gestation.

Data will be collected over a 2 month period pre and post implementation – a sample of approximately 600 women in total.

TIPS TOWARDS BETTER LITERATURE SEARCHING

Whether you're conducting a literature search as part of a research project or simply trying to answer a clinical question it is important to conduct a comprehensive search in order to ensure that your research or decision making is based upon all available evidence and that potential bias is limited.

1. First and foremost, have a clear idea of what you're searching for. This can be achieved by ensuring that your question is clearly defined;
Consider using PICO (Patient/Population; Intervention; Control; Outcomes) as a strategy to both define your question and highlight potential search terms.
2. Consider carefully which databases to search. The database you search will depend upon the nature of your question;
The UQ Cybrary provides a list of all of their databases and their contents if you are unsure of the relevance of a particular database. (www.cybrary.uq.edu.au)
3. Use the thesaurus to search by subject headings and combine with text terms to broaden your search;
4. Make use of your Boolean operators to firstly broaden your search (OR) for individual terms and then narrow the results down to a manageable amount of literature by combining (AND) the groups of terms;
5. Truncation and Wildcards: *Truncation* involves truncating a word and inserting a (*) symbol which acts as a substitute for a string of characters.
eg. Smok* will retrieve smoke and smoking

Wildcards involve inserting a (?) symbol within a word to retrieve variations of the same word and acts as a substitute for one or no characters.

eg. Randomi?ation will retrieve randomisation and randomization

6. Parentheses are used to avoid ambiguity in complex searches
eg If you were to search for **smoking and (pregnancy or postpartum)**, you should retrieve literature which discusses smoking in either pregnancy or the postpartum period. If however you should leave out the parentheses and search for **smoking and pregnancy or postpartum**, you will retrieve literature which discusses smoking and pregnancy, as well as literature on postpartum, but not necessarily smoking and postpartum.
7. You can use operators (adj, and, near, not, or, with) to combine multiple search terms into a single, more focussed search request. Different databases work differently. For example with MEDLINE:
Adj retrieves records with search terms next to each other in a specified order.
eg. **Smoking adj cessation** retrieves records in which the term *smoking* immediately precedes the term *cessation*.

And retrieves records with both search terms.

eg. **Smoking and pregnancy** retrieves records with both *smoking* and *pregnancy*.

Near retrieves records with both search terms in the same sentence.

eg. **Smoking near cessation** retrieves records where *smoking* and *cessation* appear in the same sentence (in any order).

Not retrieves records with the first of two search terms.

eg. **Cigarettes not cigars** retrieves records with *cigarettes* and excludes those with *cigars*.

Or retrieves records with either or both search terms.

eg. **Pregnancy or expectant mother** retrieves records with either *pregnancy*, *expectant mother*, or *both*.

With retrieves records with both search terms in the same field.

eg. **Smoking cessation with program** retrieves records with both *smoking cessation* and *program* in a single field.

The staff at the Mater Library provide regular courses and assistance on literature searching. Please contact Jackie Chamberlin on ext 8135 or j_chamberlin@library.uq.edu.au for further information. Some library courses are advertised in this newsletter.

UPCOMING CONFERENCES AND SEMINARS

Neonatal Nursing 5th International Conference - "Diversity in Care", **13-16 May 2004**, Ottawa, Canada

2004 General Practice and Primary Health Care Research Conference - **2-4 June 2004**, Sheraton Brisbane Hotel

International Society of Nurses - Cancer Nursing 2004 - 13th International Conference

Introductory Research Symposium "Moving Toward Evidence Based Practice"

Sunday 8 August 2004 - 0900-1600 hrs

Advanced Research Session **Tuesday 10 August 2004 - 1400-1530 hrs**

Fostering Collaborative Research Session **Wednesday, 11 August 2004 - 1100-1230 hrs**

Australian and New Zealand College of Mental Health Nurses International 30th Conference
"Mental Health Nursing - A Changing Landscape" **20-24 September 2004**, Canberra

Evidence in Practice: Leading The Way In Aged Care (4th Joanna Briggs Australasian Colloquium).
29 September-1 October 2004, La Trobe University, Melbourne

LIBRARY TRAINING FOR MAY 2004

Endnote

- Assist writers and researchers in keeping track of bibliographic references and
- Generating bibliographies for books and papers

When: Part 1 – Thursday 13 May, 2004 2.00-3.30 pm
Part 2 – Thursday 20 May, 2004 2.00-3.30 pm

Tips for Better Literature Searching

- Turn clinical problems into answerable questions using the p.i.c.o. Format
- Transform your question into an effective search strategy

When: Monday 17 May, 2004 2.00-3.30 pm

Fulltext medical resources: direct to your desk

- Investigate the following full text electronic packages so you can access comprehensive, up-to-date clinical information quickly and easily at your desktop: md consult, stat!-ref, images md, acp medicine, acs surgery online

When: Tuesday 25 May, 2004 12.30-2.00 pm

All courses are held at the Mater Library Training Room, Ground Floor, Aubigny Place
To register for any of the courses or receive more information, please phone (07) 3840 8135 or
Email: j.chamberlin@library.uq.edu.au

Mater Research Support Centre and Centre for Clinical Studies
Level 1, Aubigny Place
Ph: 3840 1591 Fax: 3840 1588

Feedback regarding this newsletter is very welcome. If you have any comments, or would like something included in the next issue, please contact one of our editorial staff:
Sue Jenkins-Manning or Anne-Maree Stout on 3840 1591