

# Evidence Live 2017 – Oral Abstracts

Research Methods - Seminar Room One

15:15 Wednesday June 21<sup>st</sup>

## The PROCESS guidelines: Preferred reporting of case series in surgery

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**INTRODUCTION:** Case series have been a long held tradition within the surgical literature and are still frequently published. Reporting guidelines can improve transparency and reporting quality. No guideline exists for reporting case series, and our recent systematic review highlights the fact that key data are being missed from such reports. Our objective was to develop reporting guidelines for surgical case series.

**METHODS:** A Delphi consensus exercise was conducted to determine items to include in the reporting guideline. Items included those identified from a previous systematic review on case series and those included in the SCARE Guidelines for case reports. The Delphi questionnaire was administered via Google Forms and conducted using standard Delphi methodology. Surgeons and others with expertise in the reporting of case series were invited to participate. In round one, participants voted to define case series and also what elements should be included in them. In round two, participants voted on what items to include in the PROCESS guideline using a nine-point Likert scale to assess agreement as proposed by the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) working group.

**RESULTS:** In round one, there was a 49% (29/59) response rate. Following adjustment of the guideline with incorporation of recommended changes, round two commenced and there was an 81% (48/59) response rate. All but one of the items were approved by the participants and Likert scores 7-9 were awarded by >70% of respondents. The final guideline consists of an eight item checklist.

**CONCLUSION:** We present the PROCESS Guideline, consisting of an eight item checklist that will improve the reporting quality of surgical case series. We encourage authors, reviewers, editors, journals, publishers and the wider surgical and scholarly community to adopt these.

## Increasing engagement with evidence in healthcare; a case study in capacity development

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**OBJECTIVES:** The National Institute for Health Research funded the Collaboration for Leadership in Applied Health Research and Care, for the West of England (CLAHRC West) in January 2014, to run for 5 years. CLAHRC West seeks to develop and expand health-related research capacity in the area; to do this our objective is to promote the development of skills

in understanding, using and producing evidence for the health, social care and commissioning workforce. We set out to target a wide range of professional groups and sectors, especially those with limited access to training.

**METHODS:** An initial scoping exercise established the gaps and needs of the workforce in research skills training. Based on this we developed an interprofessional education programme. We have analysed a database capturing the courses delivered and applicant details to describe the sectors and professional groups reached, geographical differences in engagement and how participants have evaluated the learning.

**RESULTS:** Over 18 months we have delivered 32 courses to over 300 staff. The programme offered courses relating to standard research and evidence skills, including finding the evidence, critical appraisal, questionnaire design and service evaluation. In addition the programme included some cutting edge topics such as genomics and social return on investment. Our training has successfully engaged staff from a wide range of staff groups including healthcare professionals in acute and community settings (20.5%) and public health (16.7%). We reached staff from diverse sectors including local authorities (15.3%) and the voluntary sector (11.5%). The training is reaching all areas of the geographical patch covered by CLAHRC West. The average overall rating for the courses ranged between 3 (good) and 4 (excellent) on a 4-point scale evaluating content and delivery (average across courses 3.6%).

**CONCLUSIONS:** CLAHRC West is taking an innovative approach to increase capacity and capability in research. It has delivered a unique range of courses and reached a wide range of professions and sectors. Through taking a flexible and collaborative approach we have addressed the training needs identified. There is work to be done on improving the reach of the programme at the edges of the geographical area.

## **What predicts independent external validation of cardiovascular risk clinical prediction rules? Cox proportional hazards regression analyses**

Jong-Wook Ban

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**BACKGROUND:** Performance of clinical prediction rules (CPRs) should be validated by independent researchers unrelated to their derivations. Although many cardiovascular risk CPRs have been developed, most have not been externally validated. It is not known why some CPRs are externally validated by independent researchers and others are not.

**METHODS:** We analyzed cardiovascular risk CPRs included in a systematic review. Independent external validations were identified by conducting forward citation searches of derivation studies. Time between the publication of derivation study and the first independent external validation was calculated for each cardiovascular CPR. We assessed Kaplan-Meier estimates of probability to have independent external validation after the publication of a CPR derivation. Using Cox regression, we explored whether 12 characteristics of derivation, reporting, and publication of cardiovascular risk CPRs are associated with time to the first independent external validation.

**RESULTS:** Of 125 cardiovascular risk CPRs we analyzed, 29 had independent external validation. The median follow-up time was 118 months (95% CI, 99-130). It took at least 122 months (95% CI, 91-299) for 25% of cardiovascular risk CPRs to have independent external validation. Cardiovascular risk CPRs from the US were 4.15 times (95% CI, 1.89-9.13) more likely to have independent external validation. Raising the sample size of derivation by ten times

was associated with a 2.32-fold (95% CI, 1.37-3.91) increase in the probability of having independent external validation. Cardiovascular risk CPRs presented with internal validation tend to get independent external validation quickly (HR = 1.73, 95% CI, 0.77-3.93). Reporting all the information needed for calculating individual risk were 2.65 (95% CI, 1.01-6.96) times more likely to have independent external validation. Publishing a cardiovascular risk CPR in a journal that has one unit higher impact factor was associated with a 6% (95% CI, 3-9) increase in the incidence of independent external validation

**CONCLUSIONS:** Probability for cardiovascular risk CPRs to get independent external validation was low even many years after their derivations. Authors of new cardiovascular risk CPRs should consider using adequate sample size, conducting an internal validation, and reporting all the information needed for risk calculation as these features were associated with independent external validation.

## **Assessing drug treatment effects with published FDA approval summary documents: an experience report and practical guidance**

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**BACKGROUND:** The need to incorporate regulatory summary data into evidence syntheses has been advocated repeatedly over the last years. However, regulatory information is rarely used in evidence reports and systematic reviews. This may be partly explained by the sometimes complex, exhaustive, or inconsistent structure of publicly available regulatory summary documents.

**OBJECTIVE:** To share our methods and experiences of using regulatory summary data in an ongoing research project and to provide practical guidance on the use of this source of evidence.

**METHODS:** In the ongoing CEIT-Cancer project (Comparative Effectiveness of Innovative Treatments in Cancer), we systematically acquire treatment effect information on all 92 new cancer drugs approved by the Food and Drug Administration (FDA) since 2000. For this purpose we use data provided by the FDA in the publicly accessible drugs@FDA database <sup>1</sup>. Here we describe our methods on how to systematically and efficiently (1) identify relevant drugs and approved indications, (2) obtain corresponding approval documents, (3) identify pertinent studies, (4) extract characteristics of populations, interventions, comparators, outcomes, and study designs, and (5) select and extract estimates of treatment effects. We describe database requirements and procedures for data acquisition and management.

**RESULTS:** FDA drug approval documents represent a comprehensive source of information. Based on our experience with 92 drugs, we developed a systematic approach for efficient identification, selection, and management of data that is commonly needed for systematic reviews and meta-analyses.

**CONCLUSIONS:** We believe that disseminating our experiences may encourage others to use FDA approval summary documents more frequently as a source of information to complement evidence from the peer-reviewed literature.

<sup>1</sup> Drugs@FDA database (last accessed on March 30, 2017):  
<http://www.accessdata.fda.gov/scripts/cder/daf/>

## Novel Citation-Based Search Method for Scientific Literature: a Validation Study

Cecile Janssens, Michael Goodman, Kimberley Powell, Marta Gwinn  
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**OBJECTIVE:** Finding eligible studies for meta-analysis and systematic reviews relies on keyword-based searching as the gold standard, despite its inefficiency. We recently developed a novel search method that ranks articles on their degree of co-citation with one or more known articles before reviewing their eligibility (Janssens & Gwinn, *BMC Med Res Method* 2015). In two pilot studies, we used the method to reproduce the literature searches of published meta-analyses and found that 80% of the included studies were retrieved by screening fewer than 30% of the number of articles that the authors had screened. The present study aims to validate the performance of the citation-based search method.

**METHODS:** Using a similar design as the pilot studies, we aim to reproduce the literature searches of published systematic reviewers and/or meta-analyses. We retrieved the 500 most recently published systematic reviews that (1) had 'systematic review' or 'meta-analysis' in the title; (2) cited the PRISMA/MOOSE reporting guidelines; and (3) were published in journals with impact factor >2 (search date September 2016). Reviews were included when they met the minimal criteria of (1) presented a flow chart; (2) performed bias analysis on individual studies; and (3) reported sample sizes for included studies. To start each search, we assumed that the researchers knew the two highest-cited included studies which we assumed were the best-known studies on the topic.

**RESULTS:** Of the 500 reviews, 295 met the inclusion criteria. We calculate the sensitivity as the percentage of included studies that are retrieved, and precision as the percentage of studies that needed to be screened as compared to the original searches.

**CONCLUSIONS:** We expect to confirm that our citation-based search method is an efficient and precise tool for finding related articles of known studies.

## Could CONSORT do more to improve the quality of missing data reporting in randomised controlled trials?

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**BACKGROUND:** Transparent reporting of missing data (MD) is vital to the critical appraisal, and therefore value, of trial results. This is particularly important in palliative care trials where large amounts of MD occur. The 2010 CONSORT statement recommends the impact of MD on the validity of intention-to-treat analyses be reported. However it does not provide specific guidance on how to report: methods to handle missing data, assumptions about the MD mechanism and MD sensitivity analyses. Several groups have provided further MD reporting recommendations that include such criteria. Whether trial reports comply with the recommendations by CONSORT and other groups however is not known.

**OBJECTIVES:** Assess (i) the quality of reporting and handling MD in palliative care trials against current guidance, (ii) whether there are differences in the reporting of criteria specified by the CONSORT 2010 statement compared to those not specified, (iii) the association of the reporting of MD with journal impact factor and CONSORT endorsement status, to explore how implementation of reporting guidance may be optimised.

**METHODS:** Systematic review of palliative care randomised controlled trials. An information specialist searched CENTRAL, MEDLINE, and EMBASE (2009-2014). Identified trials were screened, selected and had data extracted by two independent reviewers.

**RESULTS:** 108 trials (15,560 participants) were included. MD reporting was incomplete and not handled in accordance with current guidance. Reporting criteria specified by the CONSORT statement were better reported than those not specified by CONSORT (participant-flow 69%, number of participants not included in the primary outcome analysis 94%, the reason for MD 71%). However MD in items contributing to scale summaries (10%) and in secondary outcomes (9%) were poorly reported. The odds of reporting the majority of MD and other risk of bias reporting criteria were increased as the journal impact factor increased and in journals that endorsed the CONSORT statement.

**CONCLUSIONS:** The rigorous methods, evolving nature, and wide recognition of the CONSORT statement make it ideally placed to facilitate better reporting of missing data. Further development and implementation of the CONSORT MD reporting guidance is likely to improve the quality of reporting. Specific suggestions for CONSORT will be discussed.

## **EARLY INVOLVEMENT IN CLINICAL GOVERNANCE: AN INTRODUCTION TO THE CLINICAL AUDIT PROCESS**

MARTINIQUE VELLA-BALDACCHINO, MANNIX O'BOYLE, FRANK LIAW  
QUEEN ELIZABETH UNIVERSITY HOSPITAL, GLASGOW, UK

**OBJECTIVE:** A module was created to teach foundation doctors and University of Glasgow Students the audit process in Orthopaedic department at Queen Elizabeth University Teaching Hospital. The aims were to introduce medical students to the concept of audit data collection and to develop a long-term clinical module for QEUH Orthopaedic department.

**METHODS:** Audit topics and their standards were submitted to an easily accessible online database. Students and foundation doctors were emailed and could register interest in a topic via an online spreadsheet. The new recruits were divided into teams consisting of a medical student, foundation 1 doctor and a project leader. A power point presentation was delivered to guide members through the audit process, with a following two meetings to monitor progress. Online feedback forms were emailed to members to suggest improvements

**RESULTS:** Twelve audit topics were submitted to the database and there were 4 topics investigated. Five medical students and five foundation doctors became involved overseen by three supervisors. Preliminary results have indicated three audit topics were completed successfully and are being followed through to complete the audit cycle. Online Feedback has stated members found the process useful and positive recommendations were suggested to improve accessibility of the project.

**CONCLUSIONS:** Audits are useful for monitoring the adherence to clinical guidelines and principles and our results have shown that there is continued interest to improve adherence to guidelines and improve patient care.

Three of the completed projects have successfully been completed with an ongoing interest to complete the cycle. The audit module is planned to run its second cycle with the new rotation of students in February. Feedback suggested early recruitment with weekly update meetings would lead to increased project completion. In conclusion, this Audit Module demonstrates an excellent potential for early involvement in audit process with potential to continually improve patient care.

## Informed Decision Making - Seminar Room Two

### 15:15 Wednesday June 21<sup>st</sup>

### **Dementia Health Needs Assessment (HNA): A Review of Epidemiology, Services, Health Needs and Models of Good Practice**

Claire Beynon

*Public Health Wales, Cardiff, UK*

**BACKGROUND:** There are 35.6m people living with dementia, this will double by 2030...the overwhelming number whose lives are altered by dementia combined with the staggering economic burden on families & nations makes dementia a public health priority WHO, 2012.

**OBJECTIVE:** The aim was to summarise the following: the epidemiology of dementia, the evidence base, best practice, services, and qualitative research describing the views of PWD, carers, stakeholders and staff.

**METHODS:** A HNA is a systematic method for reviewing the health issues facing a population leading to agreed priorities and resource allocation that will improve health and reduce inequalities. The five steps are detailed below:

**Step 1: Scoping**

**Step 2: Identify health priorities**

**Step 3: Identify priorities for change**

**Steps 4 and 5: Communicating and Monitoring**

Individual interviews were undertaken with 27 carers, staff and stakeholders and a focus group was held with patients. A thematic analysis of this qualitative data was undertaken.

**RESULTS:**

9 themes were identified:

**Isolation and loneliness** is a major issue

PWD should be treated with **kindness and compassion**

Work is ongoing to improve the **co-ordination of services** but there is room for improvement

Participants recognised the value of **caring for the carers**

Carers need to know **what to do in a crisis**

**Primary care** was where people want support

An **inequity in access to services** which is unwarranted was identified

**Dementia is everyone's business:** society can adapt to make life easier for PWD

**Prevention is essential:** further work on risk factors is required

**CONCLUSION:** The focus should be on providing services earlier to people to prevent crisis and the use of more intensive, invasive and expensive services "the right support at the right time in the right place" WHO, 2012. This means refocusing action on prevention, increasing

diagnosis rates to ensure people are offered the medication, support and care they need. Much work has already been undertaken to shift services to the community, this should continue. Further efforts should be made to engage PWD and carers in the design of services.

## **Effects of the Informed Health Choices primary school intervention on the ability of children in Uganda to assess the reliability of claims about treatment effects: a cluster-randomised trial**

Allen Nsangi<sup>1</sup>, Daniel Semakula<sup>1</sup>, Andrew D Oxman<sup>2</sup>, Astrid Austvoll-Dahlgren<sup>2</sup>, Matt Oxman<sup>2</sup>, Sarah Rosenbaum<sup>2</sup>, Angela Morelli<sup>4</sup>, Claire Glenton<sup>2</sup>, Simon Lewin<sup>2</sup>, Laetitia Nyirazinyoye<sup>6</sup>, Margaret Kaseje<sup>7</sup>, Iain Chalmers<sup>8</sup>, Atle Fretheim<sup>2</sup>, Yunpeng Ding<sup>2</sup>, Nelson Sewankambo<sup>1</sup>  
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The objective was to test an intervention, which we developed, where primary school children used learning resources about how to assess claims about treatment effects.

We randomly allocated 120 primary schools in Uganda to the intervention or control group. Intervention schools received the Informed Health Choices primary school resources (textbooks, exercise books and a teachers' guide). Teachers attended a two-day introductory workshop and delivered nine 80-minute lessons during one school term. The lessons addressed 12 concepts essential to assessing claims about treatment effects and making informed health choices. We did not intervene in the control schools. The primary outcome, measured at the end of the school term, was the proportion of children with passing scores on a test with two multiple-choice questions for each of the 12 concepts and the mean score on the same test.

In the intervention schools, 69.0% of 5753 children achieved a predetermined passing score (> 13 correct answers) compared with 26.8% of 4430 children in the control schools; an adjusted difference of 49.8% (95% CI 43.8% to 54.6%). On average, the children in the intervention schools answered 62.4% of the questions correctly compared with 43.1% in the control schools; an adjusted difference of 20.0% (95% CI 17.3% to 22.7%). In the intervention schools, 18.6% mastered the concepts (> 20 correct answers) compared with 0.9% of children in the control schools; an adjusted difference of 18.0% (95% CI 17.5% to 18.2%). The intervention was effective for children with different levels of reading skills, but more effective for children with better reading skills.

This trial provides reliable evidence that the primary school resources are effective in the Ugandan context. Using the resources warrants consideration in other countries, in addition to Uganda, based on the educational value, even though the impact on health outcomes is uncertain. It is unlikely that these resources alone will have an important effect on health outcomes. However, we believe that they are an important first step towards enabling children to make informed health decisions when they grow up, as patients and future health professionals, and as citizens and future policymakers.

## **Shared decision-making and informed consent post-Montgomery**

David Spiegelhalter, [George Farmer](#), Mike Pearson, Alexandra Freeman  
Winton Centre for Risk & Evidence Communication, University of Cambridge, Cambridge, UK

**OBJECTIVE:** In 2015, a landmark legal ruling in the Supreme Court changed the basis on which informed consent for surgery must be obtained in the UK. Now, surgeons must present to a patient not just the risks that they as medical professionals think important, but risks that their particular patient might want to consider. This is a fundamental change in the ethos of medicine – shared decision-making (long a goal of guidelines such as the GMC's) is now enshrined in law. But how will this work in practice? The problems of knowing what, and how, to communicate to patients in a range of scenarios are extensive and well recognised. For example, research has shown that, worldwide, patients giving informed consent in clinical trials show 'suboptimal' understanding of the information they are presented with.

**METHODS:** By working with legal, ethical, and psychology experts and undertaking extensive user-testing in small groups and one-on-one with both clinicians and patients, we are developing practical tools that will help shared decision-making in medicine - whilst not adding to the time and administrative burden already affecting healthcare.

**RESULTS:** We will present some of the work that we are doing, both specifically on the online NHS Predict tool for aiding treatment decisions in breast cancer and more widely. This will include our work on different methods of displaying and communicating potential harms and benefits, including long-term survival analyses, and how to elicit a patient's personal values and concerns.

**CONCLUSIONS:** Shared decision-making is now something that all surgeons in the UK need to adopt, and other clinicians should also aim for. It may seem a difficult goal, but our research shows that it is possible to achieve, and we aim to provide the tools to help clinicians do that effectively and efficiently.

## **Personalized risk prediction using “predictive pursuit” machine learning: a pilot study in cardiac transplantation.**

[Amitava Banerjee](#)<sup>1</sup>, Jinsung Yoon<sup>2</sup>, William Zame<sup>2</sup>, Martin Cadeiras<sup>2</sup>, Ahmed Alaa<sup>2</sup>, Mihaela van der Schaar<sup>2</sup>

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**INTRODUCTION:** Across healthcare, risk prediction tools are suboptimal whether used in diagnosis, prognosis or treatment planning. Use of retrospective datasets for derivation and validation, lack of personalisation of tools and inadequate use of machine learning are some of the problems with the current paradigm.

**OBJECTIVE:** To improve accuracy of risk prediction using a novel personalized machine learning model ("predictive pursuit") by conducting a pilot study of wait-list and post-transplant mortality in cardiac transplantation.

**METHODS:** Using the United Network for Organ Sharing (UNOS) database of US patients registered for cardiac transplantation 1985-2015, our novel algorithm used different predictive models for different "predictive clusters" of patient characteristics. In a training phase, relevance scores were assigned to each potentially relevant characteristic. In the validation phase, the best-fitting prediction cluster and predictive models were iteratively selected. For wait-list survival and post-transplant survival, predictive accuracy of predictive pursuit was compared with currently used algorithms was assessed by Area Under Receiver Operating Characteristic curve (AUROC).



**RESULTS:** We included 96,729 individuals: 60,400 (62.4%) received transplants ("transplanted") and 36,329 patients (37.6%) did not ("wait-listed"). We identified 53 potentially usable characteristics with 33 recipient features, 14 donor features and 6 donor-recipient compatibility features. For wait-list mortality at 3 months, 1 year, 3 years and 10 years, AUROC was 0.79(95% Confidence Interval,0.78-0.80), 0.81(0.80-0.82), 0.82(0.81-0.83) and 0.82(0.81-0.83) for our algorithms; 0.63(0.62-0.65), 0.65(0.64-0.66), 0.65(0.64-66) and 0.65(0.64-0.66) for the best currently used clinical predictive model; 0.68(0.67-0.69), 0.65(0.64-0.66), 0.68(0.67-0.69) and 0.66(0.65-0.67) for Cox Regression; and 0.75(0.74-0.77), 0.77(0.76-0.78), 0.78(0.77-0.79) and 0.79(0.78-0.80) for the best machine learning models, respectively. For post-transplant mortality at 3 months, 1 year, 3 years and 10 years, AUROC was 0.67(0.66-0.68), 0.65(0.65-0.65), 0.66(0.66-0.66) and 0.62(0.61-0.63) for our algorithms; 0.60(0.59-0.61), 0.59(0.58-0.59), 0.57(0.56-0.57) and 0.57(0.58-0.67) for the best currently used clinical predictive model; 0.57(0.56-0.58), 0.60(0.59-0.61), 0.57(0.56-0.58) and 0.57(0.56-0.58) for Cox Regression; and 0.63(0.63-0.64), 0.62(0.61-0.63), 0.62(0.62-0.62) and 0.58(0.57-0.59) for the best machine learning models, respectively.

**CONCLUSIONS:** Our novel "predictive pursuit" algorithm out-performs currently available clinical risk prediction scores as well as the best machine learning tools for prediction of wait-list and post-cardiac transplant mortality. The predictive pursuit algorithm has potential to personalise and greatly improve accuracy of risk prediction.

## Developing predictive models for severe postoperative complications in cardiac patients.

Linda Lapp<sup>1</sup>, Matt-Mouley Bouamrane<sup>1</sup>, Kimberley Kavanagh<sup>1</sup>, Stefan Schraag<sup>2</sup>  
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**OBJECTIVE:** Postoperative complications are known to be significantly associated with mortality and morbidity. Severe postoperative complications after cardiac surgery can have a significant impact on patient's quality of life, hospital length of stay and healthcare costs.

**METHODS:** All patients in Golden Jubilee National Hospital undergoing cardiac surgery between April 1, 2012 and March 31, 2016 were investigated. The clinical audit database CaTHI consisted of preoperative variables describing patient characteristics, comorbidities, general cardiac status and surgery, and outcomes such as death, hospital length of stay, ICU hours, and presence of complications. A model to predict severe postoperative complications was developed, using logistic regression and performance assessed using receiver operating characteristic (ROC) curves. The predictive ability was compared to the commonly used preoperative risk of mortality model logistic EuroSCORE (LES).

**RESULTS:** Of 3700 analysed admissions, 59.7% had CABG, 26.4% aortic valve, and 13.9% combined CABG and aortic valve surgery. According to preoperatively calculated LES, 2.5% were high-risk patients (LES >20). The prevalence of severe complications was 5.0% (95% CI 4.3-5.7%). The locally developed prediction model for severe complications consisted of age, gender, diabetes, left ventricular function, previous operations, hypertension history, active endocarditis and previous myocardial infarction. The area under the ROC curve (AUC) of the model was 0.667 with 72.1% sensitivity and 56.6% specificity, with positive (PPV) and negative predictive values (NPV) being 2.5% and 92.0%, respectively. The AUC of LES model predicting severe postoperative complications was 0.672 with 60.7% sensitivity and 66.0% specificity, PPV of 3.0% and NPV of 91.4%.

**CONCLUSIONS:** The high NPVs of both models and high sensitivity of the local model show that both could be used to identify patients without severe complications in order to allocate

resources accordingly. A model predicting severe complications could help reducing overall costs of care and improve patients' quality of life.

## Using encounter decision aids to share decisions with women presenting with heavy menstrual bleeding

Johanna Aarts<sup>1</sup>, Rachel Thompson<sup>2</sup>, Shama Alam<sup>2</sup>, Michelle Dannenberg<sup>2</sup>, Glyn Elwyn<sup>2</sup>, Tina Foster<sup>3</sup>

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**OBJECTIVE:** Shared decision-making (SDM) requires providing tailored information to the patient about options and eliciting and integrating patient preferences as treatments are selected. Decision aids used in the clinical encounter may facilitate SDM. We evaluated the impact of introducing encounter decision aids (Option Grid™ decision aid) for women presenting with heavy menstrual bleeding on the level of SDM.

**MRTHODS:** A before-after study was conducted in a OB-GYN practice in an academic medical center and two community practices in the United States between December 2014 and May 2015. Consultations were compared before (T1) and after (T2) introduction of two encounter decision aids on treatment options for heavy menstrual bleeding. Clinicians participating in the study were offered a hands-on group training on the use of the decision aids before T2. Immediately after appointments, patients filled out a brief validated measure (CollaboRATE) of SDM. Additionally, three trained observers rated audio recordings of consultations for SDM using the OPTION<sup>5</sup> instrument. Based on sample size calculated we aimed to include at least 25 patients at T1 and T2.

**RESULTS:** 16 providers participated, 25 patients were enrolled in T1, and 28 patients in T2. The groups did not differ on demographic characteristics. The proportion of patients reporting SDM increased significantly from T1 (50%) to T2 (75%;  $p < 0.05$ ). The mean observer-rated level of SDM also increased significantly from T1 to T2 (mean difference = 12.50 on a scale of 0-100, where threshold for clinical relevance is 11.9). Among individual OPTION<sup>5</sup> items, item 2 (ie. 'the clinician will support the patient to become informed and to deliberate about the options') increased the least and item 4 (ie. 'The clinician makes an effort to elicit the patient's preferences') increased the most. The overall interrater reliability reached an ICC 0.723 (95% CI 0.56-0.83).

**CONCLUSIONS:** Implementation of encounter decision aids for women presenting with heavy menstrual bleeding was associated with a higher level of SDM between women and providers, both from the patient and observer perspective. Given these promising results we encourage clinicians to use these encounter decision aids with their patients

**Communication of Evidence - Seminar Room Three**  
**15:15 Wednesday June 21<sup>st</sup>**

## Factors Influencing Gastric Gavage Practices of Nurses in Tertiary Level Care

Mary Grace Anne Batalla, Ryana Anjela Quero, Jessica Christel Maglalang, Danielle Gardaya, Rophy Sly Nunes, Ginnique De Grato, Izra Mananguit, Danica Joy Christelle Pilar,

Kathlyn Sharmaine Valdez, Sheen Anne De Leon  
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**KEYWORDS:** gastric gavage, enteral feeding, nasogastric tube feeding, nurse practices

**BACKGROUND:** Gastric gavage remains a fundamental nursing skill in the provision of adequate nutritional support and medication administration for a wide range of patients. However, despite the presence of evidence-based policies and guidelines, inconsistencies are still being documented in the performance of gastric gavage practices.

**OBJECTIVES:** The study aimed to (1) describe the practices of nurses in gastric gavage; and (2) determine factors that are associated with the performance of such practices.

**MATERIALS AND METHODS:** The study utilized a descriptive correlational design. Quota sampling of nurses (n = 111) working in wards and intensive care units of a tertiary hospital for adult patients requiring nutritional support through gastric gavage was performed. Gastric gavage practices were assessed using a self-report survey. Ethical approval was obtained from an institutional review board.

**RESULTS:** Majority of respondents correctly identified x-ray as the gold standard for determining tube placement (58.5%). However, only 13.5% correctly identified air insufflation as an unreliable method. Scores on knowledge and skills on gastric gavage were found to have a significant positive correlation ( $p < 0.01$ ). There were no significant relationships found between gastric gavage practices and factors such as length of experience, nurse rank, nurse-patient ratio, and patient load.

**CONCLUSIONS:** Strengthening of knowledge on standards of gastric gavage may improve the performance of the skill in actual bedside practice. Addressing documented gaps in gastric gavage practices and standards may have an impact in the provision of safe and quality nursing care.

**CLINICAL RELEVANCY STATEMENT:** Gaps in theory and practice remain documented in the performance of gastric gavage despite it being a fundamental component in ensuring optimal nutrition and medication delivery during hospitalization. Being front-liners in bedside care, identifying the practices of nurses in gastric gavage and the factors that relate gastric gavage to patient safety can help in understanding what fuels the theory-practice gap and eventually assist in planning towards the promotion of safe and quality nursing care.

### **Alternative Evidence: science and belief *The impact of the conflicting paradigms of Western scientific and traditional medicines***

Bruce Hugman  
*Uppsala Monitoring Centre, Uppsala, Sweden*

#### **OBJECTIVES:**

1. Review meaning of the limited influence of Western scientific evidence in treatment choices of billions of people;
2. Examine the troubled relationship between cultures of alternative medical thinking and practice and (a) the assertive Western paradigm, and (b) popular responses to evidence and expertise in the West;
3. Generate options for change in the ways evidence is characterized and communicated, including rapprochement between alternative paradigms.

**METHODS (work in progress for completion in May):** literature research and debate with international colleagues for chapter on risk communication in, *Pharmacovigilance of herbal medicines: reflections, solutions and future perspectives* (Springer 2018)

**INTERIM CONCLUSIONS:** Very large numbers of people (China, Africa, Asia, South America) make treatment choices largely within a traditional, historic paradigm in which Western scientific evidence plays little or no part. Beliefs at the heart of these systems have penetrated and substantially influenced Western societies, including attitudes to allopathic medicines and scientific evidence. Other social, commercial and political developments, including the dominance of social media, have given rise to a culture in which false claims, 'fake news,' alarmism, misrepresentation, commercialization, and corruption have flourished. Western scientific medicine has not only to address the shortcomings of its own evidence base, but also a culture in which the credibility of evidence, expertise and rational debate are increasingly under threat. We must find creative and practical ways of engaging productively with those for whom Western scientific evidence is not the primary driving force behind the choices in their lives, in the West and elsewhere; see what common ground we have and agree to differ when there is none. For them and society at large, we need to reposition logical and transparent evidence as a credible and mature standard, but one alongside which other beliefs and values, which we must take seriously, will inevitably play their part. Western evidence, with all its benefits and shortcomings, has seemed arrogant in its unquestioned superiority over all other paradigms; a much more nuanced vision of what human beings feel and believe to be evidence is needed. Some possibilities will be suggested and offered for debate.

## **Classification of Recommendations Across Guidelines: When do we agree?**

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**OBJECTIVES:** Many guidelines convey the strength of recommendations, but what is a global view? It is unclear if conveying recommendations across guidelines would be similar or dissimilar to what would be conveyed by a single guideline. Conveying a global view for rapid simple understanding could quickly become unwieldy. We developed a simple model to report the consistency or inconsistency across guidelines and the most reliable evidence for specific recommendations.

**METHODS:** Healthcare Guidance for Patients Society (Healthcare GPS) includes experts in evidence-based medicine, clinical practice guidelines, and shared decision-making. We considered the National Academy of Medicine (NAM), Guidelines International Network (G-I-N), and Grading of Recommendations Assessment, Development and Evaluation (GRADE) standards and developed (via a consensus-based approach) a classification system for a recommendation that is represented across multiple entities making recommendations for the same concept

**RESULTS:** First, the consistency across the guidelines is determined regarding whether existing guidelines are for (or against) the particular recommendation. For recommendations that are consistent in direction across guidelines, consistency is checked regarding the certainty that desirable consequences outweigh undesirable consequences. Further checking for consistently strong recommendations involves confirmation of a qualified rationale requiring three elements: a systematic review, multidisciplinary input with conflict of interest

management, and explicit reporting of values and preferences to inform judgments about the balance between benefits and harms of treatment alternatives.

**CONCLUSIONS:** Final ratings are ALPHA (Consistent Strong Recommendations for), BETA (Consistent Suggestions for), DELTA (Inconsistent or Insufficient Guidance), GAMMA (Consistent Suggestions against) and OMEGA (Consistent Strong Recommendations against). Healthcare GPS ratings can provide a simple recognizable method to communicate the comprehensive view to the certainty of a recommendation across guidelines. This view may be desired in clinical decision-making, shared decision-making, and policy decision-making

## **The impact of small-group EBP education program: barriers and facilitators for EBP allied health champions to share learning with peers**

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Health professionals are expected to provide evidence-based patient care. In 2015, a group of Allied health professionals were nominated as EBP champions within Gold Coast Health, and challenged to encourage the use of EBP in clinical practice. These EBP champions identified a need for further education to increase their knowledge and confidence about EBP. They wanted to learn some practical strategies for transferring EBP skills to their teams. It was difficult for them to attend a traditional 2 day EBP training course, and maintain their clinical commitments.

**OBJECTIVE:** How does a small group EBP education programme facilitate motivated clinicians to share learning with their peers: a concurrent mixed methods evaluation.

**METHODS:** We tailored a small-group distributed model of EBP education for allied health clinicians, from a traditional 2 day Introduction to EBP programme, to meet the competing clinical demands and learning needs of the EBP champions.

All participants completed self-reports of their self-efficacy for using EBP (Evidence-based Practice Confidence Scale), their EBP Behaviours (EBP Implementation Scale) and change in knowledge and skills (adapted Fresno test) before and after the educational sessions. Participants volunteered to participate in focus groups, designed to explore the perceived barriers and facilitators for sharing their EBP knowledge and skills with work colleagues.

**RESULTS:** 16 allied health clinicians, representing 8 different professions attended 2 hour EBP interactive educational sessions for each of four months from August - November 2016. Significant differences were reported from before and after this education intervention, in clinicians' confidence and behaviours in relation to; formulating research questions, conducting searches, critically appraising the literature, discussing research evidence with patients and colleagues, and in evaluating clinical outcomes. Qualitative analysis is underway and we will utilise the Classification Rubric for EBP Assessment Tools in Education (CREATE) assessment framework to interpreting results.

**CONCLUSION:** This research study has both supported and informed the research evidence about the diversity of multifaceted educational interventions that can positively impact clinical staff. This study shows early support for regular interactive educational sessions, with a focus on clinical scenarios and specific support for participants to share learning with clinical colleagues between sessions.

# **Paving the Road to Policy: An Examination of Knowledge Translation Practices of Health Services Research Organizations in the U.S.**

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**OBJECTIVE:** As the information needs of leaders and policymakers evolve while the United States navigates ongoing health care reform, the ability of health services research (HSR) organizations to communicate research effectively remains critical. Despite the availability of many resources and strategies designed to aid researchers in optimizing communication, HSR findings do not always reach policymakers in ways that are helpful, relevant, or cost-effective.

This project aimed to understand better how HSR organizations in the U.S. communicate their research findings to policymakers; determine the degree to which they are translating research findings according to evidence-based best practices; and determine whether organizational characteristics explain any variation.

**METHODS:** 114 leaders of HSR organizations in the U.S. responded to a survey about their organizations' knowledge translation practices. The survey instrument and knowledge translation framework were largely adapted for the U.S. based on work conducted by Lavis, Robertson, Woodside, McLeod, and Abelson (2003) in Canada.

**RESULTS:** Data indicate HSR organizations largely communicate about their research in the same manner, regardless of affiliation, size, or specialty. Certain characteristics (i.e., small size, no university affiliation, and specialization in health policy/economics or quality improvement) signal higher degrees of effective knowledge translation in 10 particular situations. HSR organizations conduct knowledge translation activities throughout the course of their research project, although in many cases there are clear gaps between what the literature suggests HSR organizations optimally should be doing and what they report doing.

Findings from this study expand the Lavis et al. study by setting a baseline for knowledge translation practices, across the entire continuum of the research process, for HSR organizations in the U.S.

**CONCLUSION:** The data indicate opportunities for improvement in communicating research, including: evaluating knowledge translation activities, utilizing social media tools to extend messaging to policymakers, engaging with policymakers throughout the research process, building expectations for knowledge translation into infrastructure, and investing in knowledge translation development at the organizational and funder levels. Making improvements to research communication means more policymakers will successfully receive research findings in ways that can be useful for decision making, ultimately enhancing the quality of health care and improving patient outcomes.

## **Community Pharmacists' interest and attitude towards Pharmacy Practice-research in Ethiopia: A Cross-Sectional Study**

Akshaya Bhagavathula<sup>1</sup>, Eyob Gebreyohannes<sup>1</sup>, Begashaw Gebresillassie<sup>1</sup>, Chernet Negesse<sup>2</sup>, Yared Belay<sup>3</sup>, Daniel Erku<sup>1</sup>

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<sup>3</sup>Mekelle University, Mekelle, Ethiopia

**BACKGROUND:** Pharmacy practice-research became an important component in the

pharmacy practice. However, no studies were conducted in sub-Saharan Africa to understand the pharmacists' interest and attitude towards pharmacy practice-research. We aimed to assess the community pharmacists' interest and attitude towards pharmacy practice-research in Ethiopia.

**METHODS:** A cross-sectional survey was conducted among community pharmacists in eight major cities in Ethiopia. A validated 25-item self-administered questionnaire covering interest and attitude related to pharmacy practice-research was distributed. Responses were analysed using descriptive and interfacial statistics.

**RESULTS:** A total of 389 community pharmacists responded to the survey (response rate-88.4%). Most of community pharmacists showed a high level of interest in being involved in all aspects of pharmacy practice-research. Seventy percent identified 'research advances within pharmacy field' and more than sixty percent showed interest towards 'generating research ideas' (64%), 'interpreting the research findings' (62%), 'reviewing scientific literatures' and 'giving an oral presentation' (60%). The median summary score for interest was 38 (IQR 20-40) (range possible 11-50). More than half of the respondents showed positive attitude towards pharmacy practice-research with a median overall score of 30 (IQR 18-39), range possible 10-69. Sixty-seven percent of the respondents thought about being involved in research, felt research is important for their career (57.6%), confident to conduct the research (56.2%), and agreed that research is a part of pharmacy practice (48.5%). However, only forty-six percent agreed that they underwent research training. In multivariate analysis, a positive correlation was noticed that female gender had significantly more interest towards research than males [AOR: 1.50, 95% CI: 0.99-2.27; p<0.05].

**CONCLUSION:** Community pharmacists showed high interest towards several areas of research competencies and demonstrated positive attitude towards pharmacy practice-research. Our findings suggests that providing research training to community pharmacists may merit in undertaking research activities and build the research capacity in Ethiopia.

Keywords

Community pharmacy, pharmacy practice-research, interest, attitude, research, Ethiopia

## Evidence Synthesis - Seminar Room Four 15:15 Wednesday June 21<sup>st</sup>

### Characterization of gastrointestinal adverse effects in studies examining corticosteroid use

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**OBJECTIVE:** To examine whether 159 studies included in a previous meta-analysis reported on adverse effects in accordance with the the Consort extension for reporting harms outcomes (CONSORT Harms criteria checklist), whether differences were associated with funding source, journal or publication year, and whether the CONSORT Harms checklist is a suitable tool for evaluation of adverse effects reporting.

**METHODS:** Articles were assessed for fulfilment of the CONSORT Harms criteria, funding source, publication type and year. Agreement between reviewers was assessed by comparing scores for each study.

**RESULTS:** The mean CONSORT Harms score was 5.25 out of 10 (SD ± 2.09). Most studies included information on participant withdrawals (133 studies, 83.6%), absolute risk of gastrointestinal adverse events (130 studies, 81.8%), and how harms-related information was collected (118 studies, 74.2%). Reporting of gastrointestinal adverse effects increased with higher scores ( $p=0.042$ ). There was no significant association between CONSORT Harms score achieved and publication in a major journal, publication year, or funding source. Definitions of gastrointestinal bleeding differed between studies. Reviewer agreement was moderate with large variations.

**CONCLUSIONS:** Few studies in the systematic review received high scores using the CONSORT Harms criteria. Most studies reported on the most important criteria regarding risk of gastrointestinal bleeding. Reviewer agreement showed large variations due to imprecise texts and ambiguous criteria. Routine scoring according to CONSORT Harms criteria would be inadvisable without qualified judgment.

## **Has evidence-based medicine ever been modern? A Latour inspired understanding of a changing EBM.**

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<sup>1</sup>University of Oslo, Oslo, Norway, <sup>2</sup>University of Oxford, Oxford, UK

Evidence based healthcare (EBHC) - previously evidence-based medicine (EBM) - is considered by many to have modernised healthcare and brought it from an authority-based past to a more rationalist, scientific grounding. But recent concerns and criticisms pose serious challenges and urge us to look at the fundamentals of a changing EBHC.

In this paper we present French philosopher Bruno Latour's vision on modernity as a framework to discuss current changes in the discourse on EBHC / EBM. Drawing on Latour's work, we argue that the early EBM movement had a strong modernist agenda with an aim to 'purify' clinical reality into a dichotomy of objective 'evidence' from nature and subjective 'preferences' from human society and culture.

However we argue that this shift has proved impossible to achieve in reality. Several recent developments appear to point to a demise of purified 'evidence' in the EBHC discourse and a growing recognition - albeit implicit and undertheorised - that evidence in clinical decision-making is relentlessly situated and contextual. The unique, individual patient, not abstracted truths from distant research studies, must be the starting point for clinical practice. It follows that the EBHC community needs to reconsider the assumption that science should be abstracted from culture; and acknowledge that knowledge from human culture and nature both need translation and interpretation. The implications for clinical reasoning are far-reaching. We offer some preliminary principles for conceptualising EBHC as a situated practice rather than as a sequence of research-driven abstract decisions.

## **Assessing efficacy, security and effectiveness of weight control, overweight and obesity management apps: A systematic review**

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**BACKGROUND:** In the last years, we have faced a revolution in the area of medicine by the use of apps, mainly because they are rapid, versatile, manageable and illustrative tools that allow the empowerment of patients regarding their own health. There are over 165.000 health apps in the market, being the most downloaded ones those related with physical activity and weight control, precisely those that support healthy lifestyles. There are several initiatives that try to define how apps should be evaluated; however, all of the approaches identified face only partial aspects of the evaluation.

**OBJECTIVE:** The aim of this Project is to develop a systematic review to identify efficacy, security and effectiveness criteria that have been used to assess different weight control, overweight and obesity management mHealth interventions.

**METHODS:** PUBMED, PsycINFO, Scopus, UK Tripdatabase, Clinical Trials Register and Cochrane library have been searched up to January 2017. All kind of clinical studies have been considered. Quality is being assessed by 2 independent reviewers (peer-review) using SIGN criteria. Ratings are used to provide an overall score for each study (strong, moderate or weak). Only moderate or strong quality studies are considered. Data are synthesized in evidence tables. A non-quantitative analysis is being performed

**RESULTS:** From 125 potentially relevant publications, only 57 have been accepted for review according the inclusion criteria; 19 of not included articles are published protocols and 14 systematic reviews. Finally, outcomes from the selected studies have been extracted. Several tools to assess efficacy, security and effectiveness have been identified. Most of them are non-validated tools or self-made questionnaires.

**CONCLUSIONS:** There is a remarkable heterogeneity among studies and most of them have methodological limitations, which left important room for improvement regarding the quality of the studies. This research allows for the identification of relevant tools to assess efficacy, security and effectiveness of weight control in overweight and obesity management mHealth interventions. Once the study is finished a set of criteria to be included in a validation tool will be identified.

## **Innovative patient partnership in creating trustworthy guidelines, from protocol to publication: Case studies of BMJ Rapid Recommendations**

[Lyubov Lytvyn](#)<sup>1</sup>, Reed Siemieniuk<sup>3</sup>, Helen MacDonald<sup>4</sup>, Amy Price<sup>4</sup>, Anne Lyddiatt<sup>5</sup>, Linn Brandt<sup>1</sup>, Anja Fog Heen<sup>1</sup>, Gordon Guyatt<sup>3</sup>, Thomas Agoritsas<sup>2</sup>, Per Olav Vandvik<sup>1</sup>  
<sup>1</sup>University of Oslo, Oslo, Norway, <sup>2</sup>University of Geneva, Geneva, Switzerland, <sup>3</sup>McMaster University, Hamilton, Ontario, Canada, <sup>4</sup>BMJ, London, UK, <sup>5</sup>Cochrane Consumers, London, Ontario, Canada

**OBJECTIVE:** BMJ Rapid Recommendations (RapidRecs) are trustworthy guidelines published in the BMJ and MAGICapp, in response to practice changing evidence. RapidRecs are developed by unconflicted, international panels of clinical experts, methodologists, and patient partners. A cornerstone of RapidRecs is innovating methods for patient partnership. We sought to determine the feasibility and effect of patient partnership at each step of guideline development.

**METHODS:** For each RapidRec, we recruit patient partners from consumer organizations, panel member referrals, and Twitter. Partners receive a formal invitation, conflict of interest form, and personal call via phone or video conference describing the RapidRecs project, expected commitment, and timelines. Upon agreeing to participate, patient partners: 1) identify and prioritize patient-important outcomes for the systematic review informing the guideline, 2) identify practical issues for shared decision-making between patients and their

healthcare teams, 3) participate in an education session to review the evidence before panel deliberation, 4) participate in deliberation teleconferences, and 5) edit the draft recommendations and manuscript, as co-authors. We will conduct interviews with patient partners and panel members to identify strengths and weaknesses of our approach. We will also review impact by reporting unique contributions made by patient partners for each RapidRec.

**RESULTS:** To date, we recruited 16 partners for five guidelines, from general consumer organizations (N=9), disease-specific consumer organizations (N=4), and referrals (N=3). Preliminary feedback from patients and panel members has been very positive regarding both the guideline process and the patients' contributions. RapidRecs are focused guidelines, thus our approach may not generalize to complex guidelines or policy deliberations. Areas of improvement are maximizing patient involvement without excessive burden, producing guidance on patient partnership for guideline development organizations, and documenting challenges (e.g. recruitment, education) and resources required. Preliminary project results will be presented at the conference.

**CONCLUSIONS:** We provide a proof-of-concept that meaningful patient partnership is achievable, producing more trustworthy, relevant, and patient-centered guidelines easily translatable into shared-decision making tools.

## **Clinical Pearl: POINT OF CARE CLINICAL KNOWLEDGE MANAGEMENT PLATFORM**

Uzair Hasan MD<sup>3</sup>, Amr Jamal MD<sup>1</sup>, Shankar Srinivasan PhD<sup>2</sup>, Syed Haque PhD<sup>2</sup>, [Izhar Hasan MD, PhD<sup>1,2,3</sup>](#) <sup>1</sup>.Department of Medical Informatics & elearning unit(Mielu) & Family Medicine, KSU ,Riyadh,KSA<sup>2</sup>. Department of Health informatics, Rutgers University, Newark, NJ, USA <sup>3</sup>. Clinical Pearl, Inc., Princeton, NJ,

Uzair Hasan<sup>1</sup>, Amr Jamal<sup>2</sup>, Shankar Srinivasan<sup>3</sup>, Syed Haque<sup>3</sup>, [Izhar Hasan<sup>3</sup>](#)  
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**ABSTRACT:** Healthcare professionals are expected to be self-directed learners. Ample evidence suggests that healthcare professionals generate plenty of clinical questions during clinical practice. Unfortunately, lack of time and readily accessible knowledge capturing and organizing platform hinders the perusal of answers to these complex clinical questions. Currently, there is no such knowledge management platform to capture point of care knowledge needs of clinicians.

**OBJECTIVE:** The objective of this study was to propose an organizational centered clinical knowledge base development tool for a collaborative learning and continuous professional development activities.

**METHOD:** We designed and implemented a Clinical knowledge management platform both in web based and IOS platform, hosted at [www.Clinicalpearl.Com](http://www.Clinicalpearl.Com). The application was implemented as a SaaS-based model, using 4.5 .net version Microsoft network in C++ language. A built-in editorial flow provides an authentic local evidence-based practice knowledge repository for clinicians and organizations.

**RESULTS:** A beta testing of this web based point of care clinical knowledge management platform was performed from 2016 to date. Preliminary usability beta study results showed that a point of care clinical tool to identify knowledge needs and gaps may not only fulfill a

reflective learning activity but also encourage users to practice more evidence-based medicine for better patient outcome.

**CONCLUSION:** We have designed a comprehensive web-based clinical knowledge management platform with integrated literature appraisal tools. Our platform has provided preliminary supportive evidence of enhancing reflective learning, knowledge gaps and needs assessment among healthcare professionals. A personal knowledge repository for lifelong self-directed learning would benefit all healthcare professionals. We plan to conduct a randomized clinical trial to assess the role of clinical pearl in providing granular insights about clinicians' daily clinical knowledge needs and its impact in enhancing self-directed learning activities and professional competence.

## **Temporal characteristics of effect size in the placebo arm of surgical randomized controlled trials - a meta-analysis.**

Karolina Wartolowska, Stephen Gerry, Benjamin Feakins, Gary Collins, Jonathan Cook, Andrew Judge, Andrew Carr  
*University of Oxford, Oxford, UK*

**OBJECTIVE:** To investigate how the response in the placebo arm of surgical randomised controlled trials (RCTs) changes with time.

**METHODS:** We used data from a systematic review of surgical trials published in 2014. We calculated effect size in the placebo arm as the Cohen's *d* standardised mean difference (SMD) between baseline and follow-up values. Trials were included into the analysis if the outcomes were continuous measures for which a SMD could be calculated. We performed a mixed effects meta-analysis incorporating within- and between-trial effects. We investigated temporal changes by looking at the effect of the timing and number of follow-up visits. This analysis was performed for all trials as well as after sub-grouping trials by the type of outcome (subjective, i.e. patient-reported symptoms; assessed, i.e. third-party-assessed signs; and objective, i.e. measured).

**RESULTS:** Across the 47 trials available for analysis, time ( $\beta=-0.0070$ , 95%CI -0.024, 0.010) and visit ( $\beta=-0.033$ , 95%CI -0.082, 0.017) did not significantly affect the magnitude of effect size in the placebo arm. For trials with subjective outcomes ( $n=31/47$ , 66%) the response was constant across time ( $\beta=-0.0042$ , 95%CI -0.024, 0.016) and visits ( $\beta=-0.029$ , 95%CI -0.089, 0.031). The response in trials with objective outcomes ( $n=10/47$ , 21%) diminished with time ( $\beta=-0.030$ , 95%CI -0.050, -0.010) with a non-significant effect of visit number ( $\beta=-0.099$ , 95%CI -0.30, 0.11). The effect of time and visit in trials with assessed outcomes was not significant; however, few studies ( $n=6/47$ , 13%) of assessed outcomes were available and there was substantial heterogeneity.

**CONCLUSION:** Time and visit number do not appear to significantly affect the magnitude of effect size in the placebo arm of trials with subjective outcomes, suggesting that it is constant throughout follow-up. In trials with objective outcomes there is a reduction in the effect with time.

**Regulation, Policy & Accountability - Lecture Theatre Two**  
**15:15 Wednesday June 21<sup>st</sup>**

## Quality and trustworthiness of clinical practice guidelines developed by Italian medical specialty societies: a cross sectional study

Antonino Cartabellotta<sup>1</sup>, Antonio Simone Laganà<sup>3</sup>, Primiano Iannone<sup>2</sup>, Walter Ricciardi<sup>2</sup>  
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The Italian Parliament has recently approved a law to link medical responsibility to clinical practice guidelines (CPGs) developed by medical specialty societies (MSS) and other organizations accredited by the MoH. However, in Italy a national guidelines program has really never taken off, there are hundreds of MSS with inadequate transparency on financial issues and competing interests and there is no evidence about quality and trustworthiness of their CPGs. For this reasons GIMBE funded and conducted this study to verify if Italian CPGs match Guidelines International Network (G-I-N) standards for developing CGPs (G-I-N 1) and for disclosure and management of conflicts of interest (COIs) (G-I-N 2). The study was endorsed by G-I-N and Italian National Institute of Health (NIH).

The study was developed in 5 step: 1) Identification of developers: in this first phase the study assessed CPGs developed by MSS. 2) Identification of CPGs through web sites of MSS. 3) Sample selection: CPGs published in 2015-2016. 4) Evaluation of adherence to G-I-N 1. 5) Evaluation of adherence to G-I-N 2.

80% of the identified MSS (322/403) were not eligible for lack of website (n. 6), lack of CPGs webpage (n. 289), CPGs webpage with restricted access (n. 14), and links to other CPGs developers (n. 13). 712 documents were retrieved: 359 (50,4%) were classified as CPGs; the remaining were not accessible files (n. 9), other types of documents (n. 71) and CPGs developed by other organizations (n. 273). 75/359 CPGs (21%) were included for final evaluation. According to G-I-N 1 standards the overall quality is adequate, except for disclosure of COIs available only for 17% of CPGs: for this reason the adherence to G-I-N 2 was not assessed. 42/75 evaluated CPGs were developed by 2 MSS only.

In Italy the law on medical responsibility relies a key role on CPGs, but our study shows that few CPGs developed by MSS are trustworthy. Therefore a governance revolution in CPGs development is recommended, with a pivotal role of the Italian NIH that should set priorities, avoid duplication, promote multi-professional and multi-disciplinary CGPs, standardize quality criteria and define strategies for managing COIs.

## How is musculoskeletal evidence embedded within NHS practice? Commissioners' perspectives

Jennifer Pearson<sup>1</sup>, Sian Jones<sup>2</sup>, Nicola Walsh<sup>1</sup>

<sup>1</sup>University of the West of England, Bristol, UK, <sup>2</sup>West of England Academic Health Science Network, Bristol, UK

**OBJECTIVE:** Over the last two decades there has been an exponential increase in musculoskeletal (MSK) research, in particular, research of physiotherapy interventions. However, there is a recognised and growing gap between what is known in terms of evidence and what is delivered in clinical practice. Notably, there is an increasing length of time between research that is proven to be effective and included in guidelines, with research that is embedded into routine care. NHS commissioning managers are directly involved in high-level service re-design, yet little is known about how these managers use evidence to support their decision making. This qualitative study aimed to explore how NHS commissioners in the West of England use evidence when commissioning MSK services.

**METHODS:** An online survey was distributed to NHS commissioning groups in three local Sustainability and Transformation Plan (STP) footprints (Bristol, North Somerset, South Gloucestershire, Gloucestershire, Wiltshire, Swindon and Bath & North east Somerset). Follow-

up semi-structured interviews were also conducted. Thematic analysis was used to analyse the qualitative data.

**RESULTS:** Commissioners across all CCGs within the boundary of the West of England were represented (n=10). Two of the respondents were GP clinical commissioners, and the remainder (n=8) were NHS commissioning managers (n=2) with professional clinical training. Several key themes emerged from the qualitative data analysis: complexity of the commissioning process; NHS pressures and competing demands; relevant and appropriateness of evidence for commissioning decisions; formal and informal mechanisms to support the use of research evidence; and undefined responsibilities and ownership of commissioning research evidence-based interventions.

**CONCLUSION:** NHS commissioners in the West of England contend with a range of complexities when commissioning MSK services. To support their decisions, they use a number of different evidence sources. For more evidence-based MSK research to be used researchers should provide NHS commissioners with meaningful contextual research supported by relevant cost utilisation evidence.

## **The benefits and harms of centrally-acting anti-obesity medicines**

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**OBJECTIVE:** To evaluate the evidence for benefits and harms in pivotal clinical trials used to gain marketing authorization for centrally-acting anti-obesity medicinal products.

**METHODS:** For this systematic review and meta-analysis we searched the EMA and FDA websites to identify pivotal phase III trials used to gain marketing authorizations between January 1995 and June 2016. Using the trial ID from the pivotal trials, we then searched PubMed and clinicaltrials.gov to identify the corresponding journal publications and trial registry results. We analysed the data using RevMan Software. We assessed the risk of bias using the Cochrane criteria and the quality of the evidence using the GRADE guidelines.

**FINDINGS:** We included five products (16 trials with 24,555 participants). Significantly more participants who took the anti-obesity products achieved a 5% or greater reduction in body weight: RR 2.39, 95% CI: 2.09 to 2.74,  $P < 0.00001$ , GRADE = low. However, the products significantly increased the risk of adverse events (RR 1.12, 95% CI 1.07 to 1.17,  $P < 0.00001$ , GRADE = very low) and the risk of discontinuation because of adverse events (RR 1.52, 95% CI 1.33 to 1.74,  $P < 0.00001$ , GRADE = low). There were no significant differences for most outcomes between currently approved and withdrawn products.

**CONCLUSIONS:** The evidence from pivotal trials of centrally-acting anti-obesity products, on which market authorizations are based, is of variable quality. The benefit-to-harm profiles of currently approved products are similar to those that have been withdrawn from the market because of harms. This suggests that regulatory authorities have inconsistently assessed the benefits and harms of these products.

## **The Obstetric Anaesthesia Dashboard: feeding back data to improve care.**

Asya Mussad  
University College London Hospital, London, UK

**INTRODUCTION:** The obstetric anaesthesia dashboard is a clinical performance and governance score card to monitor the implementation of clinical governance principles in

obstetric units. The dashboard benchmarks local activity and monitors performance against locally and nationally set standards on a three-monthly basis. In this way, the dashboard can act as a strategy map in measuring progress towards achieving set objectives.

**OBJECTIVES:**

1. Provides a summary of the cases done over 9 months which will demonstrate departmental performance in various areas and the workload in an easy to visualize traffic light system

2. To provide contemporary information about activity measures and quality indicators.

Methods:

Retrospective audit conducted on 2822 cases which included Labor analgesia and anaesthesia for procedures or surgery in Obstetric patients admitted between May 2016 to Jan 2016 at University College London Hospital, a tertiary care center for Obstetrics and Perinatology.

**RESULTS:** The criteria for the color coding are based on the standard literature review 1, 2, and 3.

The compilation of data in the Dashboard gave us an instant sight into the areas of improvement, to enhance our performance, improve patient experience and potentially reduce complications. The Dashboard may help to identify patient safety issues so that the service can be improved to ensure a high-quality patient- focused and safe maternity care.

**CONCLUSION:** The Anesthesia Dashboard is a real-time display of targets and achievements and an efficient method of analyzing anaesthetic interventions and the peri-operative complications. In addition to providing a display of performance against set standards, the visual indicators flagging problems, helps timely analysis and corrective measures thus improving the standards of anesthesia care. There are many benefits of this scorecard to both the department and patients by identifying requirements and allocating resources to deliver best patient care.

## **Management of interests in conflict: another live manifesto**

Jorge Ramírez<sup>2</sup>

*<sup>1</sup>Universidad del Valle(?), Cali, Valle, Colombia, <sup>2</sup>Public Servant(!), República de Colombia, Colombia*

Whistleblowing is about being cautious instead of impulsive; it is a learning process, you need to practice different tactics and strategies in non-controlled experimental settings; nevertheless, social networks instead of complex chaotic models are "chaordic organisations". I declared my conflicts of interests (COI) over two years ago,(1) this is a live manifesto of the efficient management of those conflicts by a whistleblower who is no longer an amateur in the art (téchnae) of backfire. Nevertheless, I have always doubts, and uncertainty in scientific or legal statements are a valuable asset in the world full of judgements but little or no interpretations whatsoever when it comes to human rights.

I decided to start studying the national and internal laws, and my focus did not include only the topic of whistleblowing legal actions.(2)

This abstract is also a living manifesto: I'll not only conform myself to defend my legitimate rights, but I'll also attack relentlessly, with a due legal process (i.e., respecting human rights, national and international laws) those who violate general rights of society on a daily basis, not only in Colombia but also everywhere.

I propose a combination of whistleblowing and literacy in penal laws as an effective backfire: advanced tactics and strategies - we need to evolve to changing and chaotic social networks of organised crime in healthcare systems. We need to think and act, not just locally but also in global transnational networks of imported and exported corruption; we have a real challenge among us.

Chaos theory is not about disorder but perhaps all the opposite, not necessarily a dichotomy in the middle of a massive delusion or debate.(3,4)

If we are going to fix evidence-based medicine (and medicine), it is imperative to backfire corruption in healthcare at the same time.

We need to apply principles of national and international laws and confront our language biases: medico-legal based evidence and justice (even by the punitive means: *ius Punendi*) to prevent crimes against patients and safeguard the welfare of society as a whole.

References (i.e., documentary legal evidence and open data)

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2. [https://chaoticpharmacology.wordpress.com/2015/02/26/whistleblowing-what-protection-do-employees-have-cc-univallecol-univalle\\_fsalud-mintrabajocol/](https://chaoticpharmacology.wordpress.com/2015/02/26/whistleblowing-what-protection-do-employees-have-cc-univallecol-univalle_fsalud-mintrabajocol/)
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## **Staff and patient perspectives about the use of a standardised care plan in an acute stroke unit. A mixed methods study.**

Anneli Schwarz

*Södra Älvsborgs Sjukhus, Borås, Sweden*

A gap is repeatedly reported between the knowledge about and the use of evidence in daily clinical work. Synthesising evidence based information is an important step in transferring knowledge to clinical practice, but there is limited knowledge about ways to identify and overcome difficulties in using this evidence within specific environments. This study aimed to identify aspects that influenced the use of a standardised care plan in an acute stroke unit, from the perspectives of staff and patients.

A sequential mixed-methods design was used. A retrospective chart review of electronic patient records was conducted to quantitatively audit reporting of activities in the standardised care plan. Within the case study of a Swedish stroke unit, professionals and patients were interviewed. Information from the chart review together with literature was used to design interview guides. Patients were interviewed about their perception of care based on results of the chart review. Professionals were interviewed about their perspectives, using information from the patients' perspective. A behavioural framework was used to aid interpretation.

Integrating multiple perspectives provided a deep understanding. Patients reported awareness of initial diagnostic testing and clinical monitoring, which was also frequently reported in electronic patient records. Patients expressed wanting to be involved in planning, but it was difficult to find information in the electronic records confirming that this actually took place. For activities where several professions could be responsible, notes in the electronic records were less frequently found. Professionals reported awareness of content of the standardised care plan as well as differences in performance and described room for development.

Patients strongly focused on having had a stroke, but the way in which professionals discussed this with patients was not reflected in the electronic records. This patient perspective could be used to motivate professionals to be more explicit about their delivery

of care. Professionals need organisational support to be capable and have the opportunity to fully use a standardised care plan.

## Evidence Synthesis / Other - Seminar Room Four 17:00 Wednesday June 21<sup>st</sup>

### Use of Cochrane online tools for teaching medical students - a case study from the Czech Republic

Jan Trnka, Martin Huncovsky  
*Third Faculty of Medicine, Charles University, Prague, Czech Republic*

Evidence-based medicine forms a basis for medical practice and should therefore be included in medical curricula.

**OBJECTIVE:** As a part of a course on methodology of biomedical research we used the Cochrane online applications (Crowd and Classmate) as tools to allow fourth year medical students to familiarise themselves on real abstracts with the various types of medical studies, their uneven quality and sometimes confusing reporting.

**METHODS:** After a series of lectures on various aspects of evidence-based medicine we asked the students to complete a set of assignments using the tools Cochrane Crowd (for RCTs identification) and Cochrane Classmate (for identifying other study designs and evaluating abstracts according to the CONSORT statement). Their successful fulfilling of these tasks was a part of the assessment for the course. Marks received (quantitative outcome) and a student survey given after the course (qualitative and quantitative outcomes) are both used to evaluate the relevance of the tools for the course and the clinical practice.

**RESULTS & CONCLUSION:** We will present our experience with these tools including quantitative outcomes such as pass rate, number of extra screened studies (above required minimum), self-reported understanding of EBM before/after the Cochrane tasks, self-reported feel of tasks' relevance for medical studies and clinical practice and self-reported language barrier issues.

### The Effectiveness and Feasibility of TREAT (Tailoring Research Evidence and Theory) Journal Clubs in Allied Health: A Cluster Randomised Controlled Trial

Rachel Wenke<sup>1</sup>, Rae Thomas<sup>3</sup>, Sharon Mickan<sup>1</sup>  
*<sup>1</sup>Gold Coast Health, Gold Coast, Queensland, Australia, <sup>2</sup>Griffith University, Gold Coast, Queensland, Australia, <sup>3</sup>Bond University, Gold Coast, Queensland, Australia*

**OBJECTIVE:** The present project aimed to investigate the effectiveness of a structured journal club that is Tailored According to Research Evidence And Theory (TREAT) in improving EBP skills and practice compared to a standard journal club format in allied health professionals. The study further aimed to explore the feasibility of implementing TREAT JCs in regards to clinician perceptions and satisfaction, and influence on clinical practice.

**METHODS:** We conducted an explanatory mixed methods study using a cluster randomised controlled design involving 126 allied health participants across 9 journal clubs. Each JC was randomly allocated to receive either the TREAT or standard format 1hr/month for 6 months.



We conducted pre-post measures of EBP skills, knowledge and attitudes using the self-report EBP questionnaire and the objective Assessing Competence in Evidence-Based Medicine tool. Post intervention, participants additionally completed a tailored satisfaction and practice change questionnaire, and TREAT participants were invited to attend a focus group to further explore their perceptions of the TREAT JC format.

**RESULTS:** A total of 81 staff completed pre-post outcome measures. There were no significant differences in changes to EBP skills, knowledge, attitudes or practice between the TREAT and standard format, however significantly greater satisfaction with the organisation of the TREAT format ( $p=0.01$ ) and desire to continue this format ( $p=0.04$ ) was found. Participants from both groups reported the JC having a positive influence on their clinical practice. Qualitative data indicated that participants perceived benefits to the TREAT format and facilitating mechanisms were reported including the use of an academic facilitator, group appraisal approach and structured appraisal tools.

**CONCLUSIONS:** The study identified some key evidence-based components that are able to be feasibly implemented within a regular allied health JC and enhance clinicians' satisfaction with their existing JC. While these components were reported to be valued by clinicians, they did not significantly improve individuals' EBP skill, attitude, knowledge and/or practice compared to the standard journal club format. Future research may need to consider integrating JCs as part of a multi-faceted EBP approach to enhance outcomes.

Trial registration: ACTRN12616000811404

## **Performing eLearning systematic reviews: lessons from a global initiative on digital health professionals' education**

Pawel Posadzki, [Lorraine Tudor Car](#)  
*LKC Medicine, Nanyang Technological University, Singapore, Singapore*

**OBJECTIVES:** To present and discuss lessons learned from a series of (Cochrane) systematic reviews on the use of different eLearning modalities for health professionals' education.

**METHODS:** Digital education (i.e. eLearning) holds promise of enhancing health professionals' education worldwide. To support evidence informed decision-making in health education, our group set out to systematically analyse the literature on the effectiveness of eLearning in health professionals' education. For the past 2.5 years, our global research initiative, bringing together methodological and content expertise from several international institutions, has been undertaking over 10 (Cochrane) systematic reviews. Evidence has been gathered on pre- and in-service health professional in the areas of networked and non-networked computer based education, immersive virtual reality environments, virtual patient simulations, psychomotor skills trainers, digital game based learning, MOOCs and mLearning. We aimed to evaluate the impact of eLearning on different outcomes such as learners' knowledge, skills, attitudes, satisfaction, patient outcomes, costs effectiveness etc. We have created a comprehensive database of more than 100,000 eLearning research papers containing a subset of around 2800 eLearning randomised trials.

**RESULTS:** In most reviews, the included studies comprise a range of different interventions, controls, outcomes, and outcome measures leading to high heterogeneity and precluding an overall meta-analysis. Evidence was mostly judged as low quality due to high or unclear risk of bias, inconsistency, indirectness, imprecision, and publication bias. The included studies were largely from high-income countries and many were poorly reported in terms of the intervention content, the employed learning theory, and the control group. There was often

a lack of baseline evaluation, outcome measure validity information, patient-focused or economic outcomes etc.

**CONCLUSIONS:** Our group aims to drive the field of digital health education forward and tackle the outlined gaps in the literature by developing reporting standards for eLearning studies, reviewing validity of the existing eLearning outcomes measures and designing an eLearning economic analysis framework.

## **Safety in Surgery: the effect of an early warning system and co-management on surgical mortality**

Ronald Kaleya, [Joel Horovitz](#), Gene Sobol, Sameh Samy, Hannah Bodenstein, Patrick Borgen  
*Maimonides Medical Center, Brooklyn, New York, USA*

**OBJECTIVE:** to assess the effect of an early warning system (EWS) with automated algorithmic escalation to experienced providers on surgical mortality.

**METHODS:** We implemented a preemptive intervention system on the surgical ward using vital sign devices that calculated EWS score and wirelessly uploaded the data to the hospital EMR. The system algorithmically alerted high level providers in real-time with built in redundancy. Full time internists co-managed the medical comorbidities of the surgical patients. The effector limb of the system included smartphones with VOIP capability. A EWS of < 3 was observed; a EWS of 4-6 resulted in the RRT nurse clinician and the hospitalist being notified. A EWS of 6 or greater alerted the ICU nurse manager, ICU attending and the chief resident.

All EWS data were integrated seamlessly into the EMR.

We compared 2 consecutive years of EWS data for the purposes of the study. Escalation criteria were changed from a EWS of 5 (2015) to a EWS of 4 (2016).

**RESULTS:** Overall, we monitored 5675 patients in 2015 and 5779 patients in 2016. The primary endpoint of the study was mortality. Raw mortality rate was calculated over 2 consecutive years (2015 and 2016) and showed a decrease in mortality of patients with a EWS score of 4 from 5.7% to 2.58% (45% risk reduction)

<b>Mortality</b>	<b>2015</b>	<b>2016</b>
<b>EWS 4</b>	<b>5.70%</b>	<b>2.58%</b>
<b>EWS 5</b>	<b>10.1%</b>	<b>3.90%</b>
<b>EWS 6+</b>	<b>14.29%</b>	<b>8.77%</b>
<b>Overall</b>	<b>6.95%</b>	<b>3.30%</b>

All higher EWS scores also decreased their mortality rate as well. New York State risk-adjusted failure to rescue over the same time period decreased from an observed/expected ratio of 1.02 to 0.70, a decrease of 30%.

### **CONCLUSIONS:**

- 1) Surgical mortality was reduced by integrating a pre-emptive automated EWS, medical co-management and real-time escalation to experienced providers.
- 2) Failure to rescue (risk adjusted) has decreased significantly in the same time period (compared to the New York State average).

## **Using flawed, uncertain, proximate and sparse (FUPS) data in child mental health**

Miranda Wolpert  
UCL, London, UK

**OBJECTIVE:** The future of healthcare quality is anticipated to involve increasing scrutiny of routinely collected data from across healthcare settings. The aspiration is that such data can be used to establish benchmarks for quality assurance and underpin the evaluation of quality improvement initiatives (Keogh 2013, Coulter et al 2014). However, in reality such datasets are often flawed, due to missing or erroneously recorded data; uncertain, due to differences in how data items rated and/or variation in case-mix; proximate in that the data items are always a proxy for an indication of the impact of the service provided and sparse in that even within complete data sets the low volume of cases within a given subgroup often limits the applicability of statistical inference, making the data complex to interpret and use. This workshop seeks to explore the best use of such data drawing on real world examples from child mental health.

**METHOD:** This paper draws on the experience in the collection and use of such data in child mental health by the Child Outcomes Research Consortium (CORC), a service provider-researcher collaboration that has pioneered collecting such complex and messy real world data for the last decade .

**RESULTS:** The paper draws in particular on the recent analysis of routine data on self-reported outcomes achieved by children attending specialist mental health services 2011-15 (Wolpert et al 2016). Analysing a dataset of just under 8000 cases with paired outcomes: 1 in 3 children reported "recovery" (moving across threshold), 1 in 2 reliable improvement (scores improved more than likely due to measurement error) and 1 in 10 reliable deterioration. .

**CONCLUSION:** This workshop presents an approach to use of such FUPS data to support meaningful dialogue between service users, providers and funders. In particular rules for analysis of FUPS data are outlined including; the need provide accessible descriptive analyses first and foremost, avoiding "black box" statistical analysis wherever possible, together with specific guidance on how to consider undertaking quality improvement based FUPS data in the form of facilitated stakeholder discussions to support all those involved to challenge their own and colleagues' confirmatory biases.

## **Communicable disease mortalities trend in a University Hospital in Ghana – 37 year review of routine data**

Gloria Ansa<sup>1</sup>, Edward Sutherland<sup>1</sup>, Frank Baiden<sup>3</sup>, Afua Amoabeng<sup>1</sup>, Enoch Quaye<sup>2</sup>, Christian Amenuveve<sup>1</sup>

<sup>1</sup>University of Ghana Hospital, Legon, Accra, Ghana, <sup>2</sup>University of Ghana, Legon, Accra, Ghana, <sup>3</sup>Ensign College of Public Health, Kpong, Ghana

We conducted a cross-sectional and temporal analysis of the causes of death from 1979 to 2015, and the objective of this paper was to describe the mortality trends due to HIV/AIDS, Malaria and tuberculosis.

Secondary data from the institution's medical cause of death certificates was extracted. Diseases were grouped into three main categories and analysed by age, gender and time in years using SPSS.

Of 3263 deaths 35.6% were from communicable diseases, and 41.9% of all the deaths were in females. Although non-communicable diseases (NCDs) accounted for 60% of deaths, communicable diseases were the commonest cause of death between ages 10-39 years. More males (58%) died from communicable diseases than females (42%). Malaria accounted for 4.5% of all deaths with 71.6% of these occurring in the children below 10 years. Deaths due to malaria reduced from 7.6% in 1979-85 to 0.5% in 2011-15. Tuberculosis also accounted for 1.7% of all deaths with 58.2% of these occurring between 30 and 79 years.

HIV accounted for 7.2% of all mortalities over the period with majority of these occurring among 20 - 49 year olds. HIV mortalities were first recorded in the 1996-2000 period when HIV accounted for 3.8% of all deaths; this increased to 17.8% in the 2011-15 period. Females accounted for 52.8% of all HIV deaths as compared to 48.6% and 23.6% of deaths due to malaria and TB respectively. And HIV accounted for 9.1% of all female deaths as compared to 5.9% of all male deaths.

Although a significant shift from communicable to NCDs was observed, findings of the study depict a dual burden of diseases as observed in other developing economies. There has been a significant decrease in deaths due to malaria especially among children, attesting to the effectiveness of prevention and control strategies. However HIV and TB are the significant drivers of communicable disease mortalities among the active workforce in Ghana. It is therefore essential that while strategies are consolidated to maintain the success of malaria control towards elimination, additional contextual research is supported to address the barriers to effective HIV and TB control.

## **Why do authors derive new cardiovascular clinical prediction rules in the presence of existing rules? A mixed methods study**

Jong-Wook Ban<sup>1</sup>, Emma Wallace<sup>2</sup>, Richard Stevens<sup>3</sup>, Rafael Perera<sup>3</sup>

<sup>1</sup>Evidence-Based Health Care Programme, Centre for Evidence-Based Medicine, University of Oxford, Oxford, UK, <sup>2</sup>HRB Centre for Primary Care Research, Royal College of Surgeons in Ireland, Dublin, Ireland, <sup>3</sup>Nuffield Department of Primary Care Health Sciences, Medical Science Division, University of Oxford, Oxford, UK

**BACKGROUND:** Researchers should examine existing evidence to determine the need for a new study. It is unknown whether developers evaluate existing evidence to justify new cardiovascular clinical prediction rules (CPRs).

**OBJECTIVE:** We aimed to assess whether authors of cardiovascular CPRs cited existing CPRs, why some authors did not cite existing CPRs, and why they thought existing CPRs were insufficient.

**METHOD:** Derivation studies of cardiovascular CPRs from the International Register of Clinical Prediction Rules for Primary Care were evaluated. We reviewed the introduction sections to determine whether existing CPRs were cited. Using thematic content analysis, the stated reasons for determining existing cardiovascular CPRs insufficient were explored. Study authors were surveyed via e-mail and post. We asked whether they were aware of any existing cardiovascular CPRs at the time of derivation, how they searched for existing CPRs, and whether they thought it was important to cite existing CPRs.

**RESULTS:** Of 85 derivation studies included, 48 (56.5%) cited existing CPRs, 33 (38.8%) did not cite any CPR, and four (4.7%) declared there was none to cite. Content analysis identified five categories of existing CPRs insufficiency related to: (1) derivation (5 studies; 11% of 44), (2) construct (31 studies; 70%), (3) performance (10 studies; 23%), (4) transferability (13 studies; 30%), and (5) evidence (8 studies; 18%). Authors of 54 derivation studies (71.1% of 76 authors contacted) responded to the survey. Twenty-five authors (46.3%) reported they were aware of existing CPR at the time of derivation. Twenty-nine authors (53.7%) declared they conducted a systematic search to identify existing CPRs. Most authors (90.7%) indicated citing existing CPRs was important.

**CONCLUSION:** Cardiovascular CPRs are often developed without citing existing CPRs although most authors agree it is important. Common justifications for new CPRs concerned construct, including choice of predictor variables or relevance of outcomes. Developers should clearly justify why new CPRs are needed with reference to existing CPRs to avoid unnecessary duplication.

## **When research meets practice: methodology for eHealth studiesA white paper from the international eHealth methodology working group**

Tobias Bonten<sup>1</sup>, [Anneloek Rauwerdink](#)<sup>2</sup>, Wouter Spoelman<sup>1</sup>, Heleen Riper<sup>4</sup>, Lisette Van Gemert-Pijnen<sup>5</sup>, Leonard Witkamp<sup>3</sup>, Jeremy Wyatt<sup>6</sup>, Marlies Schijven<sup>2</sup>, Niels Chavannes<sup>1</sup>  
<sup>1</sup>Department of Public Health & Primary Care, Leiden University Medical Center, Leiden, The Netherlands, <sup>2</sup>Department of Surgery, Academic Medical Centre, Amsterdam, The Netherlands, <sup>3</sup>Department of Medical Informatics, Academic Medical Center, Amsterdam, The Netherlands, <sup>4</sup>Department of Psychiatry, VU University Medical Centre and EMGO+ Institute for Health Care and Research, Amsterdam, The Netherlands, <sup>5</sup>Department of Psychology, Health and Technology, Centre for eHealth and Wellbeing Research, University of Twente, Twente, The Netherlands, <sup>6</sup>Institute for Digital Health Care, Warwick University, Warwick, UK

**BACKGROUND:** Since the earliest ages of health sciences, randomized controlled trials (RCTs) have been considered the most ideal design with robust scientific evidence to study causal effects of medical intervention strategies. But since the rise of eHealth, researchers struggle how to empirically establish the efficacy of these interventions. Defining an adequate control group, blinding of the subjects and time limitations of a study in contrast to the continuously evolving technologies are challenges one will encounter in this novel field of research. To provide society with robust scientific evidence about new technologies and treatment strategies, new and innovative research methods are required.

**OBJECTIVE:** This white paper aims to enable the researcher to determine which research design is applicable at the specific developmental stage of its research.

**METHODS:** To collect data a mixed methods design in three phases will be performed. The first phase consisted of a systematic review of literature on eHealth research methodologies. In the second phase the results from phase one will be discussed with the experts of the international eHealth methodology working group. Through a concept mapping method the experts will be enabled to systematically elaborate on the results of the first phase. The goal of the third phase is to get insights into the usability of the results. Therefore a questionnaire will be distributed among a group of at least 200 researchers. Finally, a decision tree will be developed to assist researchers in their choice for a research design in everyday practice.

**RESULTS:** In the first phase 34 articles were selected for inclusion into the white paper. Papers presented information about study designs such as controlled simulation study, quasi-experimental design, normalization process theory, Bayesian design, single case experiment,

real-world evidence, micro-randomized trial, conceptual models, logfile analysis, rapid review, heuristic evaluation, stepped-wedge design, CeHRes roadmap and many more. The second phase will start April 2017.

**CONCLUSIONS:** Preliminary results of this white paper showed useful eHealth study designs, that could serve as alternatives for the classic RCT design. Also insights into when in the 'eHealth developmental research life cycle' which specific design should be applied, were found in literature.

## **Impact of obesity on outcomes in breast reconstruction: a systematic review and meta-analysis**

Adriana C. Panayi<sup>1</sup>, Riaz A. Agha<sup>2</sup>, Brady A. Sieber<sup>3</sup>, Dennis P. Orgill<sup>3</sup>

<sup>1</sup>University of Cambridge, Cambridge, UK, <sup>2</sup>Guy's and St. Thomas' NHS Foundation Trust, London, UK, <sup>3</sup>Harvard Medical School, Boston, USA

**BACKGROUND:** Increased rates of both breast cancer and obesity have resulted in more women seeking breast reconstruction. Studies demonstrate that these women are at increased risk for perioperative complications. A systematic review was conducted to assess the outcomes in obese women who have undergone breast reconstruction following mastectomy.

**METHODS:** Cochrane, PUBMED and EMBASE electronic databases were screened and data was extracted from included studies. The clinical outcomes assessed were surgical complications, medical complications, length of postoperative hospital stay, reoperation rate and patient satisfaction.

**RESULTS:** 33 studies met the inclusion criteria for the review and 29 provided enough data to be included in the meta-analysis (71368 patients, 20061 of which were obese). Obese women were 2.3 times more likely to experience surgical complications (95 percent CI 2.19 to 2.39; P < 0.00001), 2.8 times more likely to have medical complications (95 percent CI 2.41 to 3.26; P < 0.00001) and had a 1.9 times higher risk of reoperation (95 percent CI 1.75 to 2.07; P < 0.00001). The most common complication, wound dehiscence, was 2.5 times more likely in obese women (95 percent CI 1.80 to 3.52; P < 0.00001). Sensitivity analysis confirmed that obese women were more likely to experience surgical complications (RR 2.36, 95% CI 2.22–2.52; P < 0.00001).

**CONCLUSIONS:** This study provides evidence that obesity increases the risk of complications in both implant and autologous reconstruction. Additional prospective and observational studies are needed to determine if weight reduction prior to reconstruction reduces the perioperative risks associated with obesity.

## **Routine Data - Seminar Room One**

**11:30 Thursday June 22<sup>nd</sup>**

## **Risk of Major Lower Limb Amputation Following Revascularisation: Findings from Hospital Episode Statistics in 2005-2013**

Katriina Heikkilä<sup>1</sup>, Ian M. Loftus<sup>3</sup>, David C. Mitchell<sup>4</sup>, Amunddeep Johal<sup>2</sup>, Sam Waton<sup>2</sup>, David A. Cromwell<sup>2</sup>

<sup>1</sup>London School of Hygiene and Tropical Medicine, London, UK, <sup>2</sup>Clinical Effectiveness Unit,

Royal College of Surgeons of England, London, UK, <sup>3</sup>St George's Vascular Institute, St George's NHS Trust, London, UK, <sup>4</sup>Southmead Hospital, North Bristol NHS Trust, Bristol, UK

**OBJECTIVES:** Our aim was to estimate separate risks of major lower limb amputation and death following infrainguinal lower limb revascularisation for peripheral arterial disease (PAD) and to investigate how patient-level factors modify this risk.

**METHODS:** We used data from Hospital Episode Statistics (HES) to identify patients who underwent infrainguinal endovascular or surgical lower limb revascularisation in English National Health Service (NHS) hospitals in 2005-2013. Primary outcomes were subsequent major lower limb amputation (identified from HES) and death (ascertained from the national death register). Cox proportional hazards and Fine-Gray competing risks regression were used to examine the associations of patient characteristics with the competing risks of major lower limb amputation and death. The latter approach allows estimating the cumulative incidence of each outcome independently.

**RESULTS:** In all, 92,533 patients underwent lower limb revascularisation for PAD in 2005-2013. Most patients were men (63.2%) and the median age was 72 years. Eight-year cumulative incidence of amputation following endovascular revascularisation ranged from 7% in patients with intermittent claudication to 31% in those with severe limb ischaemia. The same estimates ranged from 7% to 35% after open artery repair, and from 19% to 36% after leg bypass. Eight-year cumulative incidence of death following endovascular and open repair varied from 30% to 51%. Competing risks methods consistently produced lower estimates than traditional methods.

**CONCLUSIONS:** Our findings suggest that the risk of amputation following infrainguinal lower limb revascularisation for PAD is lower than previously estimated, increasing steadily over the eight-year follow-up, up to 30-36% in patients with the most severe disease. As far as we are aware, ours is the first investigation to use competing risks methods to estimate the risks of amputation and death after lower limb revascularisation in England. Our findings highlight the importance of using appropriate analytical methods to reflect the clinical situation, and of producing interpretable findings, such as the cumulative incidence, which can be interpreted as separate risks of amputation and death. Based on a large set of routinely collected data, our observations are informative of patient outcomes following revascularisation during a period of reconfiguration of vascular services in England.

## **National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme research funding and UK burden of disease: a cross-sectional study**

Fay Chinnery<sup>1</sup>, Gemma Bashevoy<sup>2</sup>, Amanda Blatch-Jones<sup>1</sup>, Lisa Douet<sup>2</sup>, Sarah Puddicombe<sup>2</sup>, James Raftery<sup>1</sup>

<sup>1</sup>Wessex Institute, Southampton, UK, <sup>2</sup>NETSCC, Southampton, UK

**OBJECTIVE:** To compare the NIHR HTA Programme portfolio of research with the UK burden of disease as measured by Disability-Adjusted Life Years (DALYs).

**DESIGN:** Cross-sectional study.

**SETTING:** A cohort of all funded projects received by the HTA Programme from April 2011 to March 2016 (n=363).

**MAIN OUTCOME MEASURE:** Proportion of spend by disease were compared with burden of disease in the UK calculated using 2015 DALY data.

**RESULTS:** The just under £400m programme broadly reflected UK DALY burden by disease. Spend was lower than disease burden for cancer, cardiovascular and musculoskeletal diseases, which may reflect the importance of other, notably charity, funding.

**CONCLUSION:** HTA Programme spend, adjusted for other relevant funders, broadly matches disease burden in the UK.

## **Money for Nothing: The Evolution of COPD Treatment in Canada**

Jamie Falk, Kevin Friesen, Shawn Bugden  
*University of Manitoba, Winnipeg, Manitoba, Canada*

**OBJECTIVE:** A large number of RCTs have demonstrated modest incremental benefit gained in patient-relevant outcomes with the addition of further Chronic Obstructive Pulmonary Disease (COPD) medications to basic short-acting bronchodilators. In the case of the addition of inhaled corticosteroids (ICS) to long-acting beta-agonists (LABA), harm in the form of pneumonia increases significantly. To address a potential benefit-burden imbalance, we sought to compare the evolving evidence base and clinical practice guideline recommendations against real-world medication choice and the resulting cost per patient of COPD medications over time in a population-based cohort study.

**MRTHODS:** A population-based cohort study of COPD patients was conducted using data from April, 1997 to the end of March, 2014. Cases of COPD and medication use were analysed using administrative healthcare data from the Manitoba Population Research Data Repository. Prescriptions for medications used to treat COPD in this cohort were used to determine annual rates of utilization, total cost, and mean treatment cost per person-year, for each year in the study period. Utilization and costs were further assessed after stratification by drug class.

**RESULTS:** In our cohort of 18,162 patients, there was a 198% increase in mean total medication cost/person/year observed from 1997 to 2013. Contrary to current guideline recommendations, ICS medications were dispensed as the first medications in 28.2% of patients. The combination of ICS-LABA accounted for the vast majority of the cost increase. Although the mean actual patient cost per inhaler remained constant over the study period for all inhaler groups, the total cost of ICS-LABA rose sharply through the study period, making up 54.4% of all medication costs in 2013. Costs attributed to tiotropium also increased substantially over the study period, accounting for 20.7% of total costs in 2013. Short-acting bronchodilator costs peaked in 2006 and declined thereafter.

**CONCLUSIONS:** A dramatic increase in COPD inhaler costs per patient occurred over time despite clinical trial demonstration during this period of only modest improvements in patient-relevant outcomes with added medications. Despite this and the noted harms also attributed to ICS, the combination of ICS and LABA was the overwhelming primary cost driver.

## **An automated approach to analysing and visualising patient experience survey freetext comments to drive service improvements - Present Study: Development and Proof of Concept with patients and health care professionals**

Daria Tkacz, Sydney Anstee, Carol Rivas  
*University of Southampton, Southampton, UK*



**BACKGROUND:** Despite their value, patient experience freetext comments are inconsistently used due to being costly and time consuming to analyse. We used the Cancer Patient Experience Survey (CPES, generates 70,000+ freetext comments annually) to develop a novel approach involving text analytics 'knowledge engineering'. This uses natural language processing (NLP) to analyse unstructured and ungrammatical content of freetext. We then developed a linked '**dashboard**' display to summarise comments in themes. We have collaborated widely with patients and health care professionals (HCPs), in cancer and other conditions, to design, test and further adapt the dashboard.

**METHODS:** We ran 5 focus groups (n = 34) with patients and HCPs to gather views on their preferences for patient and professional facing versions of the dashboard. We observed different types of NHS managers (n=15) in three NHS localities (Wessex, London, Leeds) as they engaged in a Structured Walkthrough of our dashboard. The interview used standard usability principles, tested for role relevant tasks, and asked implementation questions using Normalisation Process Theory. Qualitative data gathered from focus groups and interviews was thematically analysed and used immediately throughout the development and adaption processes.

**RESULTS:** Consultations with patients and professionals has ensured collaborative development and transferability to other health areas. A final dashboard has been produced ready for practice or further definitive study. There was agreement amongst all involved that this system addresses an important gap in how to efficiently use patient freetext comments. Our manualised dashboard provides a transferable, faster, stakeholder-centric, resource-efficient way of analysing patient experience than current methods.

**IMPLICATIONS:** Our system can be used to inform and drive healthcare improvements. As immediate benefit, results from our test CPES dataset can be used to reduce continued variations across Trusts in cancer care. Other health surveys could use this system to provide useful feedback of patient experience comments.

## **Applied Data Intelligence for Clinicians – Scotland's unique tools for delivering better healthcare**

Joy Ngai, Mahmood Adil  
*NHS National Services Scotland, Edinburgh, Scotland, UK*

Established healthcare systems routinely collect huge amount of health data. Such data are traditionally seen as the realm of management and its uses to engage clinicians in delivering better healthcare outcomes is usually very patchy.

Chronic disease epidemic, increasing elderly population, new technologies and financial pressure in the UK and other countries globally have challenged us to take the opportunity to think innovatively about the use of routinely collected data to support clinicians to champion evidence based medicine.

Information Services Division (ISD) for Scotland routinely collect over 200 national datasets covering all aspects of health of the 5.2 million population. Everyone who lives in Scotland has a unique 'Community Health Index (CHI)' number – an idea adopted from Scandinavian countries almost 50 years ago. This gives Scotland a huge advantage in linking all datasets and converting them into applied intelligence to provide clinicians, researchers, policy makers, managers and the public with evidence based decision making capability. In addition, the unique identifier has made it possible to combine routinely collected healthcare data with local authority social care data to allow analysis and creation of an

evidence base across the breadth of care pathways. The potential of such rich data sources provides new opportunities to produce applied intelligence for quality improvement according to evidence based practice.

However, generating applied intelligence using large routinely collected data sets in this way require clinical engagement from the outset to ensure the resulting intelligence is clinically relevant. We have developed unique data tools in Scotland to bring clinicians and managers together through shared understanding and application of intelligence for delivering value (better outcomes with less or same resources) and evidence based clinical quality decision making.

Our presentation will reflect Scotland's journey from health data to intelligence, and introduce key health intelligence tools based on the routinely collected data that promote evidence based decision making in the NHS, which may be of benefit to other countries and healthcare settings. It will also highlight the work being done to engage clinicians to improve the quality of those data sets, so they can be reliably used in clinical practice.

## **Measuring low-value care in Australian routinely collected health data**

Kelsey Chalmers<sup>1</sup>, Sallie Pearson<sup>3</sup>, Adam Elshaug<sup>1</sup>

<sup>1</sup>The University of Sydney, Menzies Centre for Health Policy, Sydney, Australia, <sup>2</sup>Capital Markets Cooperative Research Centre, Health Quality Program, Sydney, Australia, <sup>3</sup>University of New South Wales, Medicines Policy Research Unit, Centre for Big Data Research in Health, Sydney, Australia, <sup>4</sup>Senior Fellow, Lown Institute, MA, USA

**OBJECTIVE:** To estimate the proportion and costs of low-value health care, as defined by Choosing Wisely recommendations, for Australian patients.

**METHODS:** Australian health data is siloed due to the existence of multiple payers, so capturing the extent of low-value care across the entire system is difficult. Our team is bridging these siloes, using data on hospital services provided for publicly and privately funded patients, as well as publicly funded pharmaceuticals. Our aim is to develop indicators for inappropriately used services at the patient-level for use in these routine data collections.

This presentation will focus on Hospital and Medical Benefits System supplied private health insurance (PHI) claims for in-patient admissions between 2009 and 2010. This represents approximately 10% of privately insured Australians. Choosing Wisely recommendations were selected if the service is funded by PHI. Recommendations were then excluded if appropriate and inappropriate care was not distinguishable within the data. Measures of low-value care based on these recommendations were developed using clinician and coder feedback.

**RESULTS:** Direct measures for fifteen low-value measures were developed from 17 recommendations, after excluding 811 recommendations that could not be measured in the data.

There were 1.3 million admissions in the data. The percentage of services inappropriately used ranged from 0.74% (colonoscopy for patients with constipation) to 79.34% (knee arthroscopy for osteoarthritis or meniscal tear patients). The percentage of patients receiving inappropriate care ranged from less than 0.5% (pre-discharge echocardiogram after cardiac valve replacement) to 2.95% (patients receiving open rather than laparoscopic bariatric procedures). The total Australian government contribution to these services in 2014 was at least \$2.2 million (AUD).

**CONCLUSIONS:** Investigating low-value care within a system is possible using routinely collected data, although limited by the clinical information not recorded. This work builds

actionable data on overuse to determine the scale and scope of the problem of overuse, and provides indicators for ongoing measurement to track progress towards remedying high-value care.

## Informed Decision Making - Seminar Room Two

### 11:30 Thursday June 22<sup>nd</sup>

#### Shared decision making in veterinary and human medicine - a comparison

Mary Fraser

*Vets Now Ltd, Dunfermline, UK*

Shared decision making in the NHS brings together patients, clinicians and carers to decide on an informed programme of treatment for an individual. Veterinary medicine has many similarities to human medicine but also many unique challenges which will be examined here.

Animals cannot decide on their own course of treatment with vets required to work with owners as their proxy, taking on board the needs of both the animal and owner; in law animals are regarded as property rather than sentient beings; owners are required to pay for veterinary treatment; and finally, euthanasia is regarded as a treatment option when working with animals. Veterinary clinicians therefore must be skilled to bring together the wishes of the owner (emotionally and financially), animal welfare and their own moral compass (Billeschou, *et al*, 2016)

Good communication skills are essential for both veterinary and human medical practitioners - both requiring informed consent from patients / owners (Coe *et al*, 2008). Owners may ask vets for advice about what to do, with 'What would you do if this was your animal?' being a familiar question. Whether to influence owners or maintain an independent viewpoint will depend on the individual vet / veterinary nurse. Robinson *et al* (2017) demonstrated that in a review of cases, a third did not make a decision on treatment.

With the NHS, standard operating procedures are in place for more common practices. The concept of SOPs within veterinary medicine has so far been resisted with many members of the profession regarding it as a threat to their clinical decision making.

Euthanasia is an added challenge to veterinary practitioners. It can be regarded as a positive experience to end suffering, but where euthanasia is not the wish of the veterinary team, it can cause barriers and upset. Quality of life is difficult to assess in veterinary medicine, relying mainly on behavioural assessments (Haug, 2011; Reid, 2017). With the increase in the provision of veterinary hospice care, shared decision making is becoming more important within the profession.

In conclusion, much could be learnt from both human and veterinary perspectives.

#### Assessing Information Seeking Skills of Medical Students to Improve Evidence-based Practice Curriculum

Nicole Capdarest-Arest, Henry C. Lee, Jamie M. Gray  
Stanford School of Medicine, Stanford, CA, USA

**OBJECTIVES:** At Stanford School of Medicine (SOM), medical students receive instruction in evidence-based practice (EBP) and information fluency (IF). This content is covered as a thread in the Practice of Medicine course and pediatric clerkship, resulting in four sessions. With such limited instructional time, course instructors and education administration desired to assess skills of incoming students in these areas to determine existing knowledge and readiness for the EBP curriculum. A pre-assessment was developed and delivered to all incoming students in the fall of 2016 and responses reviewed by EBP/IF instructors. This session reports on findings from the pre-assessment, which may be useful to other EBP/IF instructors.

**METHODS:** A 7-question online assessment was developed by course instructors and delivered to students via the course management system. Responses were reviewed and evaluated using descriptive statistics and qualitative description to inform curriculum design, curriculum revision and assessments.

**RESULTS:** Students (N=123) had a wide variety of educational backgrounds, with some already having completed another graduate degree (n=23). Regarding search and information management mechanics, all but one student was able to identify a biomedical/research database for searching for scholarly information. Approximately half the students were familiar with citation management tools and over 70% were familiar with Boolean operators. Twenty-five percent were already familiar with the 5 A's of EBP. Regarding potential gaps in EBP/information skills for clinical care, popular responses centered around introduction to reliable resources for clinical decision making, how to craft more efficient literature searches, finding information geared toward patients, and strategies for keeping up to date with the literature and results from clinical trials.

**CONCLUSION:** Responses indicate that due to the rising familiarity of incoming students with Internet searching in general, EBP/IF instructors can streamline instruction in techniques such as Boolean searching and craft curriculum that is geared toward introduction of the biomedical evidence landscape (e.g., which resources to use for various types of information needs), information appraisal skills, and the connection between EBP and shared decision-making. Allotted EBP curricular time in medical school can be scaffolded off of pre-existing knowledge to advance evidence-seeking skills in the clinical and research context.

## **Individualized effects for Well Informed Shared Decision Making for Atrial FIBrillation thromboembolic prophylaxis: WISDM for A FIB**

Brian Alper<sup>1</sup>, Peter Oettgen<sup>1</sup>, Marie-Anne Durand<sup>2</sup>, Arianna Blaine<sup>1</sup>, Judy Erkmann<sup>1</sup>, Meghan Malone-Moses<sup>1</sup>, Glyn Elwyn<sup>2</sup>  
<sup>1</sup>DynaMed Plus, EBSCOHealth, MA, USA, <sup>2</sup>Dartmouth College, Hanover, NH, USA

**OBJECTIVE:** We systematically determined the evidence needed for informed shared decision making for selecting treatments for stroke prevention in atrial fibrillation, and produced a tool to make it easy to use.

**METHODS:** We used DynaMed systematic literature surveillance to identify meta-analyses and randomized trials for eight options. For aspirin and warfarin, we extracted relative risk estimates compared to no treatment for ischemic stroke and for major bleeding. For clopidogrel plus aspirin, we extracted relative risk estimates compared to aspirin. For all other options, we extracted relative risk estimates compared to warfarin. We selected CHA<sub>2</sub>DS<sub>2</sub>-Vasc and HAS-BLED scores as the most accurate predictors for individual risks for embolic

stroke and major bleeding, and developed an interactive form to view an individual's estimated annual risk of embolic stroke and major bleeding with selected treatment options. We used Option Grid methods to present the results for patient use for shared decision making support.

**RESULTS:** See [www.WISDMforAFIB.com](http://www.WISDMforAFIB.com) for an online tool providing clinician-facing and patient-facing information. The tool includes best estimates for relative risks of ischemic stroke and major bleeding with each option, expression of absolute risks and number needed to treat or harm for clinicians, and for patients these concepts are expressed in numbers per 1000 people.

**CONCLUSION:** Use of WISDM for A FIB can provide accurate, individualized estimation of benefits (in terms of embolic stroke prevention), harms (in terms of major bleeding and other complications), and burdens (descriptions of use of the treatment) to facilitate shared decision-making.

## **Right For Me: Results of a Cluster Randomised Controlled Trial of Two Interventions for Facilitating Shared Decision-Making about Contraceptive Methods**

Rachel Thompson<sup>1</sup>, Kyla Donnelly<sup>1</sup>, Ruth Manski<sup>1</sup>, Gabrielle Stevens<sup>1</sup>, Daniela Agusti<sup>1</sup>, Michelle Banach<sup>2</sup>, Maureen Boardman<sup>1</sup>, Pearl Brady<sup>2</sup>, Chrissy Colón Bradt<sup>2</sup>, Tina Foster<sup>3</sup>, Deborah Johnson<sup>3</sup>, Zhongze Li<sup>1</sup>, Judy Norsigian<sup>4</sup>, Melissa Nothnagle<sup>5</sup>, Ardis Olson<sup>1</sup>, Heather Shepherd<sup>6</sup>, Lisa Stern<sup>7</sup>, Tor Tosteson<sup>1</sup>, Lyndal Trevena<sup>6</sup>, Krishna Upadhy<sup>8</sup>

<sup>1</sup>Dartmouth College, New Hampshire, USA, <sup>2</sup>Patient Partner, -, USA, <sup>3</sup>Dartmouth-Hitchcock Medical Center, New Hampshire, USA, <sup>4</sup>Our Bodies Ourselves, Massachusetts, USA, <sup>5</sup>Brown University, Rhode Island, USA, <sup>6</sup>The University of Sydney, New South Wales, Australia, <sup>7</sup>Planned Parenthood Northern California, California, USA, <sup>8</sup>Johns Hopkins University, Maryland, USA

**OBJECTIVE:** Shared decision-making is the process of health care providers and patients making health decisions together. The objective of this study, co-designed by scientists, clinicians, patients, and other stakeholders, is to assess the comparative effectiveness of patient- and provider-targeted interventions for facilitating shared decision-making about contraceptive methods in the health care visit.

**METHODS:** We are conducting a 2x2 factorial cluster randomised controlled trial of a patient-directed intervention (a brief video and accompanying prompt card that encourage patients to ask providers three specific questions about their options during the visit) and provider-directed intervention (seven one-page decision aids on contraceptive methods that can be used to facilitate shared decision-making with patients during the visit and a preparatory five-minute training video and written guidance). The clusters were 16 primary care and reproductive health care clinics in the United States. Participants were people who had completed a visit at a participating clinic, were assigned female sex at birth, were aged 15 to 49 years, could read and write English or Spanish, and had not participated in the study previously. We collected data via patient surveys administered immediately, four weeks, and six months after the visit. The primary outcome was shared decision-making about contraceptive methods and was assessed immediately after the visit. Secondary outcomes also assessed at this time point comprised the occurrence of a conversation about contraception, satisfaction with the conversation about contraception, intended contraceptive method(s), intention to use a highly effective contraceptive method, and values concordance of the intended method(s).

**RESULTS:** Data collection on outcomes assessed immediately after the visit was completed in late 2016. Altogether, 3347 eligible participants provided data during the six-month trial. Of

these, 2818 reported a conversation about contraception and 2802 provided data on the primary outcome of shared decision-making about contraceptive methods. Analysis of the effect of trial arm on shared decision-making and other outcomes assessed immediately after the visit is underway.

**CONCLUSIONS:** The findings of this study will shed important light on the comparative effectiveness of patient- and provider-targeted interventions for facilitating shared decision-making about contraceptive methods in the health care visit. [ClinicalTrials.gov Identifier NCT02759939]

## **Troubled Evidence? Tracking Excess Significance, Cherry-Picking, and Premature Closure**

Janet Martin, on behalf of the MEDICI Team at Western University  
MEDICI Centre, Schulich School of Medicine & Dentistry, Western University, London, Ontario, Canada

Troubled Evidence? Tracking Excess Significance, Cherry-Picking, and Premature Closure

**BACKGROUND:** Effective evidence-based decision making relies heavily on the quality of the available evidence base. Better understanding of the validity and relevance of the evidence base, as well as trends over time, will be imperative in order to inform current deficiencies and future research agendas.

**OBJECTIVE:** To quantify the validity and relevance of published evidence, and to explore trends over time.

**METHODS:** A meta-epidemiologic survey of the literature was performed, covering over 50 years of published randomized clinical trials from 15 medical journals.

**RESULTS:** While the number of randomized trials has increased significantly over the years, the majority failed to report on clinically-relevant outcomes. Furthermore, the mean size of randomized trials has remained small (<40-60 patients), particularly in subspecialty journals. However, the majority of randomized trials reported positive ("significant") results, and concluded in favour of the intervention under study. The size of randomized trials, proportion reporting clinically-relevant outcomes, and extent of excess significance were stable over time, indicating a general lack of progress in validity and relevance of the evidence base, and suggestive of excess researcher degrees of freedom (selective outcome reporting, outcome switching, or posthoc statistical model revision).

**CONCLUSIONS:** Despite persistently small sample sizes, and despite few clinically-relevant outcomes being measured, the majority of randomized trials report positive conclusions and advocate for the superiority of the proposed intervention. Future research is urgently required to increase awareness of these detractions to the validity and relevance of the evidence base, and to develop transparent safeguards against these biases during design, conduct, and reporting of clinical trials.

## **Clients' satisfaction with waiting time in HIV treatment centres: An urban rural comparison in Anambra State, Nigeria.**

Emmanuel Azuike, Echendu Adinma, Amobi Ilika, Simeon Nwabueze, Chinomso Nnebue, Reginald Aniemen  
Nnamdi Azikiwe University Teaching Hospital Nnewi, Nigeria, Anambra State, Nigeria

**BACKGROUND:** Patient satisfaction is very important in healthcare because a satisfied patient will be more cooperative with the medical team. Management of a Chronic disease like HIV also needs as much cooperation from clients as possible because the treatment is for life. Waiting time has been reported by several studies as a major determinant of satisfaction in health facilities.

**OBJECTIVE:** This study determined and compared clients' satisfaction with waiting time at urban and rural HIV treatment centres in Anambra State, Nigeria.

**METHODS:** This is a comparative descriptive study. Data were collected using quantitative methods. A semi-structured, pre-tested, interviewer-administered questionnaire was used to obtain information on satisfaction with waiting time from clients at the urban and rural HIV treatment centres in Anambra State Nigeria. Data were analysed with the SPSS version 20 software and summarised using proportions and means, and were presented in tables for easy appreciation.

**RESULTS:** A total of 1,100 respondents (550 each from the urban and rural HIV treatment centres) participated in this study. There were more females than males in both the urban 363(66.0%) and rural centres 355(64.5%). The commonest age group among the urban respondents was the age group 21-30 years, 170 (30.9%), the same age group was also the commonest among the rural respondents 240 (43.6%). The mean age of the urban respondents 37.09 ( $\pm 10.00$ ) was higher than the mean age of the rural respondents 34.99 ( $\pm 10.71$ ). A higher proportion of the respondents that were satisfied with waiting time were urban respondents 405(69.2%), compared with the 180(30.8%) rural respondents that were satisfied. ( $X^2 = 184.839$ ,  $p = 0.000$ ). The urban respondents were four times more likely to be satisfied with waiting time compared with the rural respondents [OR: 4.139 (95% CI: 2.945-5.817)].

**CONCLUSION:** The clients in the urban HIV treatment centres were more satisfied with the waiting time than the clients in the rural HIV treatment centres. Appropriate interventions should be instituted to reduce the waiting time of clients in the rural centres.

**KEYWORDS:** Satisfaction, waiting time, HIV treatment centres.

## Communication of Evidence - Seminar Room Three 11:30 Thursday June 22<sup>nd</sup>

### **Evidence Rounds: a targeted initiative to disseminate research evidence to health care professionals (HCPs)**

Aislinn Conway<sup>1</sup>, Declan Devane<sup>1</sup>, Maura Dowling<sup>2</sup>

<sup>1</sup>Health Research Board Trials Methodology Research Network, Galway, Ireland, <sup>2</sup>National University of Ireland Galway, Galway, Ireland

The focus of dissemination research is on examining strategies to communicate and spread information to targeted users. Evidence Rounds is a multi-component dissemination strategy (including group sessions) exploring the best available evidence on clinical questions/topics chosen by staff at a large teaching hospital. The mechanisms and approaches to communicate and spread knowledge will be reported. Evidence Rounds is being adapted in accordance with feedback from attendees and observational data regarding aspects such as delivery, structure, communication, supplementary information etc.

**OBJECTIVES:**

- to describe the process of designing, implementing and developing an initiative targeted at health care professionals to promote and facilitate evidence informed practice
- to identify the self-reported barriers and facilitators health care professionals have to attending and participating in evidence informed initiatives like Evidence Rounds

**METHODS:** We used a purposive sampling approach and invited all staff who attended at least one Evidence Rounds session to take part in the individual or focus group interviews.

**DATA COLLECTION AND ANALYSIS:** face-to-face moderately-structured focus groups and one-to-one interviews with HCPs. Online usage metrics of the Evidence Rounds website were measured. Framework analysis will be used.

**RESULTS:** 13 HCPs participated in focus groups and interviews. Data analysis currently in process (will be completed by Evidence Live 2017).

**CONCLUSIONS:** to be confirmed

## **Consensus-based surgical case report guidelines: The SCARE Statement**

Ishani Barai<sup>1</sup>, Riaz Agha<sup>2</sup>, Alexander Fowler<sup>2</sup>, Alexandra Saeta Saeta<sup>2</sup>, Shivanchan Rajmohan<sup>1</sup>, Dennis Orgill<sup>3</sup>

<sup>1</sup>Imperial College London, London, UK, <sup>2</sup>Guy's and St. Thomas' NHS Foundation Trust, London, UK, <sup>3</sup>Brigham and Women's Hospital, Boston, USA

**INTRODUCTION:** Case reports have been a long held tradition within the surgical literature. Reporting guidelines can improve transparency and reporting quality. However, recent consensus-based guidelines for case reports (CARE) are not surgically focused. Our objective was to develop surgical case report guidelines.

**METHODS:** The CARE statement was used as the basis for a Delphi consensus. The Delphi questionnaire was administered via Google Forms and conducted using standard Delphi methodology. A multidisciplinary group of surgeons and others with expertise in the reporting of case reports were invited to participate. In round one, participants stated how each item of the CARE statement should be changed and what additional items were needed. Revised and additional items from round one were put forward into a further round, where participants voted on the extent of their agreement with each item, using a nine-point Likert scale, as proposed by the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) working group.

**RESULTS:** In round one, there was a 64% (38/59) response rate. Following adjustment of the guideline with the incorporation of recommended changes, round two commenced and there was an 83% (49/59) response rate. All but one of the items were approved by the participants, with Likert scores 7-9 awarded by >70% of respondents. The final guideline consists of a 14-item checklist.

**CONCLUSION:** We present the SCARE Guideline, consisting of a 14-item checklist that will improve the reporting quality of surgical case reports.

## **Understanding drivers of behaviour to support knowledge translation: the example of urinary catheter care management following spinal cord injury**



Denise Goodwin<sup>1</sup>, Alyse Lennox<sup>3</sup>, Catherine Byrne<sup>2</sup>, Andrew Nunn<sup>2</sup>, Peter Bragge<sup>1</sup>  
<sup>1</sup>*BehaviourWorks Australia, Monash University, Victoria, Australia*, <sup>2</sup>*Victorian Spinal Cord Service, Austin Hospital, Victoria, Australia*, <sup>3</sup>*Department of Epidemiology and Preventive Medicine, Monash University, Victoria, Australia*

**OBJECTIVE:** When factors other than best current evidence are driving service delivery, understanding context and drivers of healthcare behaviour can inform knowledge translation. Current evidence suggests that transitioning from an indwelling catheter (IDC) to intermittent catheters (IC) in the early acute phase following spinal cord injury (SCI) can reduce urological complications, which are a common and costly financial and health complication of SCI. However, practice audits in one Australian SCI unit demonstrated long delays in implementing IC following SCI. This study explored barriers and facilitators of best practice in this area.

**METHODS:** Using a qualitative research design, we conducted 21 individual interviews to explore clinicians' (medical, nursing and allied health) and patients' views on SCI urinary catheter care. Thematic analysis was guided by the Theoretical Domains Framework (Cane et al., 2012) to categorise identified behavioural drivers of SCI urinary catheter care.

**RESULTS:** Although staff generally recognised that transitioning from IDCs to ICs was best evidence-informed practice, multiple factors influenced this behaviour. Participants reported access to resources (e.g. staff time and catheter type) and social influences as strong drivers of staff and patient behaviour. Staff beliefs, many of which were not aligned with best practice, strongly influenced both their colleagues and their patients. Lack of emotional and physical readiness for ICs was frequently cited as a reason to delay transition to IC, despite very little group consensus on what 'readiness' meant (particularly related to mental health). There were strong beliefs around whether patients had the capability or inclination to perform ICs, particularly beyond the clinical setting. These factors were a greater influence on practitioner behaviour than current evidence.

**CONCLUSION:** Understanding the drivers of behaviour among clinical staff and patients has been pivotal to tailoring the knowledge translation approach. An intervention to be delivered in 2017 encompasses communicating evidence on best practice to clinical staff to develop a shared understanding and dispel inaccurate beliefs; an algorithm to support best practice and help address inconsistencies relating to patient readiness for ICs; engagement with influential staff as clinical champions; and development of new educational resources for both staff and patients that reflect current evidence.

## **How to implement Patient Review and navigate The BMJ Patient Involvement Statement**

Amy Price<sup>1</sup>, Sara Schroter<sup>2</sup>, Tessa Richards<sup>2</sup>, Elizabeth Loder<sup>2</sup>, Sam Parker<sup>2</sup>  
<sup>1</sup>*University of Oxford, Oxford, UK*, <sup>2</sup>*The BMJ, London, UK*

**RATIONALE:** Widespread involvement and reporting of patients and the public in research is not frequent and therefore difficult to replicate. Patient involvement is widely considered as important but researchers struggle with the how and where to implement this in a practical way. One process through which research knowledge can be shared is through accurate reporting of public involvement. An additional way the public can increase research awareness and share knowledge is through contributing their expertise as patient reviewers.

**OBJECTIVE:** Since 2014, *The BMJ* has been inviting patients to review research papers alongside traditional peer reviews. In addition, The BMJ introduced a mandatory statement for reporting patient involvement in research. We describe potential barriers and helpful

solutions for reporting patient and public involvement and we outline the differences between what is expected for patient versus peer reviews.

**DESIGN:** Mixed Methods

**RESULTS:** Early feedback shows patients, authors, and editors find patient review a beneficial but challenging endeavor. Response times and acceptance rates for patient reviewers match those of peer reviewers. Some researchers may report initial discomfort with including and reporting patient involvement in research, however, some find both practices can add valuable insights for putting research into practice.

**CONCLUSION:** Patient review of research is feasible alongside a standard peer review process, but implementation has not been without challenges. Our experience suggests that authors have very limited understanding of what patient involvement means or how to implement this in their research. As a result, they struggle with how to report PI. Implementing the mandatory PI statement and adding patient reviews have contributed to better understanding and reporting for authors. These initiatives are a beginning and they highlight other areas in PI that need attention. We invite attendees to change the research culture through public involvement in research and by preparing their manuscripts for optimal patient and peer review.

## **Journeying through the development of an adaptive designs reporting guidance: preliminary findings**

Munya Dimairo<sup>1</sup>, Susan Todd<sup>2</sup>, Steven Julious<sup>1</sup>, Thomas Jaki<sup>3</sup>, James Wason<sup>4</sup>, Adrian Mander<sup>4</sup>, Daniel Hind<sup>1</sup>, Christopher Weir<sup>5</sup>, Franz Koenig<sup>6</sup>, Doug Altman<sup>7</sup>, Jon Nicholl<sup>1</sup>, Toshimitsu Hamasaki<sup>8</sup>, Michael Proschan<sup>9</sup>, John Scott<sup>10</sup>, Marc Walton<sup>11</sup>, Yuki Ando<sup>12</sup>, Katie Biggs<sup>1</sup>, Philip Pallmann<sup>3</sup>, Elizabeth Coates<sup>1</sup>

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**INTRODUCTION:** The need to evaluate new health interventions using efficient trial designs has increased in recent years. Adaptive Designs (ADs) are one way to enhance study design efficiency. ADs offer the opportunity to use accruing data within an ongoing trial to modify, or adapt, aspects of that trial, such as early stopping of futile or unsafe interventions, while preserving trial integrity and validity.

Although ADs appear to offer many advantages, they are not routinely applied due to a number of obstacles (Dimairo, Boote, et al., 2015; Dimairo, Julious, et al., 2015; Jaki, 2013). These obstacles include: lack of practical knowledge; limited access to case studies to learn from; concerns about credibility and potential introduction of bias.

Transparent and adequate reporting is one of the leading facilitators to address uncovered obstacles (Dimairo, Julious, et al., 2015). There is no existing reporting guidance tailored for ADs. As a result, deficiencies in their reporting may influence their credibility and limit their ability to inform future related research (Bauer and Einfalt, 2006; Hatfield et al., 2016; Stevely et al., 2015).

We aim to address reporting deficiencies to mitigate some of the obstacles to the application of ADs.

**METHODS:** A multidisciplinary international consortium of key stakeholders in clinical trials

research was formed to lead the development of a consensus driven reporting guidance tailored for trials that use ADs in the form of a CONSORT extension. As part of the ACE (Adaptive designs CONSORT Extension) project, we are surveying international clinical trial research stakeholders on their perception of the importance of potential reporting items during rounds of the Delphi process. This will be followed by a consensus meeting.

**RESULTS:** Here, we talk about the aims of the ACE project, the reporting guidance development process, report preliminary results from the first round of the Delphi process, share lessons learned, and describe the future direction of the project.

**CONCLUSION:** We hope the CONSORT guidance will mitigate some of the obstacles to the use of ADs by enhancing their credibility and helping to improve their reproducibility and replicability by better and more transparent reporting. More so, help researchers design better adaptive trials.

## **An application to auto-generate high-evidence content for the worlds most famous encyclopedia: Cochrane to Wikipedia in one mighty bound**

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**OBJECTIVE:** Cochrane is interested in disseminating high-grade evidence to a wide readership. Wikipedia is intrested in enhancing the quality of their articles and is encouraging collaboration with Cochrane. One of Wikipedia's roles is a highly influential platform for spreading knowledge - everybody reads Wikipedia.

The accuracy of Wikipedia's content is a potential risk and this is where Cochrane could help. However, to add yet another task and set of skills for the Cochrane reviewer may make the whole process - too daunting.

**AIM:** To make the process of transposing best data from a Cochrane review into Wikipedia-compatible format easy.

### **Methods**

#### **RESORCES:**

- Two innocent enthusiastic students of Applied Health Sciences from a small town in the Black Forest (5/12, FT)
- Cochrane Schizophrenia Group (Nottingham) with some expereince of auto-generation of text within Cochrane reviews (RevManHAL)
- Open source software
- Cochrane review Summary of Findings (SoF) tables

We created a java application with the purpose of:

1. Parsing any ReviewManager file and using the contained XML-structure to navigate its content
2. Targeting the SoF tables and extracting valuable information
3. Converting parts of the table into plain text to make the results more easily read
4. Embedding both extracted and converted text into a structure that can be pasted directly into the source code of an existing Wikipedia article

**RESULTS:** The resulting application has a big red button. By pressing this a Wiki-compatible table is generated from a Cochrane review. A complex and time-consuming task has been eliminated.

**CONCLUSIONS:** With vision and investment of time and skill there should be a seamless join between sophisticated reviews and a whole series of means of dissemination of their results tailored to the needs of the end user.

## Evidence Synthesis - Seminar Room Four 11:30 Thursday June 22<sup>nd</sup>

### Homeopathy for Allergic Rhinitis: A Systematic Review

Kushal Banerjee<sup>1</sup>, Robert Mathie<sup>2</sup>, Ceire Costelloe<sup>3</sup>, Jeremy Howick<sup>4</sup>

<sup>1</sup>Dr. Kalyan Banerjee's Clinic, New Delhi, India, <sup>2</sup>Homeopathy Research Institute, London, UK,

<sup>3</sup>Imperial College, London, UK, <sup>4</sup>University of Oxford, Oxford, UK

**OBJECTIVE:** To evaluate the efficacy or effectiveness of homeopathic intervention in the treatment of seasonal or perennial allergic rhinitis (AR).

**METHOD:** Randomised controlled trials evaluating all forms of homeopathic treatment for AR were included in systematic review (SR) of studies published up to and including December 2015. Two authors independently screened potential studies, extracted data and assessed risk of bias. Primary outcomes included symptom improvement and total quality-of-life score. Treatment effect size was quantified as mean difference and standardized mean difference (continuous data), or by risk ratio (RR) and odds ratio (dichotomous data), with 95% confidence interval (CI). Meta-analysis was performed after assessing heterogeneity and risk of bias.

**RESULTS:** Eleven studies were eligible for SR. All trials were placebo-controlled except one. Six trials used the treatment approach known as isopathy, but they were unsuitable for meta-analysis due to problems of heterogeneity and data extraction. The overall standard of methods and reporting was poor: eight of the 11 trials were assessed as 'high risk of bias'; only one trial, on isopathy for seasonal AR, possessed reliable evidence. Three trials of variable quality (all using *Galphimia Glauca* for seasonal AR) were included in the meta-analysis: nasal symptom relief at 2 and 4 weeks (RR: 1.48 [95%CI, 1.24 to 1.77] and 1.27 [95%CI, 1.10 to 1.46] respectively) favoured homeopathy compared with placebo; ocular symptom relief at 2 and 4 weeks also favoured homeopathy (RR: 1.55 [95%CI, 1.33 to 1.80] and 1.37 [95%CI, 1.21 to 1.56] respectively). The single trial with reliable evidence had a small positive treatment effect without statistical significance. A homeopathic and a conventional nasal spray produced equivalent improvements in nasal and ocular symptoms.

**CONCLUSIONS:** The low or uncertain overall quality of the evidence warrants caution in drawing firm conclusions about intervention effects. Use of either *Galphimia Glauca* or a homeopathic nasal spray may have small beneficial effects on the nasal and ocular symptoms of AR. The efficacy of isopathic treatment of AR is unclear.

**Do systematic review updates target questions where evidence accumulates faster?**

Rabia Bashir, Adam G. Dunn

Centre for Health Informatics, Australian Institute of Health Innovation, Macquarie University, Sydney, Australia

**OBJECTIVE:** There are several methods available for determining if a systematic review needs to be updated, but little is known about whether reviewers prioritise clinical questions with new evidence. Our aim was to determine whether systematic reviews were targeted for updating after relevant trials were published.

**METHODS:** Systematic reviews published in the Cochrane Database of Systematic Reviews in 2010 were selected if they included at least one clinical trial; updated before December 1 2016; performed a new search; and did not change populations, interventions, outcomes, or comparators. Using the updated set of trials to define the most recent evidence base, we retrospectively quantified the accumulation of new evidence between the search dates of the reviews and their updates. Recording trial publication dates (and trial completion dates where registration information was available), the ongoing completeness of a review was determined by the number of participants included in the review as a proportion of the total number of participants available as new evidence was published. We determined whether reviews with a signal of new evidence ( $\leq 90\%$  completeness within a year of the search date) were updated faster (using time between search dates) than reviews without a signal.

**RESULTS:** From 773 articles published in 2010, 53 systematic reviews were sampled for analysis. The median update time was 41 months (IQR 35-60). For 55% (29/53) of the reviews, no new trials were added in the update. Within a year of search date, the reviews covered between 72.4% and 100% of the published trial participants. Clinical questions (with  $\leq 90\%$  completeness) were not targeted for update (N=12, median 49 months) earlier than those without (N=41, median 40 months);  $p=0.017$  in a Wilcoxon rank sum test. The 14 reviews with complete registration information covered a median of 93.9% (IQR 83.8%-100%) of completed trial participants at the search date, and 85.8% (IQR 73.8%-96.0%) within a year of search.

**CONCLUSION:** Updates to Cochrane systematic reviews mostly found no new evidence, and updates were not targeted at questions where new evidence was published. Methods for automatically monitoring registrations and publications may help to prioritise systematic review updates.

## Prospective Comparison between Rapid and Systematic Reviews on the Same Topics: A Feasibility Study

Junqiao Chen<sup>1</sup>, Jon Brassey<sup>2</sup>, Yanfang Ma<sup>3</sup>, Qi Wang<sup>4</sup>, Miles Patel<sup>1</sup>, Samuel Boudreault<sup>5</sup>, Mark-Steven Howe<sup>6</sup>

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**BACKGROUND:** Rapid review (RRs) aim to provide more timely decision support than systematic reviews (SRs), but their quality has been widely questioned. Comparison of RRs and SRs on the same topic is scant, and were all conducted retrospectively using published reviews. Prospective comparison has been recommended to reduce bias. But to date, study design for such comparison has not been tested.

**OBJECTIVE:** To test a study design which prospectively compares rapid and systematic reviews on the same topics.

**METHODS:** This four-step study design begins with random selection of SRs. Clinical questions, review criteria and search strategies are then extracted from SRs, so that disagreement between reviews could be attributed to the rapid approach. Single reviewer conducts RRs based on extracted information. Finally, external assessors compare results. In this pilot, two Cochrane SRs were selected and extracted for the main reviewer. One SR explored the effect of corticosteroids on myocarditis mortality ("Steroid"). The other investigated fluoride mouthrinse on caries prevention ("Mouthrinse"). Searches were replicated in MEDLINE® only, restricting publication date (30 years) and language (English). The main reviewer completed the manuscript alone. "Steroid" RR was clinically assessed by two clinicians and a guideline developer, and "Mouthrinse" RR was assessed by a dentist. Lastly, another methodologist scrutinized both RRs' data accuracy.

**RESULTS:** "Steroid" RR includes four studies (compared to eight in SR). No data error was found. All assessors concluded that it presented the same direction of effect and quality of evidence as the SR. Two assessors had equal confidence in RR and SR, stating that SR added little value due to the poor quality in primary studies. One assessor had higher confidence in SR because of its experienced authorship and standard format. "Mouthrinse" RR, however, missed 91% of the original studies (three versus 34 in SR). Therefore, RR meta-analysis did not detect the same significant effect as the SR. Two minor data errors were identified and two risk of bias assessments were challenged.

**CONCLUSIONS:** Prospective comparison between reviews is feasible and could further explain RR to SR agreement. To enhance reliability of future study, reproducing reviewers need to have similar background as the original reviewers.

## Should we be concerned - what does access to Individual Participant Data tells us about the unreported outcomes?

Ewelina Rogozinska<sup>1</sup>, Javier Zamora<sup>2</sup>

<sup>1</sup>Queen Mary University of London, London, UK, <sup>2</sup>Hospital Ramon y Cajal(IRYCIS), Madrid, Spain

**BACKGROUND:** Within-study selective reporting of difference between evaluated interventions depending on statistical significance is one of the most important sources of bias affecting clinical trials. More frequent reporting of statistically significant findings leads to potential overestimation of underlying treatment effect in a meta-analysis of treatment effects using data extracted from trial reports. Access to Individual Participant Data (IPD) and meta-analysis using IPD has the potential to address this issue.

**OBJECTIVES:** In the IPD meta-analysis on the effect of diet and physical activity-based interventions in pregnancy (i-WIP), we gained access to data from 36 RCTs. The aim of our work is to evaluate how access to IPD changes what we know about the selective outcome reporting and its impact on the treatment effect using i-WIP IPD as an example.

**METHODS:** We formally compared two sources of information on a) the number of trials contributing data to meta-analysis, b) pooled effect estimates, and c) funnel plot asymmetry.

**RESULTS:** There were 35 pairs of IPD and respective publications. Overall, access to IPD increased the number of trials for which the outcome data was present in comparison to data extracted from trial publications. Incorporation of IPD led to a change in funnel plot asymmetry in the case of two outcomes.

**CONCLUSION:** Despite a clear guidance on reporting of outcomes their selective reporting persists to be a problem. We will provide a detailed description of our findings and their consequences based on experience in the i-WIP IPD meta-analysis.

## The development of “Evidence into Practice – Rapid Reviews”

Eve O'Toole, Patricia Heckmann  
*National Cancer Control Programme, Dublin 1, Ireland*

**OBJECTIVE:** The National Cancer Control Programme Ireland (NCCP) has developed a robust evidence based methodology for developing clinical guidelines. One of the ongoing challenges that guideline groups face is responding to rapidly changing evidence as guidelines can take two years to develop.

Another global constraint on health services is pressure on health budgets. One of the big contributors to the problem is the escalating cost of oncology drugs which can cost upwards of €100,000 per QALY. This rapid-review addresses the need of quick guidance along with providing the payer with reassurance around the impact of these treatments.

**METHOD:** An Evidence into Practice Rapid Review process was developed. This is modelled on the guideline development process but aims to address a limited number of clinical questions, in a short time period, on areas with new and emerging evidence, where there is variation in practice and potential to have large impact on patient outcomes. This was trialled on new immunotherapy drugs developed to treat metastatic melanoma. This is clinically significant as these patients typically have less than one year life expectancy.

The following steps are carried out:

- A team is established consisting of four consultants, a pharmacist, a researcher, a librarian and methodology lead.
- Clinical questions are developed
- Literature searches are performed
- High level evidence is extracted into data-tables
- A face-to-face recommendation meeting is held. Short evidence statements and clear recommendations on the use of the drugs are written.

**RESULTS:** The rapid review is submitted to the drugs group in conjunction with the NCCP recommendation on funding. It provides clinicians with treatment algorithms in areas of new and emerging evidence. There is a predetermined time frame for updating recommendations as new evidence continues to be published.

**CONCLUSIONS:** This innovation enables the development of rapid guidance and ensures, emerging evidence can be put directly into practice to improve patient outcomes while providing assurance about budget impact. By reducing variation in practice we can monitor real world outcomes in the Irish setting and contribute to the growing evidence base on these topics.

## Cochrane Crowd: using citizen science to meet the challenge of information overload in evidence production

Anna Noel-Storr<sup>1</sup>, James Thomas<sup>2</sup>, Chris Mavergames<sup>4</sup>, Julian Elliott<sup>3</sup>, Tari Turner<sup>3</sup>, Steve McDonald<sup>3</sup>, Sally Green<sup>3</sup>, David Tovey<sup>4</sup>  
<sup>1</sup>University of Oxford, Oxford, UK, <sup>2</sup>UCL, London, UK, <sup>3</sup>Monash University, Melbourne, Australia, <sup>4</sup>Cochrane, London, UK

**BACKGROUND:** At a time when research output is expanding exponentially, citizen science, the process of engaging willing volunteers in scientific research activities, has an important role to play in helping to manage the information overload. It also creates a model of contribution that enables anyone with an interest in health to contribute meaningfully and in a way that is flexible. Citizen science models have shown to be extremely effective in other domains such as astronomy and ecology.

**OBJECTIVES:** Cochrane Crowd ([crowd.cochrane.org](http://crowd.cochrane.org)) is a citizen science platform that offers contributors a range of micro-tasks, designed to help identify and describe clinical trials and diagnostic studies.

**METHODS:** The platform enables contributors to dive into needed tasks that capture and describe health evidence. Brief interactive training modules, and agreement algorithms help ensure accurate collective decisions. Contributors work online or offline; they can view their activity and performance in detail. They can choose to work in topic areas of interest. As contributors progress, they unlock new tasks.

**RESULTS:** Cochrane Crowd was launched in February 2016. Three micro-tasks are available: RCT identification and diagnostic test accuracy (DTA) identification, and PICO (Population, Intervention, Comparator and Outcomes) extraction at citation level.

The Cochrane Crowd community comprises 5000 contributors from 117 countries. Over 1 million individual classifications have been made, and 32,000 reports of randomized trials have been identified for Cochrane's Central Register of Controlled Trials. Evaluations to assess crowd accuracy have shown crowd sensitivity is 99.1%, and crowd specificity is 99%. Main motivations for involvement are that people want to help Cochrane, and people want to learn.

**CONCLUSIONS:** This model of contribution is becoming an established part of Cochrane's effort to manage the deluge of information produced in a way that offers contributors a way to get involved, learn, and play a crucial role in evidence production.

## Clinical Trials - Lecture Theatre Two

### 11:30 Thursday June 22<sup>nd</sup>

#### Large Streamlined Trials - what works, and what doesn't.

Amy Rogers, Alex Doney, Isla Mackenzie, Tom MacDonald  
University of Dundee, Dundee, UK

Large Streamlined Trials - what works, and what doesn't.

**OBJECTIVE:** The Medicines Monitoring Unit (MEMO) of the University of Dundee specialises in large-scale drug safety and effectiveness research using linkage to routinely collected data. This presentation will summarise the results of some of the methods attempted to improve this process and suggest potential areas for future development.



**METHOD:** Large clinical trials are complex studies conducted within restrictive ethical and regulatory frameworks. Streamlined, or pragmatic, trials aim to produce externally valid evidence to meet clinically relevant needs in an efficient manner. In the conduct of several recent and current projects[1-4], MEMO has experimented in various aspects of trial conduct from study design to recruitment, follow-up and clinical endpoint adjudication.

**RESULTS:** MEMO projects have utilised a number of novel techniques including web-based studies, diverse recruitment strategies, direct-to-participant drug supply, and email follow-up with varying success.

**CONCLUSIONS:** Effective trial methodologies are essential for timely and efficient production of evidence to guide clinical decisions. Future MEMO projects aim to utilise cluster randomisation and further use of IT to widen study participation. Trialists must explore novel methodologies if we are to provide the evidence that learning healthcare systems require.

1. MacDonald TM, Ford I, Nuki G, et al (2014) Protocol of the Febuxostat versus Allopurinol Streamlined Trial (FAST): a large prospective, randomised, open, blinded endpoint study comparing the cardiovascular safety of allopurinol and febuxostat in the management of symptomatic hyperuricaemia. *BMJ Open* 4:e005354
2. MacDonald TM, Hawkey CJ, Ford I, et al (2016) Randomized trial of switching from prescribed non-selective non-steroidal anti-inflammatory drugs to prescribed celecoxib: the Standard care vs. Celecoxib Outcome Trial (SCOT). *Eur Heart J*. doi: 10.1093/eurheartj/ehw387
3. Mackenzie IS, Ford I, Walker A, et al (2016) Multicentre, prospective, randomised, open-label, blinded end point trial of the efficacy of allopurinol therapy in improving cardiovascular outcomes in patients with ischaemic heart disease: protocol of the ALL-HEART study. *BMJ Open* 6:e013774
4. Rorie DA, Rogers A, Mackenzie IS, et al (2016) Methods of a large prospective, randomised, open-label, blinded end-point study comparing morning versus evening dosing in hypertensive patients: the Treatment In Morning versus Evening (TIME) study. *BMJ Open*. doi: 10.1136/bmjopen-2015-010313

## Why academic clinical trials fail: Trial 'cemetery demographics' and a case study

Penny Reynolds

*University of Florida School of Medicine, Gainesville Florida, USA*

**OBJECTIVES:** Failed clinical trials (CT) are a major cost burden, waste resources, and can pose significant risks to patients, without evidence of benefit. The most common reason given for early termination is poor patient enrolment. However, causes of failure may be disproportionally identified, and actual root causes hidden. I surveyed academic trial failures to establish prevalence of apparent causes, then performed a root-cause analysis of a single terminated RCT to match apparent with root causes and identify possible corrective actions for future trials.

**METHODS:** I surveyed closed interventional trials of known status registered in *ClinicalTrials.gov* between Jan 2006 and Jan 2017, and conducted in the USA, Canada, and UK. 'Failed' trials (45%) were classified by 'suspended', 'withdrawn', or 'terminated' recruitment status. I obtained a computer-generated random sample of 100 trials in each category. Trials were categorised as 'academic' based on the type of funder support. I performed an in-depth analysis of a single RCT, The Prehospital Use of Plasma in Traumatic Haemorrhage (PUPTH) trial, to assess root-cause factors (RCF) contributing early trial termination.

**RESULTS:** Major reasons for early trial closure (n =245) were recruitment (29%), funding (11%), and loss of key personnel and/or staff (11%). Most (86%) were single-centre trials, and 22% reported industry sponsor collaboration. More than half (56%) did not enroll any patients; the median number of patients actually enrolled was 16% of target. Over 4000 patients were enrolled without study completion. The PUPTH trial was projected to enrol 4-6 patients per month, but only 3 patients were enrolled over 5 months. RCF mapping identified that the wrong patient pool was targeted for feasibility analysis. Contributing to trial non-viability were non-scientific factors: 'med-centric myopia' (over-emphasis of medical/scientific issues at the expense of planning and management); failure to involve appropriate personnel; unexpectedly high operating costs; personnel turnover; and regulatory burden.

**CONCLUSIONS:** Project management literature identifies unrealistic expectations, coupled with lack of planning, resources, 'user' involvement, and IT management, as key factors contributing to project failure. Failed academic clinical trials may result primarily from managerial inexperience of clinical investigators, rather than being a recruiting problem.

## **"Is that it?" - Using 'Explorachoc' to engage the public with clinical trials and encourage involvement with health services research**

*Heidi Gardner, Heather Morgan, Rebecca Bruce, Gordon Fernie, Beatriz Goulao, Joanna Kaniewska, Clare Robertson, Sharon Wren, Katie Gillies  
Health Services Research Unit, University of Aberdeen, Aberdeen, UK*

**OBJECTIVE:** By helping to bring research and wider society together, public engagement can increase trust and enhance relevance, accountability and transparency of, and in, research processes and researchers. Engagement is also important because it can empower people to become involved through offering their insights and feedback on our work to ensure that the research we conduct is relevant to the societies we strive to improve. Our team's aim was to deliver public engagement activities around clinical trials and health services research (HSR) to demystify our work and facilitate public involvement.

**METHODS:** We designed a two-arm trial, 'Explorachoc', to: demonstrate the randomisation process; engaged members of the public; and recruit to a public involvement panel. We piloted this activity at the University of Aberdeen's May Festival (2016), and ran a modified version as part of the University's European Researchers' Night/Explorathon event (September 2016). The trial involved: double-blinded selection of either a blue or yellow ball (equal chance of selection); depositing the ball in a large transparent jar to demonstrate distribution; being given a chocolate with a blue or yellow wrapper corresponding to the selected ball's colour; and ranking taste on a scale of 1 (low) - 4 (high). We then engaged participants in conversations about the history of trials (using props to re-enact James Lind's scurvy trial) and our research. Finally, we asked participants whether they would be willing to be contacted to contribute to our public involvement panel.

**RESULTS:** We randomised 365 people (48.5% blue) across the two events (83% Explorathon). The median in the blue group was 4.0 interquartile range (IQR) (3.0-4.0) and 3.5 IQR(3.0-4.0) in the yellow group (Mann Whitney U p-value=0.633). The resounding response was "Is that is?" regarding randomisation, suggesting that we were able to demystify the process of randomisation. Most participants understood the connections between trials, research and the care they receive. 71 people volunteered their details for future contact regarding public involvement.

**CONCLUSIONS:** We have a proof of concept for an effective engagement model, enhanced by the use of chocolate, and are building on this to develop public engagement and involvement strategies.

## **TELEMONITORING VERSUS USUAL CARE: A MULTICENTER TRIAL AMONG TEENAGERS WITH INFLAMMATORY BOWEL DISEASE**

Anke Heida<sup>1</sup>, Alie Dijkstra<sup>1</sup>, Anneke Muller Kobold<sup>1</sup>, Angelika Kindermann<sup>2</sup>, Freddy Kokke<sup>3</sup>, Tim de Meij<sup>4</sup>, Obbe Norbruis<sup>5</sup>, Margreet Wessels<sup>6</sup>, Thalia Hummel<sup>7</sup>, Hankje Escher<sup>8</sup>, Herbert van Wering<sup>9</sup>, Danielle Hendriks<sup>10</sup>, Luisa Mearin-Manrique<sup>11</sup>, Henk Groen<sup>1</sup>, Henkjan Verkade<sup>1</sup>, Patrick van Rheenen<sup>1</sup>

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**INTRODUCTION:** Monitoring teenagers with inflammatory bowel disease (IBD) is traditionally done during scheduled visits, but this is when most patients report disease remission. IBD care could be more efficient if imminent relapses were recognised at home and if patients were seen at times of clinical need. We hypothesised that a telemonitoring programme could lead to fewer disease flares, better quality-of-life and lower costs.

**METHODS:** In a multicenter trial teenagers aged 10 to 19 years with IBD were randomly assigned to telemonitoring or usual care. Participants were eligible when the diagnosis was made >6 months before study inclusion, when their disease was in remission at baseline and when they had access to Internet. Teenagers assigned to telemonitoring received automated e-mail alerts to fill in the symptom score and to send in a stool sample for calprotectin measurement. High scores (code red) indicated disease flare and justified treatment intensification. Low scores (green) indicated disease remission and justified continuation of current therapy. Scores in the inconclusive range (orange) justified a discussion on drug adherence. The frequency of e-mail alerts depended on the preceding colour code and varied from 1 to 3 months. Participants in the usual care group had regular scheduled visits. After 52 weeks of follow-up we evaluated the cumulative incidence of disease flares per group. Secondary outcomes included the change in quality-of-life score from baseline and cost effectiveness.

**RESULTS:** We followed 170 participants, of which 84 were assigned to telemonitoring and 86 to usual care. The number of disease flares per group were not different (respectively 33 and 34%). Quality of life at baseline was comparable. After a year of telemonitoring the quality-of-life score was significantly better compared to usual care. Provided that patients are compliant to automated e-mail alerts, telemonitoring saves €360 per patient annually. Nation-wide implementation of the telemonitoring programme would lead to a cost saving of €0.8 million per year.

**CONCLUSION:** Long distance monitoring of teenagers with IBD is as safe as traditional care. Better quality of life and lower costs make this eHealth application the dominant strategy for monitoring teenagers with IBD.

## **Does health research effort match health needs? A large scale comparison between the global conduct of randomized controlled trials and the global burden of diseases**

*Ignacio Atal, Ludovic Trinquart, Philippe Ravaud, Raphaël Porcher  
INSERM U1153, Paris, France*

**BACKGROUND:** Concerns exist whether the allocation of resources in health research is aligned with public health needs, in particular in low resource settings.

**OBJECTIVE:** We aim at evaluating the alignment between the effort of health research through the conduct of randomized controlled trials (RCTs) and health needs measured as the burden of diseases for all regions and all diseases.

**METHODS:** We grouped countries in seven epidemiological regions and diseases in 27 groups. We mapped all RCTs registered at the WHO ICTRP which started in 2006-2015 to each region and group of diseases. We mapped the burden in 2005 as DALYs based on the Global Burden of Diseases 2010 study. Within regions, we identified local research gaps, i.e. groups of diseases for which there is little research as compared to the local burden. Within groups of diseases we compared the share of the conduct of RCTs and the burden across non-high-income regions.

**RESULTS:** We mapped 117,180 RCTs and 2,220 million DALYs. In high-income vs non-high-income countries, 130.9 vs 6.9 RCTs per million DALYs were conducted. We did not identify local research gaps in high-income countries. In Sub-Saharan Africa, South Asia and Eastern Europe and Central Asia, we identified local research gaps for the respective major cause of local burden. There were no local research gaps in Sub-Saharan Africa for Malaria and HIV, which were the second and third highest causes of burden, respectively. We identified few local research gaps in other regions. For some major causes of burden, there was less research in Sub-Saharan Africa and South Asia as compared to other non-high-income regions.

**CONCLUSIONS:** Most RCTs were conducted in high-income countries, and their share across groups of diseases was aligned with the burden of those countries. Despite an overall low number of RCTs in non-high-income regions, the local research effort was generally aligned with the regional burden except for some major causes of burden.