

### 0003 - A Systematic Review of the Methodological and Reporting Quality of Case Series in Surgery

Riaz A. Agha<sup>1,2</sup>, Alexander J. Fowler<sup>3</sup>, Seon-Young Lee<sup>4</sup>, Buket Gundogan<sup>5</sup>, Katharine Whitehurst<sup>5</sup>, Harkiran K. Sagoo<sup>6</sup>, Kyung Jin Lee Jeong<sup>7</sup>, Douglas G. Altman<sup>8</sup>, Dennis P. Orgill<sup>1</sup>

<sup>1</sup>Balliol College, University of Oxford, Oxford, UK, <sup>2</sup>Department of Plastic Surgery, Guy's and St. Thomas' NHS Foundation Trust, London, UK, <sup>3</sup>Department of Medicine, Guy's and St. Thomas' NHS Foundation Trust, London, UK, <sup>4</sup>University of Southampton Medical School, Southampton, UK, <sup>5</sup>University College London Medical School, London, UK, <sup>6</sup>King's College London GKT School of Medical Education, London, UK, <sup>7</sup>Norfolk and Norwich University Hospital, Norfolk, UK, <sup>8</sup>Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences, University of Oxford, Oxford, UK, <sup>9</sup>Harvard Medical School, Boston, USA

**Abstract:** Case Series are an important and common study type. Currently no guideline exists for reporting case series and there is evidence of key data being missed from such reports. We propose to develop a reporting guideline for case series using a methodologically robust technique. The first step in this process is a systematic review of literature relevant to the reporting deficiencies of case series.

**Objectives:** To conduct a systematic review of methodological and reporting quality in surgical case series.

**Method:** A systematic review of methodological and reporting quality in surgical case series was performed. The electronic search strategy was developed by an information specialist and included MEDLINE, EMBASE, Cochrane Methods Register, Science Citation index and Conference Proceedings Citation index, from the start of indexing until 5th November 2014. Independent screening, eligibility assessments and data extraction was performed. Included articles were then analysed for five areas of deficiency: failure to use standardised definitions, missing or selective data, transparency or incomplete reporting, whether alternate study designs were considered and other issues.

**Results:** The database searching identified 2,205 records. Through the process of screening and eligibility assessments 92 articles met inclusion criteria. Frequency of methodological and reporting issues identified was: failure to use standardised definitions (57%), missing or selective data (66%), transparency or incomplete reporting (70%), whether alternate study designs were considered (11%) and other issues (52%).

**Conclusions:** The methodological and reporting quality of surgical case series needs improvement. Our data shows that clear evidence-based guidelines for the conduct and reporting of a case series may be useful to those planning or conducting them.

### 0007 - Support for Reporting Guidelines in Surgical Journals Needs Improvement: A Systematic Review

Riaz Agha<sup>1</sup>, Shivanchan Rajmohan<sup>2</sup>, Ishani Barai<sup>2</sup>, Seon Lee<sup>3</sup>, Mohammed O. Anwar<sup>4</sup>, Alex Fowler<sup>5</sup>, Dennis Orgill<sup>6</sup>, Douglas Altman<sup>7</sup>

<sup>1</sup>Department of Plastic Surgery, Guy's and St. Thomas' NHS Foundation Trust, London, UK, <sup>2</sup>Imperial College School of Medicine, London, UK, <sup>3</sup>University of Southampton Medical School, Southampton, UK, <sup>4</sup>Bart's and The London School of Medicine and Dentistry, Queen Mary and Westfield University, London, UK, <sup>5</sup>Department of Medicine, Guy's and St. Thomas' NHS Foundation Trust, London, UK, <sup>6</sup>Division of Plastic Surgery, Brigham and Women's Hospital, Boston, USA, <sup>7</sup>Centre for Statistics in Medicine, University of Oxford, Oxford, UK

**Introduction:** Evidence-based medicine works best if the evidence is reported well. Past studies have shown reporting quality to be lacking in the field of surgery. Reporting guidelines enable authors to optimize the reporting of their research. The objective of this study was to analyse the frequency and strength of recommendation for such reporting guidelines within surgical journals.

**Objectives:** The objective of this study was to analyse the frequency and strength of recommendation for reporting guidelines within surgical journals.

**Methods:** The online guide-for-authors (GFA) of 198 surgical journals within the Journal Citation Report 2014 published by Thomson Reuters were screened by two independent groups. Data regarding the presence and strength of recommendation to use reporting guidelines was extracted.

**Results:** 193 journals were included (as five appeared twice having changed their name). These had a median impact factor of 1.526 (range 0.047-8.327), with a median of 145 articles published per journal (range 29-659), with 34,036 articles published in total over the two-year window 2012-2013. The majority (62%) of surgical journals made no mention of reporting guidelines within their GFA. Of the 73 (38%) that did mention them, only 14% (10/73) required the use of all relevant reporting guidelines. The most frequently mentioned reporting guideline was CONSORT (46 journals).

**Conclusion:** The mention of reporting guidelines within the GFA of surgical journals needs improvement. Authors, reviewers and editors should ensure that research is reported in line with the relevant reporting guidelines. Journals should consider hard-wiring adherence to them. Peer-reviewers can then

focus on what's present, not what's missing, raising the level of scholarly discourse between authors and the scientific community and reducing frustration amongst readers.

### **0008 - Compliance of Systematic Reviews in Plastic Surgery With the PRISMA Statement: A Systematic Review**

Seon-Young Lee<sup>1</sup>, Harkiran Sagoo<sup>2</sup>, Katharine Whitehurst<sup>3</sup>, Georgina Wellstead<sup>4</sup>, Alexander Fowler<sup>4</sup>, Riaz Agha<sup>5</sup>, Dennis Orgill<sup>6</sup>

<sup>1</sup>Southampton Medical School, Southampton, UK, <sup>2</sup>Guys Kings and St Thomas' School of Medical Education, London, UK, <sup>3</sup>University College London, London, UK, <sup>4</sup>Barts and The London School of Medicine and Dentistry, London, UK, <sup>5</sup>Guys and St Thomas' NHS Foundation Trust, London, UK, <sup>6</sup>Brigham and Women's Hospital and Harvard Medical School, Boston, USA

**Introduction:** Systematic reviews attempt to answer research questions by synthesising the data within primary papers. They are an increasingly important tool within evidence-based medicine, guiding both clinical practice, future research and healthcare policy. We sought to determine the reporting quality of recent systematic reviews in plastic surgery.

**Objectives:** Systematic reviews attempt to answer research questions by synthesising the data within primary papers. They are an increasingly important tool within evidence-based medicine, guiding both clinical practice, future research and healthcare policy. We sought to determine the reporting quality of recent systematic reviews in plastic surgery.

**Methods:** This systematic review was conducted in line with the Cochrane handbook, reported in line with the PRISMA statement and registered at the ResearchRegistry (UIN: reviewregistry18). MEDLINE and EMBASE databases were searched in 2013 and 2014 for systematic reviews by five major plastic surgery journals. Screening, identification and data extraction was performed independently by two teams.

**Results:** From an initial set of 163 articles, 79 met the inclusion criteria. The median PRISMA score was 16 out of 27 items (59.3%; range 6-26, 95% CI 14-17). Compliance between individual PRISMA items showed high variability. It was poorest for items related to the use of review protocol (item 5; 5%) and presentation of data on risk of bias of each study (item 19; 18%), while being the highest for description of rationale (item 3; 99%) and sources of funding and other support (item 27; 95%), and for structured summary in the abstract (item 2; 95%).

**Conclusion:** The reporting quality of systematic reviews in plastic surgery requires improvement. 'Hard-wiring' of compliance through journal submission systems, as well as improved education, awareness and a cohesive strategy among all stakeholders is called for.

### **0009 - Delivering Speech and Language Therapy services to mainstream schools via video-conferencing: a service evaluation**

Alys Mathers, Joanne Crouch

Oxford Health NHS Foundation Trust, Oxford, UK

**Abstract:** Demand for Children's Speech and Language therapy services in Buckinghamshire is increasing, with approximately 4,000 service users, seen by 50 whole-time equivalent therapists. Travel time and costs are high, and therapists often cannot schedule sessions at the most convenient times for children and schools due to busy timetables. Children, parents and schools have all expressed that they would like a greater degree of flexibility in when and how therapy is delivered. Video-conferencing tools such as Skype are used in other countries to deliver Speech and Language therapy remotely (ASHA, 2015) to meet these challenges, however this is not a common service delivery method in the UK. This led the Buckinghamshire Children's Speech and Language therapist to carry out a service evaluation into delivering therapy via Skype during the Spring term 2015. 22 students received half a term of face-to-face therapy and half a term of remote therapy (in a crossover design). We compared the delivery of therapy via Skype with face-to-face therapy, evaluating progress towards therapy targets, level of student engagement, acceptability to service users and therapists, and information about travel and therapy time. Clinical outcomes and levels of student engagement were comparable in both conditions, and travel time reduced significantly. Therapy sessions took a similar amount of time in both conditions. Following the evaluation, participants across all groups were more enthusiastic and perceptions were more positive than pre-Skype therapy.

#### **Objectives**

- To identify whether student progress towards their therapy targets was comparable to face-to-face therapy sessions (using therapist and student-rated goal-based outcome measures).

- To investigate the potential time savings through therapist records of time spent on various activities (including travel, liaison and preparation)
- To establish the acceptability of delivering therapy via Skype; the views of children, school staff, families and therapists were collected through focus groups before and after the Skype therapy sessions, and questionnaires at the end of the evaluation

**Method:** Twenty-two students in 17 different primary and secondary schools took part in the evaluation. An AB/BA study design was used; students received half a term of Skype therapy and half a term of face-to-face therapy, and were allocated to either Skype therapy first or face-to-face therapy first.

Therapists set targets with the students before and after both the Skype and the face-to-face sessions. Both the therapists and students then rated the targets on a 5 point scale from 'very hard' (=1) to 'very easy' (=5). Progress scores were calculated as the difference between these two ratings.

**Results:** A t-test comparing the amount of change in scores for Skype vs. face-to-face therapy suggests that there is no significant difference between progress made in one mode of therapy vs the other for therapists' or students' goal-based outcome ratings.

Therapy sessions and administration tasks took a similar amount of time regardless of mode of therapy. Skype therapy significantly reduced travel time (22 minutes for face-to-face vs. 8 minutes for Skype sessions). Following the evaluation, participants across all groups were more enthusiastic and perceptions were more positive. Some LSAs felt more involved with the Skype sessions than the face-to-face sessions.

**Conclusions:** Our results indicate that Skype may be an effective service delivery method for Speech and Language therapy input, however further research is required to draw any firm conclusions. Within this evaluation, clinical outcomes were maintained, and participants were satisfied with this new method of working.

School staff and therapists felt that that Skype therapy would be most effective when delivered as an option alongside face-to-face therapy. Offering a Skype therapy option could lead to a more flexible service if reliable IT equipment and support, for both the schools and NHS site, is in place.

## **0010 - Why are we losing our precious blood donors?. A systematic review from Pakistan.**

Ayesha Memon

Section of Haematology, Department of Pathology & Laboratory Medicine Aga Khan University Hospital Karachi, Sindh, Pakistan

**Background:** Worldwide, a great majority of blood donors are deferred and many of these deferrals are for temporary reasons. This may cause loss of precious blood donors. This is also a common practice in Pakistan. Given the limited number of blood donors in our setting it is undesirable to defer a significant number of blood donors. This systematic review was conducted to document the various reasons for temporary deferral in Pakistan.

**Aim & Objective:** To carry out a systematic review of the surveys addressing the reasons of temporary blood donor deferral in Pakistan

**Method:** PAKMEDINET, GOOGLE SCHOLAR, PUB MED, CINAHL and EMBASE search engines were used for literature search by using following terms "pre donation deferrals Pakistan", "temporary reasons for blood donation deferrals", "questionnaire related deferrals in Pakistan" and "temporary blood donor deferrals Pakistan" from January 2010 to December 2015. Studies which addressed transfusion transmitted infections and permanent causes of donor deferrals were excluded. Case reports were also excluded. Finally 4 relevant studies were selected and reviewed. Results were analyzed by using SPSS version 21. Forest plot was made to analyze these studies and p value < 0.05 was taken significant.

**Results:** The search generated 8459 records for the year 2010 to 2015. 4 relevant studies were selected and reviewed. These studies were carried out in various blood banks located in different provinces of Pakistan. Based on the collective findings of these studies; anemia 31%, low blood pressure 21%, medications 8%, donation in last 3 months 8% and low weight for age 5% were identified to be the commonly observed factors for temporary blood donor deferral.

**Conclusion:** Anemia was found to be the most frequent cause of temporary blood donation deferral in our population. It is important to provide donors with a clear message regarding their deferral status. They should be encouraged to come again after their deferral period. Public awareness and education regarding blood donation may decrease deferral rates and can prevent an unfavorable impact on the donor as well as on blood donations.

## **0019 - Slow Medicine: the Italian approach to appropriateness cannot be through a law.**

Maria Congedo<sup>1,2</sup>, Sandra Venero<sup>1</sup>, Antonio Bonaldi<sup>1</sup>, Marco Bobbio<sup>1</sup>, Andrea Gardini<sup>1</sup>

<sup>1</sup>Slow Medicine, Torino, Italy, <sup>2</sup>Cochrane Neurosciences Field (CNF), Perugia, Italy

Slow Medicine<sup>1</sup>, a movement founded in 2011 to promote a measured, respectful and equitable medicine, launched the campaign: "Doing more does not mean doing better" in Italy in 2012. The campaign, part of Choosing Wisely International<sup>2,3</sup>, is promoted by the *Federazione Nazionale dei Medici Chirurghi e degli Odontoiatri*, FNOMCeO (equivalent in the UK to the General Medical Council, GMC), by the Italian Nurses' Colleges, IPASVI, and by other associations of health professionals, patients and citizens.

The campaign aims to promote a culture that believes "Doing more does not mean doing better" to improve quality, prevent harm, engage physicians and patients in conversations about care, sharing good evidence information in plain communication. Medical societies membership at present stands at 34. Current main activity is the production of "Top five lists" of overused tests, treatments and procedures, (28 lists has been published, for 140 recommendations<sup>1</sup>) but contributing to politics is needed.

The Italian law n. 125/2015, focusing on health care costs and overuse of medical tests, was published in the *Gazzetta Ufficiale* on 14 August 2015 and established specific criteria for medical test prescriptions.

Prescriptions not following these criteria will no longer be charged to the National Health Service but to citizens. Doctors will be economically penalized for prescriptions considered inappropriate.

Slow Medicine published an open letter expressing opposition to this way of saving money, suggesting the need to pursue clinical appropriateness through a cultural change of health professionals and citizens<sup>4</sup>.

The movement is contrary to the reduction of government financing to the National Health Service, as Italy ranks below the OECD average in terms of health spending per capita<sup>5</sup>: what Italy needs is to spend better for healthcare, through the reduction of misuse (overuse and underuse) by physicians trained in EBM and medical humanities, not to spend less.

1 [www.slowmedicine.it](http://www.slowmedicine.it)

2 Hurley R. Can doctors reduce harmful overuse worldwide? *BMJ* 2014;349:g4289.

3 Levinson W, Kallewaard M, Bhatia RS, Wolfson D, Shortt S, Kerr EA. 'Choosing Wisely': a growing international campaign. *BMJ Qual Saf* 2015;24(2):167-74.

4 Slow Medicine e il decreto per limitare le prescrizioni inappropriate. September 29th, 2015

<http://www.slowmedicine.it/notizie/143-appropriatezza-prescrittiva/397-l-appropriatezza-secondo-slow-medicine.html>

5 [http://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance\\_19991312;jsessionid=c1kqtr25h88af.x-oecd-live-02](http://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance_19991312;jsessionid=c1kqtr25h88af.x-oecd-live-02)

**Objectives:** Slow Medicine published an open letter expressing opposition to the Italian law n. 125/2015, focusing on health care costs and overuse of medical tests, suggesting the need to pursue clinical appropriateness through a cultural change of health professionals and citizens.

The movement is contrary to the reduction of government financing to the National Health Service, as Italy ranks below the OECD average in terms of health spending per capita: what Italy needs is to spend better for healthcare, through the reduction of misuse (overuse and underuse) by physicians trained in EBM and medical humanities, not to spend less.

**Method:** Slow Medicine current activity is the production and diffusion of "Top Five Lists" of overused tests, treatments and procedure.

**Results:** 28 lists have already been published.

The lists are written by Italian medical societies, distributed via the web and in conferences, workshops or roundtables throughout the country. Patient-friendly material by both physicians and citizens are produced, with the collaboration of the *Altroconsumo*, journal for consumer information.

**Conclusions:** Without a shared effort to reach the roots of inappropriateness, the present law encourages private clinical activity and increases inequalities, giving Italian citizens fewer opportunities to have an efficacious, effective and equitable National Health Service.

## 0021 - The Use of Study Registration and Protocols in Plastic Surgery Research: A systematic review

Thomas Edward Pidgeon<sup>1,7</sup>, Christopher Limb<sup>2,7</sup>, Riaz Agha<sup>3,7</sup>, Katherine Whitehurst<sup>4,7</sup>, Charmilie Chandrakumar<sup>5,7</sup>, Georgina Wellstead<sup>5,7</sup>, Alexander Fowler<sup>3,7</sup>, Dennis Orgill<sup>6,7</sup>

<sup>1</sup>St. Andrews Centre for Plastic Surgery and Burns, Essex, UK, <sup>2</sup>Royal Sussex County Hospital, Brighton and Sussex NHS Trust, Sussex, UK, <sup>3</sup>Guy's and St. Thomas' NHS Foundation Trust, London, UK, <sup>4</sup>University College London Medical School, London, UK, <sup>5</sup>Barts and the London School of Medicine and Dentistry, London, UK, <sup>6</sup>Division of Plastic Surgery, Brigham and Women's Hospital, Boston, USA, <sup>7</sup>The Academic Surgical Collaborative, National, UK

**Background:** In 2013, the Declaration of Helsinki mandated that every research study involving human subjects must have its protocol registered in a publicly accessible database prior to the enrolment of the first patient. This systematic review assessed the number of studies published in leading journals of plastic surgery that had either published or registered a protocol with a publicly accessible database.

**Methods:** We examined all research articles involving human participants published in Plastic and

Reconstructive Surgery, The Journal of Plastic Reconstructive and Aesthetic Surgery and The Annals of Plastic Surgery from 1st April 2014 - 31st March 2015. The primary outcome measure was whether each study had registered or published a protocol with any mainstream registry database.

ClinicalTrials.gov, International Standard Randomised Control Trial Number (ISRCTN), WHO (World Health Organisation) International Clinical Trials Registry Platform, The Cochrane Collaboration, the Research Registry, PROSPERO and PubMed were all reviewed.

**Results:** Of 595 included articles, the most common study designs were case series (n=185, 31.1%). There were 24 randomised controlled trials (RCTs, 4.0%). A total of 24 studies had a protocol registered (4.0%), although no studies had published a protocol in a journal. The most common database to register a protocol was ClinicalTrials.gov (n=17). The study design that most commonly had a registered protocol was the RCT (n=8 of 24, 33.3% of RCTs).

**Conclusions:** Publication or registration of protocols for recent studies involving human participants in major plastic surgery journals is low. There is considerable scope to improve this and we provide relevant guidance.

### **0023 - Tweeting links to Cochrane Schizophrenia Group reviews: a randomised controlled trial**

Clive Adams<sup>1</sup>, Mahesh Jayaram<sup>2</sup>, Angeliqe Bodart<sup>1</sup>, Stephanie Sampson<sup>1</sup>, Sai Zhao<sup>3</sup>, Jun Xia<sup>3</sup>, Alan Montgomery<sup>4</sup>

<sup>1</sup>Cochrane Schizophrenia Group, Nottingham, UK, <sup>2</sup>University of Melbourne, Melbourne, Australia,

<sup>3</sup>Systematic Review Solutions, Yan Tai, China, <sup>4</sup>Nottingham Clinical Trials Unit, Nottingham, UK

**Background:** The Cochrane Schizophrenia Group produces and maintains systematic reviews and meta-analyses of randomised trials that evaluate the effects of interventions for schizophrenia and related psychotic illnesses. Each review also has an abstract and a Plain Language Summary to make the information in the review more accessible to people without specialised knowledge. Both are freely available from the Cochrane website.

Twitter is a popular free to use micro-blogging media platform which allows users to send a 140-character message (a 'tweet') to a group who has chosen to receive (or 'follow') these short messages from the sender. The use of Twitter in healthcare has increased, encompassing, for example, issues relating to public health surveillance, tracking disease activity of H1N1 pandemic and isolating the source of a cholera outbreak in Haiti.

Most Cochrane Review Groups have recently developed this method of dissemination. However, an investment of effort is required to undertake this activity, and the potential benefits for review groups with limited numbers of reviews and followers are unclear.

**Objectives:** To assess the effects of using health social media on web activity. To illustrate how objective evaluation of social media is possible, and to present one example of this.

**Design:** Individually randomised controlled parallel group superiority trial.

**Setting:** Twitter and Weibo.

**Participants:** 170 Cochrane Schizophrenia Group full reviews with an abstract and plain language summary web page.

**Interventions:** Three randomly ordered slightly different 140 character or less messages, each containing a short URL to the freely accessible summary page sent on specific times on one single day. This was compared with no messaging.

**Main outcome measure:** The primary outcome was web page visits at one week. Secondary outcomes were other metrics of web activity at one week.

**Results:** Google Analytics allowed 100% follow up within one week of completion. Intervention and control reviews received a total of 1162 and 449 visits respectively (IRR 2.7, 95% CI 2.2 to 3.3). Fewer intervention reviews had single page only visits (16% vs 31%, OR 0.41, 0.19 to 0.88) and users spent more time viewing intervention reviews (geometric mean 76 vs 31 minutes, ratio 2.5, 1.3 to 4.6). Other secondary metrics of web activity all showed strong evidence in favour of the intervention.

**Conclusions:** Tweeting in this limited area of health care increases 'product placement' of evidence with the potential for that to influence care.

Trial Registration number: ISRCTN84658943.

### **0033 - Syndication of NICE content**

Moir Godbert-laird, Iain Moir

NICE, Manchester, UK

**Abstract:** The National Institute for Health and Care Excellence (NICE) is the independent organisation responsible for providing national guidance and supporting information on promoting good health and preventing and treating ill health in England. NICE guidance is developed using the expertise of the NHS and the wider healthcare community, including healthcare and other professionals, patients, service users and carers, the academic world and the healthcare industry.

The NICE Syndication Service is part of our digital content dissemination strategy which allows commercial and non-commercial third-party organisations both within the UK and overseas to embed selected NICE content to include its guidelines within their own systems and services. This opens up new distribution channels for NICE.

**Objectives:** The service aims to formalise and control the distribution of NICE content through a quality assured service - limiting unauthorised use by providing content openly and in superior digital formats suitable for integration and presentation purposes. Benefits include seamless real-time delivery, links with NICE and the use of our logo where appropriate within your application or system. The main four delivery mechanisms currently available are:

**Method:** As content is 'pulled' by the third party directly from NICE, syndication ensures content is always up to date (although the third party can choose to locally store NICE content).

Syndication is provided through an Application Programming Interface (API). When an application is accepted, the third party will be given their own unique API key which only allows access to the specific NICE services agreed in their licence. Our site is designed as a RESTful interface for developers and content integrators to explore the services we have available and understand how to access and use the NICE API.

#### **0040 - Quantifying the Drug Safety Evidence Deficit: Analysis of the Drugs Withdrawn from the United States Market from 1976 to 2010 for Safety Reasons**

Pierre La Rochelle

*Université Laval, Quebec, Quebec, Canada*

**Context:** Drugs are regularly withdrawn for safety reasons, illustrating an evidence gap in the knowledge in this area when they are first marketed.

**Objectives:** To describe the use of different types of evidence leading to drug withdrawals for safety reason from 1976 to 2010 in the United States (US).

**Design:** Retrospective cohort study.

**Methods:** A list of drugs withdrawn from the market for safety reason was generated along with the corresponding period of time each drug was marketed. Evidence used to justify the withdrawal was obtained from searching Drugs@FDA and PubMed and evidence was classified according to the study design used to generate the evidence. The number of drugs withdrawn was plotted as a function of how long they were marketed and a mathematical model is derived from this set of data to calculate the mean time the drugs were marketed before withdrawal.

**Main Outcome Measure:** The type of study used to justify the withdrawal and the change in study types over the period analyzed.

**Results:** 34 drugs were withdrawn. At the time of withdrawal, case-reports alone justified 19/34 withdrawals. Over the study period randomized and non-randomized trials began to be used.

**Conclusions:** Evidence that leads to withdrawal of drugs from the market for safety reasons in the US predominantly comes from case-reports

#### **0044 - Intra Uterine Fetal Death And Some Related Factors: A Silent Tragedy In Southeastern Iran**

Ameneh Safarzadeh<sup>1</sup>, Maryam Ghaedniajehromi<sup>2</sup>, Morteza Ghaedniajehromi<sup>3</sup>, Farzaneh Rigi<sup>4</sup>, Nazanin Massori<sup>5</sup>

<sup>1</sup>Pregnancy Health Research Center, Zahedan University Of Medical Sciences, Zahedan.Iran., Zahedan, Cystan& Balochestan, Iran, <sup>2</sup>Midwifery Student at Pregnancy Health Research Center, Zahedan University Of Medical Sciences, Zahedan.Iran., Zahedan, Cystan& Balochestan, Iran, <sup>3</sup>Research Center of Baghiyatallah University of Medical Sciences, Tehran, Iran, Tehran, TEHRAN, Iran, <sup>4</sup>Midwifery Student at Pregnancy Health Research Center, Zahedan University Of Medical Sciences, Zahedan.Iran., Zahedan, Cystan& Balochestan, Iran, <sup>5</sup>Midwifery Student at Pregnancy Health Research Center, Zahedan University Of Medical Sciences, Zahedan.Iran., Zahedan, Cystan& Balochestan, Iran

**Objective:** To determine the incidence, and some causes of intra uterine fetal death (IUFD).

**Methods:** This was a prospective observational study of all stillbirths over a 2 years from April 2011 to April 2013 at the Imam Ali University Teaching Hospital of zahedan,Iran The variables studied were the following:

demographic characteristic, fetal factors and maternal factors. Data was collected prospectively by directly interviewing the pregnant women and from the medical chart .Data were analyzed using SPSS (Statistical Package for the Social Sciences) statistical package.

**Results:** The incidence of IUFD at our hospital was 88.7 per 1000 total births. The intra uterine fetal rate had been increased in maternal ages under 20 years and above 35 years that showed a significant difference between this group and other groups( $P=0.001$ ).There was a significant trend in parity of 1 and parity of 10 and above. The rate of IUFD tended to decreased with increasing gestational age .There were 437 (54.1%) macerated and 370 (45.8%) fresh death fetus. Unexplained' IUFD, Major congenital malformations, PROM, and preeclampsia were the three main causes of intra uterine fetal death.

**Conclusion:** Unfortunately, in our study the incidence of IUFD was very high. The main risk factors identified were lack of antenatal care. Despite the difficulty in predicting IUFD occurrence, it appears that carefully implemented antenatal care, family planning, genetic counseling and timely management of at risk patients may contribute to its prevention.

#### **0047 – The First Pioneer Two Studies which Created the Basic Evidences Behind the need for the Reform of the Jordanian Governmental Drug Quality Control Laboratory:Lessons from the past**

Laila J. Badran

Former Advisor to the Minister of Health for Drug Affairs

Although these two studies (I A 1989 and I B 1995) were performed and achieved about a decade till the date of their implementation in 2003, but they are still valid in these days; because not many changes were made in the system during those elapsed years due to managerial and economical obstacles in addition to regional political instability.

Furthermore the importance of these two studies today : is that both can be used as Evidence Models for establishing new National Drug Quality Control Laboratory in any developing country.

The particular importance of these two studies depends on the fact that Jordan used to import at the times of those two studies about 80% from all over the world of the total medicinal products consumed per annum and this required proper efficient Quality Control system.

Another reason was that as the result of thorough investigation (during the time of these studies) of random number of DQCL Reports, indicated that not all of the pharmacopoeial tests required for various dosage forms were performed by the Analysts. This might be explained by the very high workload on the Analysts, resulting in insufficient time to perform all the required Pharmacopoeial tests on each batch of Post-Licensed medicinal products Imported and Locally produced, in addition to those on new products (as part of the Pre-Licensing Process).

These facts were some of the main driving forces for the need to establish a new purpose-built, Governmental DQCL for the control of such pharmaceutical preparations in Jordan.

Therefore, the value of these studies is that they reveal the Evidence of common defects in the system that have not yet been solved, using very special characteristic analytical techniques (by comparison of the data within the DQCL system, and then by comparison of the Jordanian DQCL system with those of other International leading systems), with the provision of the applicable proposals for the expected Reform in this very vital sector (pharmaceutical and Drug Sector), at the MOH, to ensure thorough control of all batches of imported and locally manufactured Pre- and Post- Licensed medicinal products.

Objective; Presenting the Evidence to the decision making higher authority (the Minister of Health) for the Urgent need for the Reform of the existing Drug Quality Control Laboratory.

Method: Methodology is Based on comparison of the data within the DQCL system, followed by comparison of the Jordanian DQCL system with those of other International leading systems

Results: Results indicate the evidence for urgent need for the Reform, because of wide gap between Jordanian DQCL compared with worldwide highly reputable Drug regulatory systems as UK, USA, Japan.

Conclusion: The need for Reform of the Drug Quality Control Laboratory covering the increase in the number of Specialized Analysts, in the Working Area , in the required specialized Analytical instruments, and changing the Regulations and improving the computerized system and advanced training for Analysts Most have been achieved in 2003.

#### **0048 - Developing a Method and System to Evaluate Clinical Usefulness of Findings in Medical Research**

Kim Kristiansen, JG Staal

*Zignifica, Richmond, Virginia, USA*

**Background:** The clinical usefulness of findings from medical science presented in scientific medical journals depends on the quality of the study, and thereby by both the method and design of the study and of the

findings. Results presented in medical journals are rarely possible to interpret and understand for patients and untrained persons, and it is difficult and time consuming for physicians and other healthcare professionals to distinguish clinical useful and not-useful information in the plethora of medical information.

**Aim:** To develop a method and system to evaluate clinical usefulness of findings in medical research, by evaluating and rating the clinical usefulness and significance of the method and design, results and conclusion of medical research, and present this in an easily understandable and accessible structure and format.

**Method:** The method and system capture and analyzes information provided within and directly distilled from the medical research such as PubMed, Europe-PubMed-Central, scientific medical journal websites, ClinicalTrials-website etc. Based on statistical and medical accepted functions the system determines the statistical and clinical significance related to the methods and results as presented in the medical research.

**Result:** Developing a mobile application with the system and algorithms followed.

The evaluation of the individual paper is presented as scores and ranking based on evaluation of both method/design and the results of the individual study. The system also provides a description in terms understandable for both persons with and without medical education. Focusing on pain related research, the system is tested for usefulness and value in a test-panel including both healthcare professionals and non-medical persons.

**Conclusion:** The method enables healthcare professionals and non-medical persons to get easy access to useful information from clinical-relevant medical research, and when presented with information based on medical research to evaluate the clinical usefulness of this information.

#### **0049 - Is there an association between study size and study quality in dermatological clinical trials? A meta-epidemiological review.**

Sonia Ratib, Sally Wilkes, Matthew Grainge, Kim Thomas, Chanel Toninska, Hywel Thomas  
*University of Nottingham, Nottingham, UK*

**Background & objective:** To explore a possible association between study quality (internal validity) and study size in dermatological clinical trials. We hypothesised that trial size might serve as a reasonable surrogate marker for overall study quality.

**Methods:** A meta-epidemiological review of Cochrane Skin Group systematic reviews published between January 2010 and December 2014 was conducted. We extracted the following information per trial: randomised sample size, study design and year of publication. Cochrane Risk of bias tool was used for the following quality criteria: (i) methods for sequence generation, (ii) allocation concealment, (iii) blinding of participants and personnel, (iv) blinding of outcome assessment, and (v) incomplete outcome data. Kruskal Wallis and Mann-Whitney U tests were used to determine statistical associations between sample size and risk of bias categories (low, high and unclear).

**Results:** 1,130 trials were identified from 34 Cochrane reviews. The median sample size was 72 [interquartile range 40 to 152] patients. Most trials were of parallel design (n=931, 82.5%). For all criteria except random sequence generation, trials with low risk of bias had a slightly larger median sample size than those that were high risk of bias, but these differences were not statistically significant. Risk of bias was unclear for random sequence generation and allocation concealment in 64.3% and 79% of trials, respectively.

**Conclusion:** There was no clear association between sample size and risk of bias in this sample of 1,130 dermatological clinical trials included in recent Cochrane reviews. The study is limited by the high proportion of studies that included unclear risk of bias. We conclude that quickly glancing at sample size is not a reliable indicator of overall study quality.

#### **0053 - Achieving adherence: the art of shared decision making, and more**

Ted Klok<sup>1,3</sup>, Adrian Kaptein<sup>2</sup>, Paul Brand<sup>1,4</sup>

<sup>1</sup>Princess Amalia Children's Centre, Isala Hospital, Zwolle, The Netherlands, <sup>2</sup>Unit of Psychology, LUMC, Leiden, The Netherlands, <sup>3</sup>Division of Pediatric Pulmonology and Allergology, Wilhelmina Children's Hospital, Utrecht, The Netherlands, <sup>4</sup>UMCG Postgraduate School of Medicine, University Medical Centre and University of Groningen, Groningen, The Netherlands

**Objective:** Non-adherence to daily controller medication in childhood asthma is strongly dependent on potentially modifiable factors such as parental illness perceptions and medication beliefs. The extent to which adherence in children can be improved by addressing modifiable determinants of nonadherence has not been studied to date, however. We assessed long-term adherence and its determinants in children



with asthma enrolled in a comprehensive asthma care program employing shared decision making with parents.

**Method:** Observational study in 135 asthmatic children 2-12 years of age attending a hospital-based outpatient clinic. One-year adherence to inhaled corticosteroids was measured by electronic devices. Parental illness perceptions and medication beliefs, and asthma control were assessed by validated questionnaires, including the Beliefs about Medicines Questionnaire (BMQ).

**Results:** Median (interquartile range) adherence was 84% (70-92%). 55 children (41%) did not achieve the good adherence (>80%); this was associated with poorer asthma control. Parental perceived medication necessity was high. Adherence > 80% was more likely when parents answered affirmatively to the BMQ item "My child's health at present, depends on the medicines" ( $p=0.004$ ) or gave high scores to the item "How much do you think the treatment can help your child's illness" ( $p=0.040$ ). However, 92% of the nonadherent and 87% of the nonadherent families showed medication beliefs concordant with those of the medical team ( $p=0.337$ ).

**Conclusions:** Although concordance between medical team and parents of asthmatic children on the usefulness of daily controller therapy is associated with high adherence and good asthma control, poor adherence and uncontrolled asthma may persist in children despite a high level of concordance between medical team and parents on medication beliefs, even in the absence of socioeconomic barriers to good adherence. Achieving good adherence in children with a chronic disease is a complex task, requiring interventions not covered in current disease management guidelines.

#### **0054 - Systematic review of effectiveness of immunotherapy for pediatric asthma: the importance of applicability of research evidence**

Mariska Tuut<sup>1</sup>, Erik-Jonas van de Griendt<sup>2,3</sup>, Nicole Boluyt<sup>4</sup>, Hans de Groot<sup>5</sup>, Paul Brand<sup>6</sup>

<sup>1</sup>PROVA, Varsseveld, The Netherlands, <sup>2</sup>De Kinderkliniek, Almere, The Netherlands, <sup>3</sup>Flevo Hospital, Almere, The Netherlands, <sup>4</sup>Healthcare Institute of the Netherlands, Diemen, The Netherlands, <sup>5</sup>Department of Paediatric Allergology, Reinier de Graaf Hospital, Delft, The Netherlands, <sup>6</sup>Princess Amalia Children's Centre, Isala Hospital, Zwolle, The Netherlands, <sup>7</sup>UMCG Postgraduate School of Medicine, University Medical Centre and University of Groningen, Groningen, The Netherlands

**Objective:** Allergy plays a major role in both asthma and its common comorbidity allergic rhinitis.

Immunotherapy is used to treat allergic rhinitis, and is thought to have a positive effect on asthma outcomes based on results from systematic reviews (SR) from the 1990s. Because the treatment of asthma has improved considerably since daily controller treatment with inhaled corticosteroids (ICS) has become routine practice, we doubted the applicability of the immunotherapy SR results in contemporary clinical practice. We therefore investigated the effectiveness of subcutaneous (SCIT) and sublingual immunotherapy (SLIT) for paediatric allergic asthma treatment by performing a GRADE systematic review.

**Method:** Patient relevant outcomes and clinical relevance thresholds were predefined. We applied a sensitive search to retrieve systematic reviews and randomized controlled trials (RCT) on immunotherapy for asthma in children (1960 - 2015). The GRADE approach was used to judge the body of evidence.

**Results:** The quality of the evidence for SCIT (one Cochrane review and two RCTs) was very low due to bias and indirectness. No differences were found for asthma symptoms; no studies reported on asthma control, quality of life or FEV<sub>1</sub>. For asthma exacerbations, studies favouring SCIT were performed >30 years ago, with asthma management (no routine ICS use) incomparable to current practice.

For SLIT, the evidence quality (2 SRs) was very low due to bias, indirectness and imprecision. The outcome "asthma symptoms" could not be calculated due to lack of standardization. FEV<sub>1</sub>, reported in one study, showed no difference.

**Conclusions:** Using the latest methods for critical appraisal, there was absence of evidence for the effectiveness of immunotherapy in paediatric asthma treatment. These findings highlight the importance of examining the applicability of results from RCTs and SRs to contemporary clinical practice.

#### **0055 - Practice for Sensible Care: effects of 8-years evidence based practice**

Jolita Bekhof<sup>1</sup>, Veerle Langenhorst<sup>1</sup>, Paul Brand<sup>1,2</sup>

<sup>1</sup>Isala, Zwolle, The Netherlands, <sup>2</sup>University Hospital Groningen, Groningen, The Netherlands

**Objective:** One of the criticisms of Evidence Based Medicine (EBM) is that there is no evidence of the effects of evidence based practice on quality of care and little is known about the effects of implementing EBM in daily clinical practice. At the department of paediatrics in Isala, Zwolle, a large teaching hospital in the Netherlands, EBM has been systematically and actively practiced since 2007. One of the hallmarks of our

EBP is a weekly held CAT-(Critically Appraised Topic)-meeting, where a clinically relevant answerable question is answered in a systematic manner. Our aim is to evaluate the effects on medical care of this evidence-based practice.

**Methods:** We performed a prospective observational study, systematically recording the resumes as well as the results of the CAT-meetings. Every CAT-meeting was rounded off with the question: "What do these results mean for our local practice?" Hereafter the consequences of the CAT's were denoted as 1) no change in local policy or guideline 2) change of policy or guideline or 3) formulation of a research question.

**Results:** In the 8-years period 300 CATs were presented. In one-third of the CATs useful evidence was found. One in four CATs resulted in a change of our policy, in the vast majority resulting in the discontinuation of apparently non-effective treatments or unnecessary diagnostic testing. Furthermore, in one of eight CATs a research question was formulated. These research questions have resulted in 12 definite research protocols, of which seven have been finished by now, resulting in changes of five other local guidelines.

**Conclusion:** Structurally practicing EBM leads to significant changes in clinical practice and more sensible choices. Especially in the era of diagnostic testing, the extent of which is not only driven by uncertainty around a diagnosis, but partly also by historically evolved routines, we have noticed that EBM helps medical staff to deal with this uncertainty in a more objective way, resulting in a significantly diminished use of diagnostic testing compared to the benchmark. Moreover, Evidence Based Practice has helped us to develop to increase scientific activity resulting in immediate adaptation of our local guidelines.

### **0058 - The Effects of Aromatherapy massage on Improvement of Anxiety among Patients Receiving Palliative Care: A Systematic Review of Randomized Controlled Trials**

Tao-Hsin Tung<sup>1</sup>, Chia-Hsien Hsu<sup>2</sup>, Pei-Shih Chen<sup>2</sup>, Shu-Hui Wang<sup>3</sup>, Ching-Chi Chi<sup>4,5</sup>

<sup>1</sup>Department of Medical Research and Education, Cheng Hsin General Hospital, Taipei, Taiwan,

<sup>2</sup>Department of Public Health, College of Health Science, Kaohsiung Medical University, Department of Public Health, College of Health Science, Kaohsiung Medical University, Taiwan, <sup>3</sup>Department of Dermatology, Far Eastern Memorial Hospital, New Taipei, Taiwan, <sup>4</sup>Department of Dermatology, Chang Gung Memorial Hospital, Chiayi, Taiwan, <sup>5</sup>Graduate Institutes of Clinical Medical Science, College of Medicine, Chang Gung University, Taoyuan, Taiwan

**Background:** Palliative care patients' anxiety is a worthy-noted problem because it may influence the quality of life. Aromatherapy is widely utilized to improve anxiety among patients receiving palliate care.

**Objective:** To investigate the effectiveness of improvement compared the intervention group (aromatherapy massage) with control group (common massage alone) on anxiety in palliate care patients.

**Methods:** A literature search was carried out using PubMed and Cochrane Library Central database for all relevant studies without a restriction for language. A quantitative synthesis of randomized controlled trials is conducted to evaluate the effectiveness of score difference between aromatherapy massage and only common massage by fixed-effect model.

**Results:** There were 2 randomized controlled trials included in our systematic review, and we conducted a quantitative synthesis within 114 participants (58 in the intervention group and 56 in the control group). The secondary data from the reviewed trials was pooled with fixed-effect model. Anxiety (mean difference = -0.72 [95% CI: -6.71, 5.27], p = 0.81) was assessed with anxiety scores from State-Trait Anxiety Inventory (STAI).

**Conclusion:** Aromatherapy massage that compared with common massage alone does not provide the significant effectiveness on the improvement of anxiety among patients receiving palliative care.

### **0059 - EBMPICO : a web-based tool for teaching all 4 steps of EBM**

Guylene Theriault<sup>1,2</sup>, Michal Iglewski<sup>2</sup>, Gilles Brousseau<sup>1,3</sup>, Valerie Levasseur<sup>2</sup>

<sup>1</sup>McGill University, Montreal, Quebec, Canada, <sup>2</sup>Universite du Quebec en Outaouais, Gatineau, Quebec, Canada, <sup>3</sup>Centre intégré de sante et services sociaux de l'Outaouais, Gatineau, Quebec, Canada

**Abstract:** For many students and clinicians EBM seems very complicated. It is believed to be out of reach, like if only expert were able to answer their questions using the steps of EBM.

One of the big limitations is remembering how to analyse different types of studies. Appraisal has been shown to be perceived as complex (ref).

Our tool guides the student-clinician in the different steps. It helps them formulate the question using a PICO format and search different databases. Once the student has chosen one or more articles, he only has to identify the type of study and he will be guided throught the appraisal steps.

Our tool is unique and different because it allows to appraise many articles on the chosen question, not only one. It also has an integrated feedback fonction making it useful in teaching as the student and supervisor can communicate in the tool itself, making all the discussion an integral part of the PICO.

At the end the PICO can be printed in a format that is easy to read and always the same

**Objectives:** To demonstrate how EBMPICO can be used in teaching or by individual clinicians.

To share what has been learned since we started to use this tool in teaching

Discuss limitations and future developments.

**Method:** We will introduce the tool and then proceed with examples of how it has been used to help students master the steps of EBM.

**Results:** We will share data on how the tool is perceived and show examples of how the tool helped answer questions in an EBM way.

**Conclusions:** The goal of the short presentation is to introduce a tool that we believe helps teaching EBM. We believe that to actualise the use of evidence by teaching the complete knowledge of EBM steps is a very difficult task and that our tool shows a passive mean of remembering those steps. We think that is a way to make EBM more accessible to students and clinicians

### **0061 - The Cochrane Tobacco Addiction Group at 20: ensuring our evidence is relevant**

Nicola Lindson-Hawley, Jamie Hartmann-Boyce

*Cochrane TAG, University of Oxford, Oxford, UK*

**Objectives:** The Cochrane Tobacco Addiction Group (TAG) carry out systematic reviews of interventions to prevent and treat tobacco addiction. 2016 is the 20<sup>th</sup> anniversary of the group and we are carrying out a project funded by the NIHR School for Primary Care Research to: 1) raise awareness of Cochrane TAG, and the group's achievement; 2) identify where further research is needed in tobacco control and smoking cessation from a wider stakeholder perspective; 3) identify Cochrane TAG specific research goals from a wider stakeholder perspective; and 4) raise awareness of the group's future goals and opportunities arising for authors from this.

**Method:** We are achieving these objectives through a priority setting exercise, involving public and stakeholder dialogue. This includes a two stage survey for TAG stakeholders, including policy makers, healthcare providers, smokers, former smokers and researchers, on questions that still need to be answered in tobacco control. A one-day workshop, led by independent expert facilitators, will then examine the Cochrane TAG review portfolio in light of the previously identified questions and set future priorities - for new reviews, updating existing reviews, and considering ways in which the portfolio could better meet the needs of user groups. The James Lind Alliance advocate such an approach and we are drawing on their key principles to pioneer an inclusive methodological approach to priority setting.

**Results:** At the time of presentation we will have the results of the project's survey element. We will report on these and on our experiences of carrying out this exercise so far, including our motivation, details of our methods, and any benefits and pit falls identified. We will also explain how we plan to implement our findings to benefit the group.

**Conclusions:** Until now, Cochrane TAG's portfolio of reviews has been shaped by researchers. Broadening input will ensure reviews meet a wide range of needs, are relevant to current trends in smoking, and therefore create the highest possible impact, whilst guarding against research wastage. This approach to priority setting could easily be transferred to other research groups.

### **0062 - Impact of a community based evidence based medicine (EBM) workshop on participants' clinical practice and teaching of EBM**

David Allen, Jacques Abourbih, Catherine Cervin, James Goertzen, Marion Maar, Priya Aronnilakkara, Lisa Boesch

*Northern Ontario School of Medicine, Sudbury, ON, Canada*

**Abstract:** As Canada's newest medical school, the Northern Ontario School of Medicine is based on an innovative community-based medical education model. Over 1200 widely distributed clinical faculty support undergraduate and postgraduate medical training. In response to discomfort expressed by clinical faculty with teaching EBM skills in daily clinical practice, a one-day travelling EBM workshop was developed and delivered in nine communities across the region. Since previous research had shown no demonstrable lasting benefit from a half-day critical appraisal workshop, the study workshop focused on question framing, searching for quick, evidence-based answers, keeping up to date, detecting bias and avoiding cognitive traps.

Using a mixed-methods combination of interviews and questionnaires, the researchers assessed participants' post workshop changes in clinical practice or clinical teaching, as well as their comfort with

practicing and teaching EBM.

**Objectives:** The goal of this study was to assess whether a one day EBM workshop for community-based clinical faculty led to a persistent change in comfort with teaching and practicing EBM, and which components of the workshop led to demonstrable change in clinical or teaching practice.

**Method:** Participants completed questionnaires immediately before and after the workshop, which included four Likert scale questions rating comfort with searching clinical questions, keeping up to date, role modeling and teaching EBM. There were also free-text and dropdown questions about how they were currently using evidence based resources in patient care.

Several months later, a similar questionnaire was sent to the participants to assess changes in responses. Telephone interviews of fifteen workshop participants were conducted one year after the workshop, to assess their attitudes towards EBM and continuing professional development in general, and whether the workshop had led to lasting practice changes.

**Results:** Following the workshop, participants' comfort levels on four questions about practicing, teaching and role modeling EBM increased by an average of 0.89 on a five point Likert scale. Most of this improvement was sustained 3-6 months later.

Three to twelve months after the workshop, one half of questionnaire respondents and telephone interviewees reported that they were using the PICO method to frame questions related to clinical practice, teaching or both.

Participants reported that the most useful parts of the workshop were the introduction to new internet-based resources, and the opportunity to practice clinical searches using these resources.

**Conclusions:** A one-day community-based faculty development workshop on EBM significantly increased comfort with both teaching and practicing EBM among clinical faculty. This increased comfort was sustained 3-6 months post-workshop.

Attendees reported that exposure to new resources, with the opportunity to practice their use in clinical searches, was the most valuable component of the workshop. Half of responding participants reported that they were using PICO question-framing for teaching, clinical practice or both 3-12 months after being introduced to it.

## **0063 - Development of Standards for Clinical Practice Guidance in Ireland**

Niamh O'Rourke<sup>1,2</sup>

<sup>1</sup>Department of Health, Dublin, Ireland, <sup>2</sup>Royal College of Surgeons, Dublin, Ireland

**Background:** In clinical practice, there are different types of clinical guidance that vary in complexity and scope. It is important that the development of all clinical guidance uses an evidence-based approach, to ensure evidence-based clinical policy.

Clinical guidance includes clinical policies, procedures, protocols and guidelines.

Clinical practice guidance is defined as systematically developed statements or processes to assist clinician and patient decisions about appropriate health care for specific clinical circumstances.

**Objectives:** These Standards have been developed for healthcare staff developing clinical practice guidance for healthcare in Ireland; to improve the development of evidence based clinical policy.

The objectives of the standards are to:

- Provide a standardised terminology and methodology for the development of evidence-based clinical practice guidance nationally.
- Ensure consistency of approach and minimise duplication of clinical practice guidance in the health system.

**Methods:** The Standards for Clinical Practice Guidance were developed by the Clinical Effectiveness Unit (Department of Health, Ireland). A systematic literature review was conducted. An expert advisory group was convened, with multidisciplinary representation from both public and private health services and a public consultation process was carried out.

**Results:** The Standards for Clinical Practice Guidance were published in November 2015. These Standards will promote consistency of approach and utilisation of appropriate methodology to develop evidence-based clinical practice guidance nationally.

**Conclusions:** It is not in the interests of patient safety for individual organisations/units to develop or implement different guidance for similar clinical circumstances. Through consistency in approach and reduction in duplication, variation in practice can be reduced. Sharing of best practice will optimise the use of health service resources and expertise.

Clinical effectiveness is a key component of patient safety and quality. The integration of best evidence in service provision, through clinical effectiveness processes such as clinical practice guidance, promotes healthcare that is evidence-based, up-to-date and effective.

These standards aim to translate evidence into policy and practice, closing the gap between research and

clinical care. The standards promote the implementation of evidence-based solutions in health care, ultimately providing better quality health services for our patients.

### **0066 - Indirect evidence of publication bias in medical research**

Loai Albarqouni<sup>1</sup>, José A. López-López<sup>2</sup>, Julian Higgins<sup>2</sup>

<sup>1</sup>Bond University, Gold Coast, Australia, <sup>2</sup>University of Bristol, Bristol, UK

**Background:** Complete publication of study results is essential to allow healthcare professionals and policy makers to make informed decisions. The validity of research synthesis is threatened if published studies comprise a biased selection of all studies. Our aim was to explore indirect evidence of publication bias by examining the distribution of p-values reported in a large random sample of medical research studies and comparing p-value distributions across different contexts.

**Objectives:** We aimed to explore indirect evidence of publication bias by examining the distribution of p-values reported in a large random sample of medical research studies and comparing p-value distributions across different contexts.

**Methods:** We selected a random sample (n=1500) of peer-reviewed articles published in PubMed on March 2014. We included articles that reported sufficient details of the results of inferential statistics. Specifically, we included articles investigating the efficacy/side effects of a medical or surgical intervention; or investigating risk factors/exposure/prognostic factors (epidemiological associations). Additionally, we extracted information on study type, design, medical discipline and p-value for the first reported outcome and primary outcome (if specified) from each article.

**Results:** Out of the 1500 randomly selected records, 758 (50.5%) were included. We retrieved 758 p-values for first reported outcomes and 386 p-values for primary outcomes. The distributions of p-values for first reported outcomes and primary outcomes was positively skewed, with a clear majority of significant p-values (e.g. smaller than 0.05) and two noticeable discontinuities at 0.01 and 0.05. The concentration of p-values below both thresholds was more extreme for first reported outcomes than for primary outcomes. Similar results were observed across various study designs and types, whereas some differences were found across medical disciplines.

**Discussion and Conclusions:** Our findings provide some indirect evidence that publication bias is still a widespread issue in the medical literature across different medical disciplines, study designs and types.

### **0067 - Impact of a web-based tool (WebCONSORT) to improve the reporting of randomised trials: results of a randomised controlled trial**

Sally Hopewell<sup>1,2</sup>, Isabelle Boutron<sup>2</sup>, Doug Altman<sup>1</sup>, Philippe Ravaut<sup>2</sup>

<sup>1</sup>University of Oxford, Oxford, UK, <sup>2</sup>Université Paris Descartes, Paris, France

**Objective:** To evaluate the impact of a simple web-based tool (WebCONSORT, which incorporates a number of different CONSORT extensions) on the completeness of reporting of randomised trials published in biomedical journals. WebCONSORT allows authors to obtain a customised CONSORT checklist and flow diagram specific to their trial design and type of intervention.

**Methods:** We conducted a parallel group randomised trial. Journals which endorsed the CONSORT Statement (i.e. referred to in Instruction to Authors) but do not actively implement it (i.e. require authors to submit a completed CONSORT checklist) were invited to participate. Authors of participating journals were requested at the manuscript revision stage to use the web-based tool to improve the reporting of their randomised trial. Authors registering to use the tool were randomised (centralised computer generated) to intervention (WebCONSORT) or control. In the control group, authors received a different version of the WebCONSORT tool which included the CONSORT flow diagram but not the main checklist or elements relating to CONSORT extensions. Authors and journal editors were blinded to the allocation. The primary outcome was the proportion of CONSORT items (main and extensions) reported in each manuscript post revision.

**Results:** 46 journals actively recruited authors into the trial (25 March 2013 to 22 September 2015). 324 author manuscripts were randomised (WebCONSORT n=166; control n=158); of which 197 were included in the final analysis (n=94; n=103). Reasons for exclusion included: not randomised (n=46); secondary publication (n=9); animal (n=8) review (n=7); prognostic study (n=6). Of those included in the analysis (n=197), the most common CONSORT extensions selected were nonpharmacologic (n=43; n=50), pragmatic (n=20; n=16) and cluster (n=10; n=9). Most trials were two arm (n=81; n=85), half were multicentre (n=42; n=48), the median sample size was 98 (IQR 51 to 180). Analysis of the primary outcome is being completed and final results will be presented at Evidence Live.

**Conclusions:** Twenty years since its first publication, poor adherence to CONSORT recommendations remains common in published reports of randomised trials. Our randomised trial will show whether a customised CONSORT checklist helps authors to prepare better trial reports. ClinicalTrials.gov: NCT01891448; Funded by French Ministry of Health.

### **0069 - CEBIS: Bringing research knowledge to the clinician and patient to inform evidence based practice.**

Anna Brown, Amber Dunlop

*University Hospitals Coventry and Warwickshire NHS Trust, Coventry, UK*

**Abstract:** The Clinical Evidence Based Information Service (CEBIS) is a team of 3 full time equivalent Information Specialists based at University Hospitals Coventry and Warwickshire NHS Trust.

**Objectives:** In the acute hospital setting, we need a way to integrate research evidence, clinical expertise, and informed patient preference to enable evidence based decision making. This needs to take into account:

- Individual patient complexity and concerns
- The need for speedy, targeted evidence reviews
- The lack of high level evidence in many situations

**Method:** CEBIS specialists are embedded within clinical teams, attending clinics, multi-disciplinary meetings, and ward rounds. They provide a search and summary of the best available evidence in response to queries raised by patients and clinicians in the clinical setting. CEBIS also facilitates Evidence in Practice Groups (EPG) for full discussion of the evidence, or lack of, and how to apply it to real patients. CEBIS utilises an innovative ICT system, which captures all work undertaken, thereby linking the evidence and the decision-making process to individual patient records.

**Results:** Is the macular hole closure rate after Jetrea (ocriplasmin) lower than after surgery without Jetrea? CEBIS involvement enabled Ophthalmologists to empower their patients to make evidence informed decisions as to whether to go ahead with Ocriplasmin injection or Vitrectomy as an initial treatment.

Use of hypertonic saline nebulisers in infants with bronchiolitis? Recommended by Cochrane review in 2008, standard practice in other NHS Hospitals.

Critical analysis identified that the evidence did not apply to our population where average length of stay was substantially shorter than in Cochrane's included trials. Several months after the EPG, a UK multicentre study confirmed our findings.

**Conclusions:** CEBIS facilitates clinicians' point-of-care decision making to help improve the patient experience, even where the evidence base is low or does not apply to the local population.

### **0073 - Collaborating to combat the inefficiency of randomised trials**

Heidi Gardner<sup>1</sup>, David Pickles<sup>2,3</sup>, Shaun Treweek<sup>1</sup>

*<sup>1</sup>University of Aberdeen, Aberdeen, UK, <sup>2</sup>Leeds Teaching Hospitals NHS Trust, Leeds, UK, <sup>3</sup>University of Leeds, Leeds, UK*

**Abstract:** Randomised trials are the gold standard of evidence-based healthcare. They guard against selection bias and offer the best way of evaluating healthcare interventions from medicinal products to devices and methods of delivering care. Thousands of trials are conducted each year allowing researchers to gather evidence that informs the decisions of policy makers, clinicians and healthcare professionals. What is perhaps most shocking then, is the distinct lack of evidence available to guide trialists in how to design, run, analyse and report trials. This remarkably thin evidence-base has resulted in the trials we base clinical decisions on being riddled with inefficiency. Trial Forge aims to change this.

Trial Forge, led by the University of Aberdeen, is an international collaborative effort to increase the evidence surrounding clinical trials methodology. The initiative collaborates with multiple global projects all sharing the aim of embedding efficiency and reducing research waste.

One example Trial Forge project is investigating the volume of work associated with collecting trial primary (most important) and secondary outcomes. The volume of work required to collect data in trials is vast. The effort and cost of collecting secondary outcome data are higher than primary outcomes; there are more of them so this is perhaps of no surprise. What this Trial Forge project is finding though, is the sheer scale of the difference in time devoted to the collection of primary and secondary outcomes. Initial work with publicly-funded trial protocols published between 2010 and 2014 suggests that the time spent collecting secondary outcome data can be more than 20 times that of primary outcome data. In the worst case to date, almost 34 times more time was spent on secondary than primary outcome data collection. In terms of cost this amounts to \$790 versus \$27500, a shocking comparative figure given that secondary outcomes are, by

definition, of lesser importance than primary outcome measures of the trial.

This is just one example of the inefficiency we know is widespread in trials today. There is room for improvement across every stage of trial work; from crafting the research question through to disseminating our trial results.

**Objectives:** This talk aims to give an overview of the Trial Forge initiative to improve trial efficiency, paying particular attention to the problem of extensive data collection processes that can have a huge impact on the time, feasibility, effort and costs required to complete a trial.

**Method:** A random selection of 115 protocols for publicly funded, randomised trials published between 2010 and 2014 were selected (an average of 24 per year) for analysis. Details of the primary and secondary outcomes were extracted from each protocol. Where available, the time taken to complete data collection for each outcome was extracted from the protocol. Where unavailable, these data were requested from the corresponding author, or from trial managers familiar with the outcome measurement involved.

**Results:** Much more time is spent collecting secondary outcome data than primary. This may not be surprising; there are more secondaries than primaries. What is shocking is the time consumption disparity. Some trials spend <20 times as much time collecting secondary outcome data than primary. One trial spent 12 hours collecting primary outcome data, and 418 hours on secondaries; that's almost 34 times more time collecting data that is by definition not as important to the trial as primary outcome data. In terms of UK costing approximations that is \$790 on primary outcome data and \$27500 on secondary.

**Conclusions:** Trialists routinely spend a far greater proportion of their time obtaining outcome data that they themselves deem of lesser importance. Given the expense of collecting data, the impact that substantial data collection may have on recruitment and retention and the widely reported fact that much trial data goes unreported, we suggest that trialists should have an increased awareness of the burden of time and cost associated with each outcome when making their selections.

This work is part of the Trial Forge initiative to improve trial efficiency.

#### **0074 - Reducing overtreatment by optimizing sequence of diagnostic tests ordering**

Benjamin Djulbegovic<sup>1,2</sup>, Iztok Hozo<sup>3</sup>

<sup>1</sup>University of South Florida, Tampa, FL, USA, <sup>2</sup>Moffitt Cancer Center, Tampa, FL, USA, <sup>3</sup>Indiana University, Gary, IN, USA

**Background:** Clinical decision-making is characterized by the use of heuristics- decision strategies that rely on limited information to reduce estimation error and facilitate fast decisions. One such a heuristic is fast-and-frugal trees (FFT)- a simple decision tree composed of sequentially ordered cues (tests) and binary (yes/no) decisions formulated via series of *if-then* statements. The previous theoretical work (Luan et al 2011; Hozo et al, 2015) showed that the exit structure of the FFTs determines its overall diagnostic accuracy. We extend these theoretical findings to show how over-treatment can be reduced by changing the order of tests within the FFT.

**Objectives:** To determine the effects of cues (test) ordering on the overall accuracy of fast-and-frugal (FFT) heuristic.

**Methods:** We employed methods by Hozo et al to analyze the accuracy of FFT for prescribing statins for primary prevention of cardiovascular disease (CVD). This simple, 3 cues FFT can be used to determine the probability of CVD and statin treatment. It includes the following yes/no questions: 1. Does the patient have diabetes? 2. Is the patient being treated for high blood pressure (BPRx)? 3. Is the patient older than 44? We determined the accuracy of the FFT by changing order in which these questions were asked. If the goal is to avoid over-treatment, a clinician should use the FFT with the lowest number of false-positives (FPs) findings.

**Results:** The statin FFT consists of 4 possible FFTs; for each individual patient there are 8 possible exit paths. The cues can be ordered in 6 different ways. The analysis indicated that the overall accuracy depends on how the cues are ordered. For example, asking the patient for age first (followed by history about diabetes and BPRx) will result in about 19% of FPs if the questions were affirmative to two first questions (FFTyy and FFTyn). In contrast, asking first about BPRx (followed by questions about age and diabetes) reduces FPs to about 1.6% for the FFTyn. However, regardless of order of cues, the strategies FFTny and FFTnn result in virtual 0% of FPs.

**Conclusions:** Much of over-treatment can be reduced if we pay attention how to sequentially order cues (tests) that are routinely available to us at the same time.

#### **0075 - Are patients naively optimistic about health care? A systematic review of expectations of the benefits and harms of treatments, tests, and screens.**

**Objective:** Unrealistic patient expectations of the benefits and harms of interventions can profoundly influence decision-making and may be contributing to increasing intervention uptake and healthcare costs. This study aimed to systematically review all studies which have quantitatively assessed patients' expectations of the benefits and/or harms of any treatment, test, or screening test.

**Method:** This systematic review used a comprehensive search strategy in four databases (MEDLINE, Embase, CINAHL, PsycINFO), with no language or study type restriction, cited reference searches of included studies, and experts and study authors were also contacted. Two researchers independently evaluated methodological quality and extracted participants' estimates of benefit and harms and authors' contemporaneous estimates.

**Results:** Of the 15,343 records screened, 36 articles (from 35 studies) involving a total of 27,323 patients were eligible. Fourteen studies focused on a screen, 15 on treatment, 3 a test, and 3 on treatment and screening. More studies assessed only benefit expectations (22, 63%), than benefit and harm expectations (10, 29%), or only harm (3, 8%). Fifty-four outcomes (across 32 studies) assessed benefit expectations: of the 34 outcomes with overestimation data available, the majority of participants overestimated benefit for 22 (65%) of them. For 17 benefit expectation outcomes, we could not calculate the proportion of participants who over- or under-estimated, although for 15 (88%) of these, study authors concluded that participants overestimated benefits. Expectations of harm were assessed by 27 outcomes (across 13 studies): underestimation data were available for 15 outcomes and the majority of participants underestimated harm for 10 (67%) of these. A correct estimation by <sup>~</sup>50% participants only occurred for 2 outcomes about benefit expectations and 2 outcomes about harm expectations.

**Conclusion:** The majority of participants overestimated intervention benefit and underestimated harm. Clinicians should discuss accurate and balanced information about intervention benefits and harms with patients, providing the opportunity to develop realistic expectations and make informed

## **0082 - Reaching the patient: how the NIHR Dissemination Centre uses the views of patients and carers.**

Alison Ford<sup>1</sup>, Alan Lovell<sup>2</sup>

<sup>1</sup>NIHR Dissemination Centre, Wessex Institute, University of Southampton, Southampton, UK, <sup>2</sup>NIHR Dissemination Centre, Bazian, Economist Intelligence Unit, London, UK

**Abstract:** The NIHR Dissemination Centre was established in April 2015 to summarise health and social care research outputs for NHS decision-makers and to ensure the relevance and accessibility of Signals, its new-format summaries of published reviews. The Centre uses 'rater' input to help determine which abstracts should be developed as Signals. Over one thousand raters have been recruited, enabling the Centre to seek professional and patient views on the suitability of abstracts. Raters include clinical practitioners, managers, researchers and academic/health policy staff. Almost one-fifth are patients or members of the public. Each week the Centre team scans 101 peer-reviewed clinical and public health journals. Criteria are applied to select abstracts that may be suitable for development in to Signals. All abstracts are sent to five raters, including one patient/public rater, for an assessment of how interesting and useful they would be to these audiences. The rater responses inform the decision by the Centre's editorial board whether or not to develop the abstract as a Signal. As part of an internal review of the rating process, a survey of rater experience was conducted during January 2016 among the 390 registered raters who had undertaken at least one rating task.

Our presentation will report on our audit of the rating process and the results of the rater survey. Findings will include comparisons of perceptions and responses among professional groups and between professional and public respondents, an exploration of the most useful issues raised and an examination of how best to incorporate rater viewpoints into the weekly production process.

Our aim is to understand, update and improve the rating process so that (a) it can add more value to the Signals selection process and (b) be a more enjoyable process for our raters. Our conclusions will include a series of process recommendations for the Dissemination Centre board. By investing in the raters and the rating process in this manner we reflect the Dissemination Centre's commitment to valuing the perceptions of raters, its trusted advisors.

**Objectives:** The NIHR Dissemination Centre was established in April 2015 to summarise crucial health and social care research outputs for NHS decision-makers. Each week the centre publishes 'Signals' - short, accessible summaries of published reviews. An innovative feature of our work is the use of 'rater' input to help determine which abstracts should be developed as Signals. A pool of over one thousand raters has been recruited, enabling the Centre to seek professional and patient views on the suitability of abstracts. Raters include clinical practitioners, managers, researchers and academic/health policy staff. Almost one-



fifth are patients or members of the public.

**Method:** Each week the Centre team scans 101 peer-reviewed clinical and public health journals. Criteria are applied, selecting abstracts that may be suitable for development into Signals. All abstracts are sent to five raters, including one patient/public rater, for an assessment of how interesting and useful they would be to these audiences. The rater responses inform the decision by the Centre's editorial board to develop the abstract as a Signal, or not.

As part of a review of the rating process, a survey of rater experience was conducted during January 2016 among 390 raters who had undertaken at least one rating task.

**Results:** Our presentation will report on our audit of the rating process and results of the rater survey. Survey findings will include comparisons of perceptions and responses among professional groups and between professional and public respondents, an exploration of the most useful issues raised and an examination of how best to incorporate these rater viewpoints into the weekly rater process. These results will be set in the context of the editorial board's perception of the value of rating and their openness to new developments in rating methods.

**Conclusions:** Our aim is to understand, update and improve the rating process so that (a) it can add more value to the selection process and (b) be a more enjoyable process for our raters. Our conclusions will include a series of process recommendations for the Dissemination Centre board. By investing in the raters and the rating process in this manner we reflect the Dissemination Centre's commitment to valuing the perceptions of raters - its trusted advisors.

### **0085 - Communicating risks and benefits of preventive tuberculosis treatment: Australian physicians' perspectives**

Claudia Dobler<sup>1,2</sup>, Sinthia Bosnic-Anticevich<sup>1</sup>, Carol Armour<sup>1</sup>

<sup>1</sup>Woolcock Institute of Medical Research, University of Sydney, Sydney, Australia, <sup>2</sup>Liverpool Hospital, South Western Sydney Clinical School, UNSW Australia, Sydney, Australia

**Objectives:** The aim of this study was to explore the views of physicians on how to communicate and make decisions about preventive tuberculosis (TB) treatment during clinical encounters.

**Method:** We conducted semi-structured interviews in person or over the phone with physicians working in Australian TB clinics. We utilised an inductive-deductive approach working back and forth between data and themes to develop a coding framework until a comprehensive set of themes was established.

**Results:** Twenty physicians from five different Australian states and territories participated in an interview. Participants varied in their views on how much physicians should guide patients' decision to take preventive TB treatment. In general, they indicated that they would try to influence patients' decisions when the estimated individual benefit of the intervention clearly outweighed the risk. Some stated that they always provide a recommendation for or against preventive TB treatment, while others emphasised that they try to provide a balanced view about the risks and benefits. Physicians stated that they were more likely to use shared decision making in discussions about preventive TB treatment than in discussions about treatment of actual diseases.

Most physicians were open to the idea of using a decision aid for preventive TB treatment, at least in certain cases. The estimated risk of developing TB was considered the most important information to inform the decision about preventive TB treatment and to communicate to patients, followed by the estimated risk of developing a significant adverse event from treatment. While some physicians would welcome an individually tailored treatment recommendation obtained from a decision analysis, others said they would prefer to only use plain estimates of risks and benefits in their discussion with patients. Most physicians thought that line graphs and pictograms are very helpful to communicate risks and benefits to patients.

**Conclusions:** Physicians supported shared decision making in situations with unclear overall treatment benefit, but would try to convince patients to take preventive TB treatment when the perceived risk of developing TB is high. Visual aids, especially to communicate the risk of developing active TB, were considered to be very helpful for the clinical encounter.

### **0086 - Evaluating the efficacy of a web-based monitoring program for teenagers with IBD before implementation in clinical practice.**

Anke Santema<sup>1</sup>, Anke Heida<sup>1</sup>, Alie Dijkstra<sup>1</sup>, Henk Groen<sup>2</sup>, Patrick van Rheenen<sup>1</sup>

<sup>1</sup>University Medical Center Groningen, department of pediatric gastroenterology, Groningen, The Netherlands, <sup>2</sup>University Medical Center Groningen, department of epidemiology, Groningen, The Netherlands

**Introduction:** Telemedicine solutions are believed to improve the affordability of care for the chronically ill when compared with traditional approaches, but they are usually implemented without a solid evidence base of their efficacy. Monitoring of teenagers with inflammatory bowel disease (IBD) is traditionally done during scheduled visits, but this is when most patients report full disease control. IBD care could be more efficient if imminent relapses were recognised at home and if patients were seen at times of clinical need. We hypothesize that a web-based monitoring program (IBD-live) leads to more stable disease and lower healthcare costs.

**Objectives:** Telemedicine solutions are believed to improve the affordability of care for the chronically ill when compared with traditional approaches, but they are usually implemented without a solid evidence base of their efficacy. Monitoring of teenagers with inflammatory bowel disease (IBD) is traditionally done during scheduled visits, but this is when most patients report full disease control. IBD care could be more efficient if imminent relapses were recognised at home and if patients were seen at times of clinical need. We hypothesize that a web-based monitoring program (IBD-live) leads to more stable disease and lower healthcare costs.

**Methods:** This ongoing multicentre randomized controlled trial compares the efficacy of IBD-live with usual practices in teenagers (10-19 years) with quiescent disease at baseline. Teenagers assigned to IBD-live have fewer scheduled encounters with their IBD team and instead are monitored at home by means of the *flarometer* -an automatic cumulation of a disease activity questionnaire and fecal calprotectin measurements- to estimate probability of relapse. The frequency of flarometer measurements and treatment advice depend on the previous risk stratification. Trial participants are followed for 12 months. Primary outcome is time-to-relapse. Secondary outcomes include cost-effectiveness and quality of life.

**Results:** At the time of data cut-off for this interim analysis 120 of 180 required patients were followed for at least 2 months. Median (range) age at baseline was 15.4 (10.1-19.6) years. Mean follow-up time was 9.7 months. 48% had Crohn's Disease and 52% had ulcerative colitis. In the IBD-live group 14 of 53 patients (26%, 95% confidence interval (CI) 16-40) experienced disease relapse, compared to 19 of 67 patients (28%, 95% CI 19-40) monitored in the traditional way.

**Conclusion:** Based on our current data, we conclude that there is no difference in efficacy between web-based monitoring and usual follow-up care. We expect that use of IBD-live will be associated with lower costs of disease management. Web-based monitoring strategies such as IBD-live should have to show true value before being implemented in clinical practice. If IBD-live care proves to be (cost-)effective, health care insurance companies are hopefully enticed to reimburse providers for home-based telemedicine services.

## **0088 - Using research based films for effective dissemination of qualitative systematic review – an example of a film used in post-graduate clinical training**

Fran Toye<sup>1,4</sup>, Sue Jenkins<sup>2</sup>, Kate Seers<sup>3</sup>, Karen Barker<sup>1,4</sup>

<sup>1</sup>Oxford University Hospitals NHS Foundation Trust, Oxford, UK, <sup>2</sup>Cardiff University, Cardiff, UK, <sup>3</sup>Warwick Medical School, University of Warwick, Coventry, UK, <sup>4</sup>Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

**Background:** Short films presenting research evidence can be used to reach a wide audience and can support the dissemination of evidence to key stakeholders, including policy makers. Film lends itself to an interactive, or dialectic, style of learning and can stimulate engagement beyond that from reading report.

**Aim:** We aimed to understand the impact on healthcare professionals of watching and discussing a 10 minute You Tube film 'Struggling to be me' which presents findings from a qualitative systematic review of adults' experiences of chronic musculoskeletal pain.

**Method:** Nineteen healthcare professionals undertaking an inter-professional postgraduate e-learning module were recruited into the study. All worked in the UK and had an interest in chronic pain management. Focus groups took place on 'oovoo' at convenient times. This facilitated access to diverse geographical locations. We wanted to explore the film's impact in a specific educational setting. Participants were invited to watch the film in their own time, and to consider some questions before attending the groups. Recordings were transcribed verbatim and loaded onto Nvivo 9 software. We thematically coded data with the aim of developing a conceptual model that describes the co-construction of meaning between viewers and the film.

**Results:** We identified four related conceptual categories: (a) a glimpse beneath the surface explored a more pro-active way of seeing the patient (b) pitfalls of the Medical Model recognised the challenge of 'sitting with' rather than 'fixing'; (c) Feeling bombarded by despair acknowledged the intense emotions that the clinicians brings to the clinical encounter; (d) Reconstructing the clinical encounter as a shared journey reconstructed the time-constrained clinical encounter as a single step in a shared journey towards healing.

**Conclusion:** Findings indicates that the film made viewers think about the themes reported in the original systematic review. Watching this film, followed by discussion, has a valuable educational potential. Films that portray qualitative research findings can allow clinicians to recognise the emotions they bring into practice within a safe environment removed from the clinical encounter. Qualitative films can stimulate a dialectic form of knowing, with implications for providing compassionate and person centred care.

### 0090 - Identifying Cochrane citation classics

Gavin Stewart

Wiley, Chichester, UK

**Abstract:** The concept of 'citation classics' was first mentioned in a 1977 essay by the creator of the Impact Factor, Eugene Garfield (Garfield 1977). The first group of citation classics contained the 500 papers most cited from 1961 to 1975. In October 2013, a paper published in PLoS ONE identified and assessed a group of the 100 most cited systematic reviews and meta-analyses (SRM) from 1977 to 2008 (Uthman 2013). The 100 most cited SRM did not feature a Cochrane Review despite Cochrane Reviews being internationally recognised as representing the gold standard for systematic review methodology and production.

**Objectives:** To identify and examine the characteristics of a group of citation classics from the Cochrane Database of Systematic Reviews and to investigate how citation classics from the Cochrane Database of Systematic Reviews compare with citation classics from other SRM published in the same time period.

**Method:** The Web of Science Core Collection of Thomson ISI will be searched to identify the highest cited Cochrane reviews from 2005-2014. Data on the year of publication, associated keywords, average number of cites per year, the country and institution of the corresponding author and the Cochrane Review Group (CRG) responsible for producing the review will be gathered.

**Results:** Initial investigations have found that 7,068 Cochrane reviews have been indexed in the Web of Science Core Collection from 2005-2014. The highest cited Cochrane review in this time period has been cited 452 times. The 100th highest cited Cochrane review has been cited 89 times. The results of the data analysis will be made available at the meeting.

**Conclusions:** By identifying Cochrane citation classics it is hoped that opportunities for future engagement in topic areas and with institutions and individuals will be discovered.

### 0091 - A new scoring method highlights major discrepancies between what clinical trial registries report and paediatric randomised controlled trials publish

Paola Rosati<sup>1</sup>, Gabriella Ricciotti<sup>1</sup>, Giuseppina Testa<sup>1</sup>, Rita Inglese<sup>1</sup>, Ferruccio Giustini<sup>1</sup>, Ersilia Fiscarelli<sup>1</sup>, Marco Zazza<sup>1</sup>, Cecilia Carlino<sup>1,2</sup>, Valerio Balassone<sup>1</sup>, Roberto D'Amico<sup>3</sup>

<sup>1</sup>G.A.L.I.L.E.O. Gruppo per l'Apprezzamento Letteratura e l'Implementazione dei Livelli di Evidenza in Ospedale, Bambino Gesù Children's Hospital IRCCS, Rome, Italy, <sup>2</sup>Faculty of Medicine and Surgery, La Sapienza University, Rome, Italy, <sup>3</sup>Department of Diagnostic, Clinical and Public Health Medicine, University of Modena and Reggio Emilia, Modena, Italy

**Abstract:** Whether internal validity and outcome data from clinical trial registries (CTRs) and published paediatric randomised controlled trial (RCTs) differ remains unknown. Knowing more about discrepancies should alert paediatricians relying on RCTs for medical decision-making to possible dissemination bias.

**Objectives:** To assess discrepancies between what CTRs state and RCTs actually publish, we developed and applied a new scoring method (CTR-RCT score) comparing trial internal validity domains, namely risk of bias, including funding, design, and outcome reported in a sample of paediatric clinical trials.

**Method:** We collected data for 20 unselected RCTs published from July to November 2013 in a widely read peer-reviewed paediatric journal. To assess discrepancies between published RCTs and CTRs, two reviewers detected and graded six validity domains (reported funding; sample size, inclusion and exclusion criteria not respected or cross-over undeclared; primary outcome downgraded and secondary outcomes upgraded, early study completion unjustified, and main outcome selectively reported or unreported), and rated total discrepancy scores as low, medium, and high. Five reviewer couples crosschecked and appraised CTRs and matching RCTs, then scored discrepancy. Higher discrepancy scores suggested risk of bias.

**Results:** Our new scoring method rating the trial validity domains for the 20 paediatric trials gave 19 trials medium or high total discrepancy scores for what the 5 CTRs stated and the matched 20 RCTs reported. Seven CTRs failed to index the URL address or the RCT reference, and 12 reported RCT details, but the authors failed to report results. All 20 RCTs selectively reported main outcomes, 9 had funding discrepancy and 8 discrepancies in the sample size, 9 failed to respect inclusion or exclusion criteria, 11 downgraded or modified primary outcome or upgraded secondary outcomes, and 13 completed early.

**Conclusions:** Assessing and reporting the CTR-RCT score with little effort should help clinicians, relying on RCT results for medical decision-making, to be aware of human dissemination bias, motivate clinical researchers to design RCT protocols and report outcome results in CTRs in a rigorous manner, and require those who prepare clinical recommendations and guidelines to think more critically.

#### **0094 - A systematic review of evidence-based strategies for developing health literate organisations**

Jane Lloyd<sup>1</sup>, Hyun Song<sup>1</sup>, Mark Harris<sup>1</sup>, Sarah Dennis<sup>2</sup>, Nicola Dunbar<sup>3</sup>, Elizabeth Harris<sup>1</sup>

<sup>1</sup>University of New South Wales, Sydney, NSW, Australia, <sup>2</sup>University of Sydney, Sydney, NSW, Australia,

<sup>3</sup>Australian Commission on Safety and Quality in Healthcare, Sydney, NSW, Australia

**Abstract:** Health care systems in Australia and the UK are responsible for providing universal health care; however, there are inequities in the access to and use of health care services. People with low health literacy are more likely to delay seeking care and experience adverse outcomes. While health literacy is the product of an individual's capacities, it is also affected by the demands and complexities of the health care system. Organisational changes are needed to align health care demands better with the public's skills and abilities. We aimed to identify the evidence base for effective strategies for creating health literate organisations.

A systematic review and realist synthesis of scientific literature was performed. Medline, Embase, PsychInfo and CINHAL databases were searched for English-language empirical studies from OECD countries published after 2007. Thematic analysis of the interventions was guided by the Institute of Medicine's five-dimensional framework for the attributes of a health literate organisation.

The title and abstract of 867 records were screened according to the selection criteria, leading to full text review of 125 articles. Seven studies were selected for the final review. Four studies from US, Australia, and Spain conducted an environmental scan, using the Health Literacy Environment Review of the health care organisation to ascertain organisational responsiveness to patients' health literacy needs. The navigation component of this tool assesses patient experience when making first contact with the clinic or hospital, and in physically navigating the building. Three studies examined the implementation of other health literacy tools such as the brief health literacy screening questions in health services.

Environmental scans serve as an important agent for organisational change. However health literacy tools alone may not be sufficient for generating the system changes that are required for building organisational health literacy.

A commitment to patient-centred care requires health literate patients and also organisations that are sensitive and responsive to patients' needs. The current lack of research in this area will ultimately limit efforts to engage patient in their care, if health care organisations, by their structures and processes, act as barriers rather than enablers to patient-centred care.

**Objectives:** We aimed to identify the evidence base for effective strategies for creating health literate organisations.

**Method:** A systematic review and realist synthesis of scientific literature was performed. Medline, Embase, PsychInfo and CINHAL databases were searched for English-language empirical studies from OECD countries published after 2007. Thematic analysis of the interventions was guided by the Institute of Medicine's five-dimensional framework for the attributes of a health literate organisation.

**Results:** The title and abstract of 867 records were screened according to the selection criteria, leading to full text review of 125 articles. Seven studies were selected for the final review. Four studies conducted an environmental scan, using the Health Literacy Environment Review of the health care organisation to ascertain organisational responsiveness to patients' health literacy needs. The navigation component of this tool assesses patient experience when making first contact with the health service, and in physically navigating the building. Three studies examined the implementation of other health literacy tools such as the brief health literacy screening questions in health services.

**Conclusions:** Environmental scans serve as an important agent for organisational change. However health literacy tools alone may not be sufficient for generating the system changes that are required for building organisational health literacy.

A commitment to patient-centred care requires health literate patients and also organisations that are sensitive and responsive to patients' needs. The current lack of research in this area will ultimately limit efforts to engage patient in their care, if health care organisations, by their structures and processes, act as barriers rather than enablers to patient-centred care.

#### **0099 - Implementing and evaluating an electronic solution to support general practice for patients with low back pain.**

Kay Stevenson, Simon Wathall, Helen Duffy, Adrian Chudyk, Simon Somerville, Steven Blackburn, Rhain

Hughes, Krysia Dziedzic  
Keele University, Newcastle under Lyme, Staffordshire, UK

**Objectives:** Stratified care for back pain (screening plus matched treatments) is clinically and cost effective (Hill et al, 2011). We looked to design, embed and evaluate the uptake of a computer protocol and template (e-STARt Back) to assist General Practitioners (GP) in their clinical decision making for patients with low back pain.

**Method:** Funded by West Midlands Academic Health Science Network (WMAHSN), key stakeholders, including GPs, physiotherapists and patients recommended revisions to an e-template developed as part of the STARt Back trial. Refinements included:

- Design of an electronic process to assist GP consultations and referrals to physiotherapy
- Use of patients expertise to refine information within the template
- Inclusion of an automatic physiotherapy referral

A Research User Group designed accessible information for the [www.patient.info](http://www.patient.info) website. Quality measures were built into the electronic system, including how many times the e-STARt Back protocol and tool was used and referrals to Physiotherapy.

**Results:** The e-STARt Back protocol and tool was embedded in 17 general practices in North West Midlands between January and November 2015. Within this time, all GP practices used e-Start Back to some extent with 866 patients consulting with low back pain and activating the e-STARt Back . GPs completed the e-STARt Back tool with 190 (22%) patients. Of these 41 (22%) patients received bespoke information embedded in the EMIS protocol and 97 (51%) patients were referred to Physiotherapy utilising the automated referral.

**Conclusions:** An e-STARt Back template and tool was co-designed to assist clinicians in delivering optimal care for patients with low back pain. This innovation assists in helping clinicians change practice and adopt evidence-based care. Additional support, such as funding, training, audit, patient and public engagement, feedback and clinical champions, may be required to further spread this innovation.

## 0101 - When are tailored interventions for guideline implementation successful? A systematic review of randomized controlled trials

Ulrich Siering<sup>1</sup>, Stefanie Butz<sup>2</sup>, Wiebke Hoffmann-Eber<sup>1</sup>, Cathleen Muche-Borowski<sup>2</sup>, Martin Scherer<sup>2</sup>, Dagmar Lühmann<sup>2</sup>

<sup>1</sup>Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany, <sup>2</sup>Institute for General Medicine, University Medical Centre, Hamburg-Eppendorf, Germany

**Background:** Clinical practice guidelines are tools for transferring complex research findings into clinical practice. If their recommendations are properly implemented, these guidelines are supposed to improve health care. The success of implementation can be influenced by various barriers or facilitators. It is currently assumed that the more guideline implementation is tailored towards influencing factors ("tailored interventions"), the more successful implementation is.

**Objectives:** Against this background we tried to identify factors that are associated with the success of tailored interventions for guideline implementation.

**Methods:** We conducted a systematic review of randomized controlled trials measuring the success of tailored interventions in an inpatient or outpatient setting by means of indicators of process quality (e.g. consistency of actions of guideline users with guideline recommendations). The search was conducted in MEDLINE, Embase und CENTRAL. Data were extracted into standardized tables by 2 reviewers. The risk of bias of results was assessed at the study and outcome level. The following factors potentially influencing the success of tailored interventions for guideline implementation were analysed: method of barrier analysis, complexity of tailoring, influencing factors on the guideline, system and organizational level, attitude of guideline users, number of components of the intervention, and type of setting.

**Results:** A total of 20 studies were included. The risk of bias at study level was high in 17 out of the 20 studies. Only 1 study had a low risk of bias at outcome level. 9 studies reported successful results (i.e. significant effect of the intervention on  $\geq 50\%$  of outcomes). Neither the method of barrier analysis, the complexity of tailoring, the consideration of influencing factors, the number of components of the intervention, nor the type of setting were consistently associated with positive results of guideline implementation.

**Conclusions:** No factors consistently associated with the success of tailored interventions for guideline implementation could be identified. No direct indications can thus be inferred from the findings of our analysis with regard to the required characteristics of such tailored interventions. Knowledge in this field should be improved through appropriate randomized controlled studies.

## **0102 - NIHR Signals: A system for disseminating important, trustworthy, relevant research for decision makers in the NHS**

Rob Cook, Anelia Boshnakova, Alan Lovell, Janet Clapton, Elly O'Brien

*NIHR Dissemination Centre; Bazian an Economist Intelligence Unit business, London, UK*

**Objectives:** Easy access to evidence is critical for NHS users of research, including patients, clinical decision makers, commissioners and policy makers. Exponential increases in research output, competing channels of communication, such as social media or email alerts, and busy lives can all increase the chance that important relevant evidence is missed or is inaccessible. Against this noisy background, the NIHR Dissemination Centre seeks to identify important, trustworthy, relevant research as "signals" worthy of wider promotion to decision makers. Here we assess the first year's output against a broad measure of NHS need and map signals against the journal sources.

**Method:** In April 2015 the NIHR Dissemination Centre began a service to help decision makers in the NHS make better use of reliable evidence. Signals add value by sifting only the most important and trustworthy papers and provide accessible, plain language summaries alongside added critical appraisal, practice context and commentary on potential NHS impact.

We sought to assess the performance of this initiative by analysis of the first 94 signals published up to February 2016:

- Signals categorised by major topic area were mapped against UK burden of disease
- The distribution of signal by journal source was evaluated

In the first nine months, 31 journals provided 94 signals, 70 signals came from just nine journals, Health Technology Assessment, Cochrane Database of Systematic Reviews, PLoS One, The Lancet, BMJ, New England Journal of Medicine, Diabetes & Endocrinology, Journal of Epidemiology and Community Health, and Stroke.

Burden of disease data was used as a proxy for NHS need and analysis showed a close fit with the early counts across topic categories. Cardiovascular disease, surgery, mental health and illness, respiratory disorders, infections and musculoskeletal conditions all featured highly. The aim of 'signals' is to prioritise research for commissioners, public health and social care professionals. To meet this need, a number of signals were prioritised for abstraction and categorised as health service management, public health or social care. NIHR research addresses some of the gaps.

**Results:** From contents of the top 101 journals, 200 potential abstracts of systematic reviews were selected weekly. Five raters, from a pool of over 1000, were invited to score each of 20 potential signals and comment.

The potential NHS-relevant signals are reviewed by an editorial board together with other NIHR research. Up to five papers are selected for developing into a "Signal". One or two experts are approached to add NHS context and commentary.

In the first ten months, 31 journals provided 94 signals, 70 signals came from just nine journals, with a long tail of journals providing one signal only.

**Conclusions:** The selection of research worth disseminating to NHS decision makers is not straight forward. The categories covered reflect broadly the needs of the wider NHS but it is a challenge to find high quality systematic reviews in some important areas. Most of the trustworthy and relevant primary and secondary research of importance to decision makers is reported in less than ten major journals. Other journals ensure a broad coverage of specialisms. Important health service management, public health and social care research is relatively unrepresented in these journals although NIHR research addresses some of these gaps.

## **0104 - Biases that affect the quality of research evidence for improving organisational health literacy**

Jane Lloyd, Marilyn Wise

*University of New South Wales, Sydney, NSW, Australia*

**Introduction:** Health literacy has been conceptualised, primarily, as the knowledge, skills and confidence required by patients to enable them to access health care, to interact with health care providers effectively, to manage treatment regimens, and to prevent complications.

Effective patient outcomes require both health literate patients and health care organisations that are responsive to patients' needs. However, the transition of health care systems from provider and system-centred care towards patient-centred care is challenging. There is a need for research evidence to support the changes.

But recent evidence is showing that the biases of researchers and policy makers can affect the focus and quality of research evidence.

We examine how researchers' biases may limit their ability to conduct and act upon research evidence that assists organisations to ensure that patients' develop the health literacy needed to self-manage their chronic diseases effectively. This is particularly important when patients' pre-existing literacy levels are low

and when their living and working conditions limit their capacity to self-manage their chronic disease effectively.

**Findings:** One bias that influences the focus and quality of research in this area includes, for example, framing health literacy as patient problem and risk factor to be mitigated, rather than as a system problem requiring an organisational response – a framing bias. But other biases, too, can influence the effectiveness of research in this area.

Three themes emerged from our critical examination of researchers' biases including the positivist culture of health services research; the methodological and political challenges inherent in researching complex health care systems; and the question of who is included in the research design and conduct.

**Conclusions:** In an era of evidence-based practice, it is timely to examine the biases that influence the questions that researchers ask, the selection of respondents, and the interpretations of findings - with resultant biases in the evidence. As the health literacy example demonstrates, health care researchers have focused primarily on health literacy as a mechanism through which to change patient behaviour (compliance) at the expense of generating evidence to support the development of systems' own health literacy and the delivery of patient-centred care.

**Objectives:** We examine how researchers' biases may limit their ability to conduct and act upon research evidence that assists organisations to ensure that patients' develop the health literacy needed to self-manage their chronic diseases effectively

### **0105 - An examination of the characteristics, recommendations and quality of published guidance for exercise and physical activity in cardiac rehabilitation**

*Bridget Abell, Paul Glasziou, Tammy Hoffmann*

*Centre for Research in Evidence-Based Practice, Bond University, Gold Coast, Australia*

**Abstract:** Guideline-based management in the secondary prevention of coronary heart disease is advocated to provide patients with efficient and consistent evidence-based care. The expanding number of publications addressing the use of physical activity and exercise training may however confuse cardiac rehabilitation (CR) practitioners.

**Objectives:** We aimed to examine the characteristics, quality and usefulness of these publications in clinical practice.

**Method:** We included scientific literature published to December 2015 with physical activity, exercise or cardiac rehabilitation recommendations for coronary heart disease. Publications were obtained via structured electronic searches of cardiology and cardiac rehabilitation societies (in Australia, New Zealand, Canada, the United Kingdom, United States of America and Europe), international guideline databases, and PubMed. Epidemiological characteristics such as year, organisation and format were extracted from each included publication. Two independent assessors also evaluated quality using the Appraisal of Guidelines Research and Evaluation II (AGREE-II tool). Statistical comparisons of publication characteristics specified a priori were performed using the t-test or Chi-square test.

**Results:** 53 publications from 1994-2015 were included: 33 journal articles, 16 online documents and 4 books. Most were found within cardiology associations (81%), and were freely accessible (92%). Wide variation in publication quality was observed, with Applicability the worst rated domain. 30 publications contained broad recommendations for increasing physical activity and/or referral to CR. 23 publications appeared more useful to CR practice, providing detailed recommendations for exercise training. These publications however displayed significantly lower rigour of development than those with broad advice (37% vs 56%;  $p=0.003$ ), and were more likely to be documents such as position papers rather than guidelines ( $p=0.025$ ).

**Conclusions:** While we identified a large number of publications providing recommendations for exercise in CR, questions remain about their quality, ease of identification and usefulness for practitioners. The identification of rigorously developed, evidence-based clinical guidelines with a specific focus on the exercise prescription remains a challenge that needs to be addressed.

### **0106 - Evidence Flowers: Improving accessibility and engagement with evidence based guidance.**

*Opeyemi Babatunde, Joanne Jordan, Danielle van der Windt D, Krycia Dziedzic, Carolyn Chew-Graham, Valerie Tan, Joanne Protheroe*

*Research Institute for Primary Care & Health Sciences Keele University, Staffordshire, UK*

**Background:** NICE Clinical guidelines are based on large volumes of synthesised evidence, but the technical language, reading time, as well as identification of core guidance in the guideline, may deter engagement and subsequent application into to practice. Therefore, we explore the feasibility of summarising core guidance information within NICE clinical guidelines for osteoarthritis and depression

visually as “evidence flowers”.

**Aims:** To suggest a simple, visual and novel method of expressing core guideline recommendations to improve stakeholder accessibility and engagement with clinical guidelines.

**Methods:** Two recent NICE guidelines (NICE depression guideline 2009; NICE OA guideline 2014) were selected and evidence flowers representing core recommendations of the guidelines were created. Strength of the research evidence behind each recommendation, graded in guidelines based on the GRADE system (<http://www.gradeworkinggroup.org/>), was indicated by using different coloured ‘petals’ in the evidence flowers. Narrative summary of the information on the petal was kept brief and written in plain language. NICE working group members gave informal feedback on agreement of the evidence flowers with original evidence in the guidelines. Stakeholders’ (non-academic GPs, Allied Health Professionals and health service managers) engagement with the clinical guideline was assessed via structured questionnaires before and after seeing the evidence flowers. Accessibility and acceptability of the evidence flowers were also evaluated

**Results:** Evidence flowers for the two clinical guidelines will be presented with comments on stakeholders’ accessibility and engagement with the guideline recommendations. Feedback and comments on agreement with original evidence by guideline working group members will also be discussed.

**Conclusions:** Evidence flowers are novel and visually stimulating for collating and presenting evidence to stakeholders and policy makers. We propose that they are used in conjunction with clinical guideline core statements to promote and facilitate stakeholder engagement with evidence as well as bridge the gap between research evidence and clinical practice.

### **0107 - Lesbian and bisexual womens' gynaecological disorders: a systematic review**

Catherine Meads<sup>1</sup>, Catherine Robinson<sup>2</sup>, Kim Yen Galloway<sup>2</sup>, Susan Bewley<sup>2</sup>

<sup>1</sup>RAND Europe, Cambridge, UK, <sup>2</sup>King's College London and King's Health Partners, London, UK

**Background:** Little is known about the physical health of lesbian and bisexual (LB) women, including their gynaecological health. The aim of this systematic review was to examine differences in incidence and/or prevalence of gynaecological conditions in LB compared to heterosexual women.

**Methods:** The protocol was prospectively registered (PROSPERO-CRD42015027091) and searches conducted in 6 databases. Included were comparative studies published 2000-2015, reporting any benign (non-inflammatory) and/or malignant gynaecological conditions in LB compared to heterosexual women, with no language or setting restrictions. Inclusions, data extraction and quality assessment were conducted in duplicate. Quality assessment considered selection, performance, attrition and detection biases. Meta-analyses of condition prevalence rates were conducted in RevMan 5.3 where  $\geq 3$  studies reported results.

**Results:** From 608 records (41 duplicates), 208 abstracts were selected and 47 full papers examined. Included were 11 studies of mixed designs. No studies were found directly addressing the question. The conditions (numbers of studies) with reported prevalence rates were polycystic ovary disease (5), endometriosis (3), fibroids (3), pelvic pain (2), cervical cancer (3), uterine cancer (3), oligoamennorrhoea (2) and gynaecological operations (1). Both pelvic pain studies reported higher rates in bisexual women compared to heterosexual women (38.5% vs 28.2% and 18.6% vs 6.4%). The only meta-analysis with statistically significant results showed higher rates of cervical cancer in LB women overall (1.49 [1.03, 2.16]) and specifically in bisexual women (1.94 [1.46, 2.59]).

**Conclusion:** Preliminary results suggest more bisexual women may experience pelvic pain and cervical cancer than heterosexual women, but there is no information on potential confounding factors. This is consistent with previous research showing higher rates of teenage pregnancy in adolescent LB women. More would be known if better evidence were available, through monitoring of sexual orientation in research using the existing validated measure of sexual orientation and full reporting of results.

### **0108 - Improving the quality of veterinary randomised controlled trials**

Kathryn Wareham, Robert Hyde, Douglas Grindlay, Marnie Brennan, Rachel Dean

University of Nottingham, Loughborough, UK

**Background:** The evidence base in veterinary medicine has a number of limitations and there are many important evidence gaps remaining. To make good clinical decisions, including those relating to ‘One Health’, we need reliable, high quality evidence. Randomised controlled trials (RCTs) are a crucial part of the evidence base and it is important to understand current shortfalls in RCT conduct and reporting in veterinary medicine to make improvements.

**Objective:** To describe the size, power and outcome specifications of veterinary RCTs published in 2011



examining the efficacy of pharmaceutical interventions.

**Methods:** A structured search of PubMed was performed to identify canine, feline, equine, bovine and ovine clinical trials examining the efficacy of pharmaceutical interventions published in 2011. The number of outcomes measured, whether a primary outcome was identified, whether a sample size calculation was reported, and the number of animals enrolled in the trial was recorded.

**Results:** Searches returned 972 papers, of which 86 (containing 126 trials) were included in the analysis. Trials measured a median of 5.0 (IQR=3.0-11.0) outcomes per trial, with only 40.5% of trials identifying a primary outcome. The median number of animals enrolled per trial was 30.0 (IQR=17.5-98.8) with only 14.3% of trials reporting a sample size calculation.

**Conclusions:** Poor conduct and reporting of RCTs was identified which hinders the assessment and use of the limited evidence available to the profession. Targeted methods for improving the current situation e.g. Veterinary All-Trials need to be implemented.

### 0109 - Nurturing the lifecycle of research

Sheetal Bhurke<sup>1,2</sup>, Ria Osborne<sup>2</sup>, [Amanda Young](#)<sup>1,2</sup>, Sally Bailey<sup>2</sup>

<sup>1</sup>Wessex Institute, University of Southampton, Southampton, UK, <sup>2</sup>National Institute for Health Research (NIHR), Evaluation, Trials and Studies Coordinating Centre (NETSCC), University of Southampton, Southampton, UK

**Background:** Using evidence to generate research recommendations and initiate new research can beneficially shape the commissioning of research, especially given the large financial commitment to commission research, within a limited health care budget. Cochrane and Database of Abstracts and Reviews of Effects (DARE) systematic reviews are two of the many sources used by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme's topic identification team to prioritise research for its commissioner-led workstream. This study investigates how Cochrane and DARE SRs inform the NIHR HTA Programme's topic identification and prioritisation process, how they complement each other and what is the impact of subsequent NIHR HTA studies.

**Objectives:** To establish the link between how the research recommendations from Cochrane and DARE systematic reviews inform the NIHR HTA commissioning process and the impact of the subsequent NIHR HTA studies.

**Methods:** The National Institute for Health Research Evaluation Trials and Studies (NETS) management information system was searched to identify the total number of Cochrane and DARE systematic review research recommendations prioritised by the NIHR HTA Programme during 1999-2013. One author (SB) extracted the data and was checked by another author (RO). Google scholar was used for citation analysis. We used several methods to measure the impact of NIHR HTA studies including bibliometrics to measure citation analysis plus citations in high impact journals, citation in NICE Clinical Guidelines and quantifying the total website sessions, page views and number of downloads for the included NIHR HTA studies.

**Results:** Seventy-four Cochrane and 109 DARE systematic review research recommendations had been prioritised and commissioned by the NIHR HTA Programme during 1999 - 2013. Sixty-four studies were funded from Cochrane research recommendations of which 20 (31%) NIHR HTA studies (10 primary and 10 secondary studies) were published before 2012. Ninety seven studies were funded from DARE systematic review research recommendations, of which 28 (29%) studies (5 primary and 23 secondary studies) were published before 2012.

**Conclusions:** The study not only demonstrates a robust NIHR HTA prioritisation process to prioritise, commission and fund research that is important to patients, clinicians and policy makers but also demonstrates how the life-cycle of research is completed by complementing each other. The study will make recommendations for Cochrane to be broader in reporting their research recommendations.

### 0112 - Missing data in palliative care randomised controlled trials: beyond statistical palliation

[Jamilla Hussain](#)<sup>1,2</sup>, Ian White<sup>2</sup>, Miriam Johnson<sup>3</sup>, David Currow<sup>4,1</sup>, Martin Bland<sup>5</sup>

<sup>1</sup>Hull York Medical School, York, UK, <sup>2</sup>MRC Biostatistics Unit, Cambridge, UK, <sup>3</sup>University of Hull, Hull, UK, <sup>4</sup>Flinders University, Adelaide, Australia, <sup>5</sup>University of York, York, UK

**Background:** To increase the value and reduce the waste missing data (MD) present to trial results, MD should not only be handled appropriately at the analysis (palliative) stage, but more importantly potentially reversible MD risk factors must be identified and modified at the design and conduct stage. This mixed-methods study focussed on palliative care trials where MD due to death and disease are expected.

**Objectives:** (i) Quantify the extent and risk of bias of MD in palliative care trials; (ii) explore participant, trial site and trial-level MD risk factors.

**Methods:** (i) Systematic review of primary outcome MD in 108 palliative care trials (random-effects meta-analyses and meta-regression); (ii) individual participant-level data (IPD) meta-analysis of factors associated with MD in 10 palliative care trials (multi-variable multi-level cross-classified modelling); (iii) in-depth interviews with 24 palliative care trial research personnel (thematic analysis).

**Results:** (i) Systematic review: The estimate for MD at the primary end-point was 23.1% (95%CI 19.3, 27.4). Once MD was accounted for 62% of RCTs were inadequately powered and 59% used only complete case analysis. At the trial-level, larger MD proportions were associated with increasing numbers of questions/tests (odds ratio (OR) 1.19 per-doubling, 95%CI 1.05, 1.35) and longer study duration (OR 1.09 per-doubling, 95%CI 1.02, 1.17). Meta-analysis found evidence of differential rates of MD between trial arms that varied in direction (OR 1.04 (95%CI 0.90, 1.20),  $I^2$  35.0,  $p=0.001$ ), thus potentially introducing bias. (ii) IPD: At the participant-level ( $n=1,846$ ), greater odds of missingness were associated with baseline missingness (OR 17.6, 95%CI 8.64, 35.89), poorer Karnofsky Performance Status (10-unit increase: OR 0.78, 95%CI 0.70, 0.87), and cancer diagnosis (OR 1.64, 95%CI 1.05, 2.56). At the site-level ( $n=35$ ), at the end of follow-up sites that undertook home-visits were less likely to have MD (OR 0.37 95%CI 0.17, 0.80). (iii) Interviews: themes including 'clinical vs. research-role tension', 'attention-to-detail vs. attention-to-person,' and "GCP training doesn't cover the difficult questions" will be explored.

**Conclusion:** This study highlights the need for holistic research to develop a theoretical understanding on how to reduce the waste and bias caused by MD. Interventions informed by this must be tested within trials.

### **0113 - ROLES AND IMPACT OF NURSES IN PROMOTING MEDICATION ADHERENCE OF PATIENTS UNDER THE TB-DOTS PROGRAM IN DISTRICT V, MANILA**

Hyacinth Faune, Keith Roger Serrano, Arielle Arcangel, Ma. Antonette Calipjo, Cleoanne Lourdes Gallegos, Charles Bryan Alvarez, Ericka Louise Gilo, Dianne Marie De Castro  
*University of the Philippines, Manila, National Capital Region, The Philippines*

**Abstract:** Through the National Tuberculosis Program (NTP), TB-DOTS reached and sustained 100% nationwide coverage, achieving the global target for detection of new cases. NTP *Manual of Procedures* (MOP) enlists functions of health workers in TB-DOTS.

#### **Objectives of the Study**

Specifically, the study aims to:

1. Identify the activities and specific interventions that nurses provide in relation to tuberculosis management.
2. Describe the current state of adherence of TB patients undergoing TB medication in specific health centers of District V, Manila.
3. Analyze the impact of nurses in the current state of adherence of TB patients undergoing TB medication in specific health centers of District V, Manila.
4. Explore perceived barriers and opportunities of nurses to promote tuberculosis medication adherence of patients under the TB-DOTS Program in District V, Manila.

**Purpose:** The purpose of this study is to determine the actual roles and activities of nurses in promoting medication adherence of patients under the TB-DOTS Program in District V, Manila.

**Methods:** The study employed a descriptive exploratory design to gather baseline data on the actual roles and activities of nurses in promoting medication adherence. Eleven TB nurses were profiled and surveyed using a questionnaire drafted from the 2005 NTP MOP, 29 former TB patients (cured) were interviewed, and a cohort of 723 TB case records were tabulated to determine the cure rate, treatment completion rate, and relapse rate for District V Manila. Descriptive statistics, content analysis, and data triangulation were performed and further analyzed using Williams et.al's *Self-Determination Model of Medication Adherence* (1998). A pool of experts on TB-DOTS and health policies were consulted to validate the findings and conclusions made from the analysis.

**Results:** The specific activities carried out by nurses to facilitate TB-DOTS treatment and promote medication adherence include the following: case-finding, case-holding, recording/reporting TB cases in the local and national register, management of anti-TB drugs and diagnostic supplies, TB DOTS referral, health education, patient advocacy, communication, and social mobilization. The current treatment success rate of 73% ( $n=600$ ) in District V Manila did not meet the target National Treatment Success Rate of 90%. The computed cure rate is 26.55% ( $n=192$ ), relapse rate of 1.24% ( $n=9$ ), treatment completion rate of 56.43%.

**Conclusion:** The roles and activities of nurses related to patients' adherence to TB medications were deemed essential towards better TB patient outcomes. The independent and collaborative roles performed by nurses exert a positive impact in promoting medication adherence, and contribute to the overall treatment outcome of the TB-DOTS strategy. The study recommends further training of nurses for them to improve in carrying out the TB treatment regimen to improve patient adherence.

## 0114 - Reducing uncertainty in clinical diagnostic genetic testing

[Kate Thomson](#)<sup>1,2</sup>, Roddy Walsh<sup>3,4</sup>, James Ware<sup>3,4</sup>, Martin Farrall<sup>1</sup>, Anneke Seller<sup>2</sup>, Karen McGuire<sup>2</sup>, Edward Blair<sup>2</sup>, Stuart Cook<sup>3,5</sup>, Hugh Watkins<sup>1,2</sup>

<sup>1</sup>University of Oxford, Oxford, UK, <sup>2</sup>Oxford University Hospitals NHS Foundation Trust, Oxford, UK, <sup>3</sup>Imperial

College, London, UK, <sup>4</sup>Royal Brompton and Harefield NHS Trust, London, UK, <sup>5</sup>Duke-NUS, Singapore, Singapore, <sup>6</sup>National Heart Centre, Singapore, Singapore

**Abstract:** In recent years we have seen a dramatic increase in the number of genes linked to Mendelian disorders and a corresponding rise in the number of genes incorporated into clinical diagnostic test panels. However, our ability to interpret the results of these genetic tests has not kept pace; rather than an increase in high confidence genetic diagnoses we are seeing a higher proportion of patients with inconclusive results that are not clinically actionable. This increased uncertainty not only reduces the clinical utility and cost effectiveness of genetic testing, but also increases the risk of over-interpretation and misdiagnosis, which could have serious consequences for both patients and their family members.

One of the main challenges in interpretation is that recent large-scale population based genomic studies have revealed unexpectedly high levels of very rare variation in putative disease genes in the general population. This casts doubt on the pathogenicity of many rare variants previously reported in patient cohorts and even calls into question some published gene: disease relationships.

The challenges of variant interpretation in Mendelian disorders are particularly well illustrated by inherited cardiomyopathies, which are among the most common serious inherited disorders. Clinical diagnostic testing has been available for these conditions for over a decade and the number of genes incorporated into routine testing has increased significantly in recent years. However, the pathogenicity of several variants and also now some genes has been discredited by recent population data. To reduce uncertainty in interpretation, and minimise the risk of over-interpretation and misdiagnosis, there is an urgent need to re-evaluate the genes on current test panels and ensure that clinical diagnostic analysis is restricted to genes showing clear evidence of disease causation.

**Objectives:** Our aim was to re-evaluate the genes in current cardiomyopathy test panels. Fully penetrant pathogenic variants are presumed to be rare in the general population; therefore, in true causal genes we expect to see a significant excess of rare variation in patients compared to controls. We explored this hypothesis using data from ~8000 cardiomyopathy patients and reference data from ~60,000 individuals analysed by the Exome Aggregation Consortium (ExAC). The ExAC cohort is the first publically available database large enough to provide sufficient precision about rates of rare variants in the population to allow reliable re-evaluation of previously implicated disease genes.

**Method:** Variant data from 7855 index cases with a clinical diagnosis of cardiomyopathy (Hypertrophic Cardiomyopathy, Dilated Cardiomyopathy or Arrhythmogenic Right Ventricular Cardiomyopathy) was obtained from two diagnostic genetic laboratories (Oxford Medical Genetics Laboratory, UK and the Laboratory for Molecular Medicine, USA). An upper bound for the frequency of confirmed cardiomyopathy-causing mutations was empirically derived and the number of variants below this threshold compared between cardiomyopathy cases and 60,706 ExAC reference samples.

Fisher's exact test was used to confirm whether the observed differences in variant frequency were statistically significant and odds ratio were calculated for each gene and variant class.

**Results:** Our results confirm the casual role of several key cardiomyopathy genes, however, we find that many genes previously reported as important causes of a given cardiomyopathy do not show any significant excess of rare variants in cases. Further, our findings suggest that some published gene: disease pairs may not be valid at all.

**Conclusions:** We outline a method, which could be applied across a wide range Mendelian disorders, to re-evaluate genes in current diagnostic test panels. We show how analyses of existing datasets can provide critical information that informs results interpretation. Crucially, these analyses provide empirical evidence that can be used to select and prioritise genes for clinical testing. By restricting analysis to robustly validated, and therefore interpretable, genes and classes of variant we hope to reduce uncertainty in interpretation and the potential for misdiagnosis.

## 0115 - What does the research say? - developing a themed review of evidence on end of life care for NHS decision-makers

[Tara Lamont](#), Tansy Evans, Alison Ford, Stephen Williams, Robert Squire

NIHR Dissemination Centre, Southampton, UK

**Abstract:** There is often a disconnect between available evidence and information commissioners need. The most reliable evidence is often narrowly defined around very specific questions. This can

frustrate those struggling with larger problems, like making access to specialist palliative care fairer. The NIHR Dissemination Centre was set up in April 2015 to make research more used and useful to service decision-makers. One priority was to provide helpful overviews of NIHR and other relevant research on pressing service problems. This activity was informed by evidence on getting research into practice - using tailored, multifaceted strategies; making the format engaging to target audiences; engaging stakeholders early and working in partnership with opinion leaders; addressing the policy context.

Our first themed review was on the organisation and quality of end of life care services. This builds on existing Cochrane reviews and highlights 30 recent NIHR funded studies in the context of what is already known. Other features include:

- Expert group of opinion leaders to verify and interpret evidence and mobilise audiences
- Narrative structure defined by stakeholders - right care, right place, right time
- Case studies of evaluated service innovations
- Quotes from frontline clinical staff
- Questions for Boards arising from the evidence

The review was launched in December 2015. The report was accompanied by video interviews and podcasts exploring the review with the national clinical director and a leading general practitioner. A launch event with key partners from charities, patient and professional groups engaged key stakeholders. Targeted communications included features and blogs in the Nursing Times and BMJ. There was an active social media campaign, including a tweetchat with the leading online end of life community.

Our review was co-produced with targeted stakeholders - GPs, palliative care staff, carers, commissioners. The narrative highlights important recent research in the context of what is known and identifies gaps in current evidence. The format is designed to engage frontline practitioners and others who would not read formal research outputs. We will continue to evaluate reach and impact of this work.

**Objectives:** Commissioners need to know what is known and not known about services and systems before making investment decisions. Evidence is often narrowly cast, incomplete and fragmented. The NIHR Dissemination Centre was set up in April 2015 to make research more used and useful to service decision-makers. One priority was to provide helpful overviews of NIHR and other relevant research on pressing service problems. This activity was informed by evidence on getting research into practice - using tailored, multifaceted strategies; making the format engaging to target audiences; engaging stakeholders early and working in partnership with opinion leaders; addressing the policy context.

**Method:** Our first themed review was on the organisation and quality of end of life care services. This builds on existing Cochrane reviews and summarises recent primary research. It focuses particularly on 30 recent NIHR funded studies. The narrative places these studies in the context of what is known. Other features include:

- Expert group of opinion leaders to verify and interpret evidence and mobilise audiences
- Narrative structure defined by stakeholders - right care, right place, right time
- Case studies of evaluated service innovations
- Quotes from frontline clinical staff

Questions for Boards arising from the evidence

**Results:** The review was launched in December 2015. The report was accompanied by video interviews and podcasts exploring the review with the national clinical director and a leading general practitioner. A launch event with key partners from charities, patient and professional groups engaged key stakeholders. Targeted communications included features and blogs in the Nursing Times and BMJ. There was an active social media campaign, including a tweetchat with the leading online end of life community.

**Conclusions:** There is often a disconnect between available evidence and information commissioners need. The most reliable evidence is often narrowly defined around specific questions. This can frustrate those struggling with larger problems, like making access to specialist palliative care fairer. Our review was co-produced with targeted stakeholders - GPs, palliative care staff, carers, commissioners. The narrative highlights important recent research in the context of what is known and identifies gaps in current evidence. The format is designed to engage frontline practitioners and others who would not read formal research outputs. We will continue to evaluate reach and impact of this work.

## **0116 - Can an online, consultant-led advice service accurately diagnose oral cancer? Implications for streamlining the two-week wait referrals pathway. A service evaluation.**

[Amrita Bose](#)<sup>1</sup>, Iain Hutchison<sup>1,2</sup>

<sup>1</sup>*Saving Faces- The Facial Surgery Research Foundation, London, UK*, <sup>2</sup>*Barts Health NHS Trust, London, UK*

**Abstract:** Early detection of oral cancer has an undeniable impact on patient survival. It is equally vital for reducing morbidity, deformity and costs to the healthcare system. To improve the outcomes of cancer patients by early detection and treatment, the two-week wait pathway for urgent referrals was introduced in the UK in 2000. It is estimated to be used around a million times every year. However, since its introduction, several studies have highlighted the low diagnostic yield for head and neck malignancies, ranging between 6-12%. As a consequence, a large proportion of patients fill the urgent clinics when they could attend a routine appointment or do not need to be seen by a specialist at all. This highlights a need for an additional system that may facilitate appropriate use of the urgent referral pathway. Telemedicine has been effectively used in other dental specialities and could be used to triage referrals in oral cancer. This retrospective service evaluation was carried out to study if suspicious oral lesions seen for the first time in primary dental care and submitted to an online diagnostic advice service could be identified correctly by a consultant maxillofacial surgeon. This would ensure only appropriate cases were referred to a cancer specialist. Dental practitioners based in England, who subscribed to the service, made 166 submissions over a period of three years and seven months. Preliminary data obtained from the final outcomes of 83 submissions suggest a success rate of 94% which included 4 correctly diagnosed malignant lesions advised as 'urgent referrals' to a nearest specialist surgeon. This service evaluation shows that incorporating a consultant-led triage system may enable efficient prioritisation of patients with potentially sinister lesions and prevent inappropriate referrals, thereby assuring correct use of the two-week wait referral pathway.

**Objectives:** The primary objective of this retrospective service evaluation was to examine how accurately an online diagnostic service, Saving Faces Diagnostic Advice Service (SFDADS), could identify suspicious oral lesions seen for the first time in primary dental care.

**Method:** Thirty nine dental practices based in England (55 dentists) paid an annual fee to subscribe to the service. Between May 2012 and December 2015 details of 166 patients (personal identifiable information anonymised) and their medical/dental history were submitted via an online form. Dentists were also able to upload up to three digital pictures of suspect oral lesions. The consultant maxillofacial surgeon then gave expert advice back to the referring dentist within three working days. The dental practitioners were asked to submit the final outcome of each of the submissions once the patient had an established diagnosis from the hospital.

**Results:** To date, a total of 83 outcomes have been obtained, 8 of which were advised to be referred as 'urgent', 56 as 'routine' and 7 did not require a referral. Twelve of the patients did not return to the dentist and therefore the advice could not be followed. Out of the 8 urgent referrals, 4 were correctly diagnosed with malignancy and 4 were shown to be benign lesions. The rate of referral accuracy is 94% (60/64) with a 50% (4/8) diagnostic accuracy for sinister lesions.

**Conclusions:** These findings suggest that SFDADS is successful in accurately diagnosing oral cancer. Its diagnostic yield is considerably higher than that reported for the two-week wait referral pathway. This shows that incorporating a consultant-led triage system may enable efficient prioritisation of patients with potentially sinister lesions and prevent inappropriate referrals.

## 0117 - Evidence for Everyday: getting evidence into people's hands through social media

Sarah Chapman

*Cochrane UK, Oxford, UK*

**Introduction:** At Cochrane UK, we aim to disseminate health evidence and encourage engagement with it through 'short, shareable and sociable' content on social media. Building on the success of our blog, Evidently Cochrane, and our 'blogshots' (brief information in a picture, shared on social media), we wanted to create social media content clearly tailored to specific audiences, each with their own ongoing series.

**Objectives:** To raise awareness and use of reliable health evidence, especially (but not exclusively) Cochrane evidence, to inform clinical practice and health decisions.

**Methods:** In November 2015 we launched two 'Evidence for Everyday' series, for midwives and nurses, to be followed in 2016 by 'Evidence for Everyday Health Choices' for anyone making decisions about health, and by 'Evidence for Everyday Allied Health'. The core products of the series, which are ongoing, are blogshots and blogs, content chosen and presented for maximum relevance and usability by target audiences. The blogshots, shared on several social media platforms, are available to download and share. We planned to host tweetchats and to form partnerships with relevant organizations to improve our reach and bring other perspectives to the evidence.

**Results:** The Nursing and Midwifery series have been very well received and the Allied Health series has been planned partly in response to requests for it on social media. For the first two series, we have formed partnerships with *The Practising Midwife* and with The Royal College of Nursing. Conveying brief, accurate and accessible information about evidence for a lay audience has particular challenges and we are currently working on how we will adapt the content for the next series, 'Evidence for Everyday Health Choices'.

**Conclusions:** The first Everyday series are helping us achieve our aims of enabling and encouraging the use of reliable health evidence by putting relevant and accessible content into people's hands through social media. We hope the new series will be as popular.

### **0119 - Quantifying common adverse effects of a drug used for any indication from RCTs: the example of amoxicillin**

Malcolm Gillies<sup>2,1</sup>, Ranakusuma Anggi<sup>3</sup>, Sarah Thorning<sup>1</sup>, Treasure McGuire<sup>1</sup>, Paul Glasziou<sup>1</sup>, [Chris Del Mar](#)<sup>1</sup>  
<sup>1</sup>Bond University, Gold Coast, Australia, <sup>2</sup>NSW Ministry of Health, Sydney, Australia, <sup>3</sup>University of Indonesia, Jakarta, Indonesia

**Background:** Antibiotic over-use in primary care contributes to antibiotic resistance. Additional reasons for reducing antibiotic use include weak effectiveness for most acute respiratory infections in the community, but also adverse effects (AEs). Yet AEs are poorly quantified for clinicians and patients.

**Methods:** We searched for adverse effects by searching for any published trials of amoxicillin without clavulanic acid, and with it (co-amoxiclav), for any indication, arguing that this will identify AEs with minimal bias from confounding symptoms of the disease being treated, inherent in observational studies. We searched 3 databases for randomised participant-blinded placebo controlled trials. Two of us screened and extracted data into forms prepared *a priori*, using Cochrane methods.

**Results:** There were 730 studies identified by the search, from which we discarded all but 45 (27 of amoxicillin and 17 co-amoxiclav: one trial had both forms in a 3-arm trial). There was a wide range of patients, duration, and indications, including prophylaxis for procedures (endoscopy, dental procedures and urinary investigations) and established or potential infections (obstetric, Lyme disease, recurrent otitis media, gastrointestinal, dental, soft tissue, and respiratory), and nutritional. 20/45 reported no usable information about AEs. Therefore many may have only collected AE data unsystematically. The risk of bias was otherwise assessed as low.

Diarrhoea was caused by amoxicillin only when associated with clavulanic acid (OR 3.3, 95% 2.2-4.9); candidiasis by amoxicillin with or without clavulanic acid (OR 7.8, 95% 2.2-27.1) although only 3 trials reported this. Neither rashes, nausea, itching, vomiting nor abnormal liver function tests were significantly increased.

**Conclusions:** Randomised controlled trials poorly report AEs, yet provide some evidence of common AEs for amoxicillin (+/- clavulanate). The combination with clavulanate makes diarrhoea more likely, but either formulation causes candida. If there is poor reporting, then the number of prescriptions dispensed needed to harm (NNH) (for diarrhoea with co-amoxiclav ~10, [95%CI 6-17]; and for candidiasis 27 [95%CI 24-42]) will be grossly under-estimated.

This method of quantifying AEs depends on their reporting in RCTs – poor in the past. We are currently reviewing a new set of antibiotics with more recent trials.

### **0120 - A qualitative study of medical knowledge creation: how mindlines develop and their link with clinical guidelines**

[Sietse Wieringa](#)<sup>1,2</sup>, Eivind Engebretsen<sup>2</sup>, Kristin Heggen<sup>2</sup>

<sup>1</sup>Nuffield Department Primary Care Health Sciences, Oxford, UK, <sup>2</sup>Institute of Health and Society, Department of Health Sciences / Centre for Health Science Education University of Oslo, Oslo, Norway

**Background:** The evidence-based medicine (EBM) movement has fundamentally changed the way medical knowledge is created and generated thousands of guidelines – which are rarely fully followed, for complex reasons. Evidence based guidelines are typically based on randomized controlled trials (RCTs), but they are less good at capturing other sources of evidence, including laboratory studies, qualitative studies, routinely collected data and clinical intuition (1). This was clearly not intended by the pioneers of EBM. They argued that clinical expertise and patient preferences should be integrated with the best evidence (2). The Guidelines International Network AID working group, which members include staff from NICE, NHG and other influential guideline developing institutions, is currently trying to identify “methods and promising initiatives for appraising and including a wider range of knowledge sources in guidelines”. In a large study however (3), researchers found that clinicians most often don't use guidelines or research papers. Instead, they base their decisions on ‘mindlines’: mostly inexplicit ('tacit') knowledge, shaped by subconscious memories from training, previous personal experiences and what is shared among colleagues. Mindlines challenge the basic philosophical assumptions of evidence based medicine, including the nature of reality, causality and what counts as valid knowledge(4). Since mindlines play such an important role and provide an innovative way of thinking about clinical knowledge and evidence, they offer a useful conceptual

framework to further improve guideline development.

**Aim:** To inform closer links between the development and use of clinical guidelines and the 'mindlines' that emerge informally among communities of clinicians.

**Study design:** A mixed method qualitative research project consisting of a literature review, an international ethnography of guideline development and an ethnography of mindline development in social virtual networks of clinicians.

**Anticipated outcomes:** 1. A richer theorization of the notion of mindlines in clinical knowledge development, especially how they emerge and get refined through group interaction. 2. Insights into how to overcome the barriers that guideline development panels face incorporating a broad range of knowledge sources into their recommendations. 3. Preliminary criteria for critically appraising guidelines that have sought to incorporate such broad knowledge sources.

**Objectives**

1. To review the literature and capture expert opinion on the incorporation of broader knowledge sources in clinical guidelines.

2. To explore how mindlines develop in communities of doctors.

3. To explore how broader knowledge sources including mindlines influence the development of clinical guidelines.

Three research questions will guide this study: 1. What is known about how non-RCT evidence is incorporated into guidelines? 2. How do clinical guideline developers engage in producing recommendations from evidence and how are mindlines involved in these processes? 3. What can we learn about mindlines from the study of knowledge construction in virtual communities?

**Method:** The proposed study involves a collaboration of the Universities of Oxford and Oslo and guideline development groups in the UK as well as some in Norway and the Netherlands supervised by professors Trish Greenhalgh and Eivind Engebretsen. A theoretical framework based on a meta-narrative review of several research traditions (in particular epistemology and knowledge management) will be informed by and compared with empirical data using a similar ethnographic approach as Gabbay and Le May (3) to study mindlines in panels involved in guideline development as well as the mindlines of the wider medical community as represented in virtual social networks.

**Results:** We anticipate to find 1. A richer theorization of the notion of mindlines in clinical knowledge development, especially how they emerge and get refined through group interaction. 2. Insights into how to overcome the barriers that guideline development panels face incorporating a broad range of knowledge sources into their recommendations. 3. Preliminary criteria for critically appraising guidelines that have sought to incorporate such broad knowledge sources. Preliminary results from the meta-narrative review will be shared.

**Conclusions:** By exploring the idea of mindlines theoretically and empirically in guideline development organisations and the wider medical community (using conversations exchanged on virtual social networks), we hope to find innovative ways to appraise and incorporate a wider range of evidence in guidelines, thereby helping to ensure that guidelines interact in a meaningful way with the mindlines that exist in the community of clinicians and patients and help evidence based decision making in every day practice.

**0121 - Cochrane Crowd: The role of citizen science in evidence synthesis**

Anna Noel-Storr<sup>1,2</sup>, James Thomas<sup>3</sup>, Chris Mavergames<sup>1</sup>, Julian Elliott<sup>4</sup>

<sup>1</sup>Cochrane, London, UK, <sup>2</sup>University of Oxford, Oxford, UK, <sup>3</sup>UCL, London, UK, <sup>4</sup>Monash University, Melbourne, Australia

**Objectives:** 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.

Inspired by the success of the Zooniverse platform, Cochrane Crowd aims to attract willing citizens from around the world to help curate, filter, classify and describe health evidence so that we can answer questions about the effects of a treatment or the accuracy of a diagnostic test more quickly.

**Method:** Cochrane's Embase project – whereby contributors were tasked with identifying reports of randomized trials that had not been indexed as such in the bio-medical database, Embase, highlighted that it is feasible to recruit willing volunteers to perform such a task: over 2000 people signed up to take part. It also demonstrated that the task could be done well with evaluations resulting in 99% on both recall and precision. During a 20-month period, over 250,000 citations were screened and over 17,000 reports of randomized trials were identified.

**Results:** Cochrane is now scaling this model up by developing a new platform, Cochrane Crowd. This platform will offer more tasks, better support and feedback mechanisms for contributors, and ways for

contributors to build up a track record of progress

The new platform went live in late February 2016. This presentation will describe progress to date with a focus on uptake and quality.

**Conclusions:** Citizen science is becoming an established part of Cochrane's effort to manage the deluge of information being produced. It has so far proved an effective way of managing large, ongoing, data sets in a way that offers willing contributors a way to get involved, learn and hopefully develop skills, experience and expertise in certain evidence production activities.

## **0122 - Project Transform: bringing people and technology together for evidence production**

James Thomas<sup>1</sup>, Julian Elliott<sup>2</sup>, Sally Greene<sup>2,4</sup>, Chris Mavergames<sup>4</sup>, Anna Noel-Storr<sup>3</sup>, Steve McDonald<sup>2,4</sup>, David Tovey<sup>4</sup>, Tari Turner<sup>2,4</sup>

<sup>1</sup>UCL, London, UK, <sup>2</sup>Monash University, Melbourne, Australia, <sup>3</sup>University of Oxford, Oxford, UK, <sup>4</sup>Cochrane, London, UK

**Objectives:** In 2015 Cochrane funded Project Transform which aims to improve evidence production significantly through four, related project components. Each component aims to address the significant challenges we face in evidence synthesis from identifying relevant research in a timely way to ensuring that our evidence is up-to-date.

**Method:** The first component is *Evidence Pipeline*. Here, machine learning is used to help identify reports of randomized trials across a broad range of sources, automatically identifying the relevant domain of interest for each; the *Getting Involved* component uses crowdsourcing to classify and describe the trials. The project's third component, *Task Exchange*, enables review authors and others to post review-related tasks to a task marketplace where willing contributors can sign-up to complete them. The final component, *Production Models*, has conducted an extensive evaluation of current review production models and will be followed by pilot studies in a number of new models.

**Results:** After 18 months the project has delivered two new platforms, Cochrane Crowd and Task Exchange. Each enables willing contributors to access needed tasks, either on large ongoing datasets through Cochrane Crowd or on tasks related to Cochrane reviews, through Task Exchange. Through the Evidence Pipeline component, text mining and machine learning now provides a substantial workload reduction in the identification of randomized trials and the Production Models component has completed its evaluation of various models of systematic review production and is now entering its pilot phase.

**Conclusions:** The starting point for Project Transform is the assertion that evidence production is Cochrane's core business and our global network of contributors is our greatest asset. By better mobilising these contributor networks through the appropriate use of technology, we can maximise the value of our content and our long-term sustainability in a changing external environment.

## **0123 - Development of the Appraisal tool for Cross-Sectional Studies (AXIS)**

Martin Downes<sup>1</sup>, Marnie Brennan<sup>2</sup>, Hywel Williams<sup>3</sup>, Rachel Dean<sup>2</sup>

<sup>1</sup>Centre for Applied Health Economics, Griffith University, Queensland, Australia, <sup>2</sup>Centre for Evidence-based Veterinary Medicine, The University of Nottingham, Nottingham, UK, <sup>3</sup>Centre for Evidence Based Dermatology, The University of Nottingham, Nottingham, UK

**Abstract:** Critical appraisal (CA) is a skill central to undertaking evidence based practice which is concerned with integrating the best evidence with clinical care. Teaching critical appraisal has become an important part of the curriculum in medical schools and plays a central role in the interpretation and dissemination of research for evidence based practice. Whereas well established appraisal tools have been developed for assessing the quality of cohort and case control studies, there is currently a lack of an appraisal tool specifically aimed at cross sectional studies. The aim of this study was to develop a critical appraisal tool that addressed study design quality and risk of bias in cross sectional studies. We also aimed to provide an easy to use explanatory document that would help enhance the knowledge of those using the tool and give them the skills required to conduct a critical appraisal of a cross sectional study. Areas that needed to be included in the development of a critical appraisal tool were identified using results of a scoping review and from key epidemiological texts. These were tested and developed before being examined using a Delphi process. A Delphi panel was initiated to examine and generate consensus on the contents of the critical appraisal tool. Three rounds of consensus were carried out before the final tool was agreed upon. The Appraisal tool for Cross-Sectional Studies (AXIS) was developed; which was a 30



point questionnaire that addressed study quality and reporting. Key areas addressed in the AXIS include; Study Design, Sample Size Justification, Target Population, Sampling Frame, Sample Selection, Measurement Validity & Reliability, and Overall Methods.

A detailed explanatory document is provided with the tool, giving expanded explanation of each question and providing simple interpretations and examples of the epidemiological concepts being examined in each question. AXIS is currently being used by a number of research groups for systematic reviews and guidelines, and as with other evidence based initiatives the AXIS tool is intended to be an organic item that can change and improve where required, as such the validity of the tool will be measured and continuously assessed.

**Objectives:** The aim of this study was to develop a critical appraisal tool that addressed study design quality and risk of bias in cross sectional studies. We also aimed to provide an easy to use explanatory document that would help enhance the knowledge of those using the tool and give them the skills required to conduct a critical appraisal of a cross sectional study.

**Method:** Areas that needed to be included in the development of a critical appraisal tool were identified using results of a scoping review and from key epidemiological texts. These were tested and developed before being examined using a Delphi process. A Delphi panel was initiated to examine and generate consensus on the contents of the critical appraisal tool. Three rounds of consensus were carried out before the final tool was agreed upon.

**Results:** The Appraisal tool for Cross-Sectional Studies (AXIS) was developed; which was a 30 point questionnaire that addressed study quality and reporting. Key areas addressed in the AXIS include; Study Design, Sample Size Justification, Target Population, Sampling Frame, Sample Selection, Measurement Validity & Reliability, and Overall Methods.

**Conclusions:** A detailed explanatory document is provided with the tool, giving expanded explanation of each question and providing simple interpretations and examples of the epidemiological concepts being examined in each question. AXIS is currently being used by a number of research groups for systematic reviews and guidelines, and as with other evidence based initiatives the AXIS tool is intended to be an organic item that can change and improve where required, as such the validity of the tool will be measured and continuously assessed.

## **0124 - Evidence to inform the National Institute for Health Research Adding Value in Research agenda**

Amanda Young, Kirsty Rogers

*NETSCC RoR, University of Southampton, Southampton, UK*

**Background:** The NIHR, Evaluations Trials and Studies Coordinating Centre (NETSCC) has an internal programme of work to assess, evaluate and improve the research management processes, functions and systems as well as the research managed by NETSCC. The programme has now conducted a number of studies to better understand where improvements are needed and how these improvements are being implemented in practice.

**Objectives:** To discuss the value and role of NETSCC Research on Research Programme (RoR) in terms of how it addresses important questions under the Adding Value in Research framework (AViR) (from the point of topic initiation through to publication).

**Methods:** An overview of Research on Research in terms of its development, purpose and objectives will be presented. Reported findings from a collection of RoR studies will be presented under the five stages of the AViR framework.

- - Are the right questions being asked - appropriate to the patients, public, NHS?
- - Is the research design, conduct and analysis appropriate?
- - Efficient research regulation and delivery
- - Accessibility to full reports/publications
- - Unbiased reporting of findings - transparency

**Results:** Evidence provided by RoR is important. It demonstrates how a major UK funder of health research actively seeks to assess its management, commissioning and dissemination processes to ensure maximum impact and benefit to patients. By evaluating these research management processes, as well as the research we manage, we are also able to maximise the effectiveness and value of health research. So by providing evidence to improve how research is initiated, conducted and reported we are strengthening the evidence base for high quality scientific research.

**Conclusions:** Work disseminated through RoR not only informs a major UK funder of health research but also the wider research community. Through RoR studies we are able to provide the evidence to suggest new

ways of improving the overall quality of funded research but also to what extent these changes will make in practice.

### **0125 - The First 500 Registrations of the Research Registry: Advancing the Cause of Research Registration in Compliance with the Declaration of Helsinki 2013**

Riaz Agha<sup>1</sup>, Alexander Fowler<sup>2</sup>, Chris Limb<sup>3</sup>, Yasser Al Omran<sup>4</sup>, Harkiran Sagoo<sup>5</sup>, Kiron Koshy<sup>6</sup>, Daniyal Jafree<sup>6</sup>, Mohammed Omer Anwar<sup>4</sup>, Peter McCulloch<sup>1</sup>, Dennis Orgill<sup>7</sup>

<sup>1</sup>University of Oxford, Oxford, UK, <sup>2</sup>Guy's and St. Thomas' NHS Foundation Trust, London, UK, <sup>3</sup>St Helier Hospital, Surrey, UK, <sup>4</sup>Barts and The London School of Medicine and Dentistry, London, UK, <sup>5</sup>GKT School of Medical Education, London, UK, <sup>6</sup>University College London Medical School, London, UK, <sup>7</sup>Harvard Medical School, Boston, USA

**Abstract:** The Declaration of Helsinki 2013 encourages the registration of all research studies involving human participants. However, emphasis has been placed on prospective clinical trials, and it is estimated that only 10% of observational studies are registered. In response, Research Registry was launched in February 2015; a retrospectively curated registry that is free and easy to use. Research Registry enables prospective or retrospective registration of studies, including those study types that cannot be registered on existing registries. In this study, we describe the first 500 registrations on Research Registry. Since the launch of Research Registry in February 2015, data of registrations have been collected, including type of studies registered, country of origin and data curation activity. Inappropriate registrations, such as duplicates, were identified by the data curation process. These were removed from the database or modified as required. A quality score was assigned for each registration, based on Bradford-Hill's criteria on what research studies should convey. Changes in quality scores over time were assessed. 500 studies were registered on Research Registry from February 2015 to October 2015, with a total of 1.7 million patients enrolled. The most common study types were retrospective cohort studies (37.2%), case series (14.8%) and first-in-man case reports (10.4%). Registrations were received from 57 different countries; the most submissions were received from Turkey, followed by China and the United Kingdom. Retrospective data curation identified 80 studies that were initially registered as the incorrect study type, and were subsequently correct. The Kruskal-Wallis test identified a significant improvement in quality scores for registrations from February 2015 to October 2015 ( $p < 0.001$ ). Since its conception in February 2015, Research Registry has established itself as a new registry that is free, easy to use and enables the registration of various study types, including observational studies and first-in man case reports. Going forward, our plan is to continue developing Research Registry in line with user feedback and usability studies. We plan to further promote Research Registry to advance the cause of registration of research, to increase compliance with the Declaration of Helsinki 2013.

**Objectives:** The Declaration of Helsinki 2013 encourages the registration of all research studies involving human participants. However, emphasis has been placed on prospective clinical trials, and it is estimated that only 10% of observational studies are registered. In response, Research Registry was launched in February 2015; a retrospectively curated registry that is free and easy to use. Research Registry enables prospective or retrospective registration of studies, including those study types that cannot be registered on existing registries. In this study, we describe the first 500 registrations on Research Registry.

**Method:** Since the launch of Research Registry in February 2015, data of registrations have been collected, including type of studies registered, country of origin and data curation activity. Inappropriate registrations, such as duplicates, were identified by the data curation process. These were removed from the database or modified as required. A quality score was assigned for each registration, based on Bradford-Hill's criteria on what research studies should convey. Changes in quality scores over time were assessed.

**Results:** 500 studies were registered on Research Registry from February 2015 to October 2015, with a total of 1.7 million patients enrolled. The most common study types were retrospective cohort studies (37.2%), case series (14.8%) and first-in-man case reports (10.4%). Registrations were received from 57 different countries; the most submissions were received from Turkey, followed by China and the United Kingdom. Retrospective data curation identified 80 studies that were initially registered as the incorrect study type, and were subsequently correct. The Kruskal-Wallis test identified a significant improvement in quality scores for registrations from February 2015 to October 2015 ( $p < 0.001$ ).

**Conclusions:** Since its conception in February 2015, Research Registry has established itself as a new registry that is free, easy to use and enables the registration of various study types, including observational studies and first-in man case reports. Going forward, our plan is to continue developing Research Registry in line with user feedback and usability studies. We plan to further promote Research Registry to advance the cause of registration of research, to increase compliance with the Declaration of Helsinki 2013

## 0129 - Quality of reporting and method of randomized controlled trials in diabetes in Iran; a systematic review

Hamid Reza Baradaran, Morteza Tabatabaee, Faeze Gohari, Shabnam Anjidani, Fatemeh Mohammadpour, Azadeh Aletaha

Endocrine Research Center Institute of Endocrinology and Metabolism Iran University of Medical Sciences, Tehran, Iran

**Abstract:** To determine the quality of randomized controlled clinical trial reports in diabetes research in Iran, this systematic review including RCTs conducted on Diabetes Mellitus in Iran carried out. Animal studies, educational interventions, and non-randomized trials were excluded. Two investigators, independently, assessed the quality of reporting by CONSORT (Consolidated Standards of Reporting Trials) checklist statement, and also evaluated the methodological qualities by Jadad Score. Discrepancies were resolved by third reviewer consulting. One hundred and eight five (185) studies were included and appraised. Half of them (55.7%) were published in Iranian journals. Most (89.7%) were parallel RCTs, and being performed on type2 diabetic patients (77.8%). Less than half of the CONSORT items (43.2%) were reported in studies, totally. The reporting of randomization and blinding were poor. A few studies 15.1% mentioned the method of random sequence generation and strategy of allocation concealment. And only 34.8% of trials report how blinding was applied. The mean Jadad score was 2.25 [95% CI: 2.07, 2.42]. Of 185 RCTs analysed, only 35.5% had high quality (defined by a Jadad score  $\geq$  3) and most (64.4%) had poor methodological quality.

The findings of this study show that the quality of RCTs conducted in Iran in diabetes research seems suboptimal and the reporting is also incomplete however an increasing trend of improvement can be seen over time. Therefore, it is suggested Iranian researchers pay much more attention to design and methodological quality in conducting and reporting of diabetes RCTs.

**Objectives:** To determine the quality of randomized controlled clinical trial reports in diabetes research in Iran, this systematic review including RCTs conducted on Diabetes Mellitus in Iran carried out

**Method:** Animal studies, educational interventions, and non-randomized trials were excluded. Two investigators, independently, assessed the quality of reporting by CONSORT (Consolidated Standards of Reporting Trials) checklist statement, and also evaluated the methodological qualities by Jadad Score. Discrepancies were resolved by third reviewer consulting.

**Results:** 185 studies were appraised. . Most (89.7%) were parallel RCTs, and being performed on type 2 diabetes (77.8%). Less than half of the CONSORT items (43.2%) were reported in studies, totally. The reporting of randomization and blinding were poor. A few studies 15.1% mentioned the method of random sequence generation and strategy of allocation concealment. And only 34.8% of trials report how blinding was applied. The mean Jadad score was 2.25 [95% CI: 2.07, 2.42]. Of 185 RCTs analysed, only 35.5% had high quality (defined by a Jadad score  $\geq$  3) and most (64.4%) had poor methodological quality.

**Conclusions:** The findings of this study show that the quality of RCTs conducted in Iran in diabetes research seems suboptimal and the reporting is also incomplete however an increasing trend of improvement can be seen over time. Therefore, it is suggested Iranian researchers pay much more attention to design and methodological quality in conducting and reporting of diabetes RCTs.

## 0130 - Waste in independent drug research in Italy: a cross-sectional study

Antonino Cartabellotta<sup>1</sup>, Corrado Iacono<sup>1</sup>, Sandra Petraglia<sup>2</sup>, Marco Mosti<sup>1</sup>, Alessia Cirilli<sup>2</sup>, Elena Cottafava<sup>1</sup>, Luca Pani<sup>2</sup>, Mario Melazzini<sup>2</sup>

<sup>1</sup>GIMBE Foundation, Bologna, Italy, <sup>2</sup>Italian Medicine Agency (AIFA), Rome, Italy

**Abstract:** The program on independent research of the Italian Medicines Agency - Agenzia Italiana per il Farmaco (AIFA) - funded 207 studies with nearly € 100 million in 2005-2009. The registration of studies and the publication of results were not required to gain all assigned funds. Currently no public monitoring has been conducted to verify publication of results. In order to estimate the potential research waste, our study investigated: registration status of funded studies, time gap between grant approval and start of study, fate of funded studies (never started, interrupted, ongoing, concluded), and their publication status. Data from 5 different AIFA databases were first standardized, merged and checked for consistency, then integrated with information from study protocols and other documents. Publication status of studies was verified through literature searches (PubMed, Google, CENTRAL, EMBASE, etc.) and contacts with principal investigators. The registration status was explored using the WHO International Clinical Trials Registry Platform. Among 207 funded studies 164 were clinical trials, 28 observational studies and 15 systematic reviews. Only 52/207 (25%) protocols were registered. The regulation process from grant approval to start of study is very long: mean 515 days ( $\pm$ SD 318), range 7-2058 days. 3 studies (2%) never started, 125 were concluded (60%), 33 (16%) studies are ongoing, and 46 (22%) were interrupted. Insufficient recruitment was the most frequent reason for interruption, wasting more than € 10 million even so delivered by AIFA. Currently 87/204 (43%)

studies remain unpublished: 21 (24%) are concluded, 39 (45%) were interrupted and 27 (31%) are ongoing. The results of investigating the fate of studies funded from governative bodies may be very helpful for redefining selection and funding criteria for future calls, in order to maximize value and reduce waste of independent research in Italy. Further analyses to estimate research waste are ongoing.

**Objectives:** The program on independent research of the Italian Medicines Agency - Agenzia Italiana per il Farmaco (AIFA) - funded 207 studies with nearly € 100 million in 2005-2009. The registration of studies and the publication of results were not required to gain all assigned funds. Currently no public monitoring has been conducted to verify publication of results. In order to estimate the potential research waste, our study investigated: registration status of funded studies, time gap between grant approval and start of study, fate of funded studies (never started, interrupted, ongoing, concluded), and their publication status.

**Method:** Data from 5 different AIFA databases were first standardized, merged and checked for consistency, then integrated with information from study protocols and other documents. Publication status of studies was verified through literature searches (PubMed, Google, CENTRAL, EMBASE, etc.) and contacts with principal investigators. The registration status was explored using the WHO International Clinical Trials Registry Platform.

**Results:** Among 207 funded studies 164 were clinical trials, 28 observational studies and 15 systematic reviews. Only 52/207 (25%) protocols were registered. The regulation process from grant approval to start of study is very long: mean 515 days ( $\pm$ SD 318), range 7-2058 days. 3 studies (2%) never started, 125 were concluded (60%), 33 (16%) studies are ongoing, and 46 (22%) were interrupted. Insufficient recruitment was the most frequent reason for interruption, wasting more than € 10 million even so delivered by AIFA. Currently 87/204 (43%) studies remain unpublished: 21 (24%) are concluded, 39 (45%) were interrupted and 27 (31%) are ongoing.

**Conclusions:** The results of investigating the fate of studies funded from governative bodies may be very helpful for redefining selection and funding criteria for future calls, in order to maximize value and reduce waste of independent research in Italy. Further analyses to estimate research waste are ongoing.

### **0132 - Evolution of European Society of Cardiology Guidelines Since 2000: a Systematic Appraisal**

Charles Badu-Boateng<sup>1,3</sup>, Arash Yavari<sup>1,2</sup>, Rizwan Sarwar<sup>1</sup>

<sup>1</sup>Cardiology Dept, John Radcliffe Hospital, Oxford University Hospitals NHS Trust, Oxford, UK, <sup>2</sup>Division of Cardiovascular Medicine, University of Oxford, Oxford, UK, <sup>3</sup>GKT School of Medical Education, King's College London, London, UK

**Background:** Guidelines from the European Society of Cardiology (ESC) summarise the best available evidence in the management of cardiac disease. These guidelines are graded according to ESC-predefined scales of class of recommendation from I-III and levels of evidence from A-C. We evaluated the development of ESC guidelines since 2000.

**Objectives:** Guidelines from the European Society of Cardiology (ESC) summarise the best available evidence in the management of cardiac disease. These guidelines are graded according to ESC-predefined scales of class of recommendation from I-III and levels of evidence from A-C. We evaluated the development of ESC guidelines since 2000.

**Method:** We reviewed recommendations from all ESC guidelines from 2000-14, collating classes of recommendation and level of evidence for each. We assessed the number and percentages of each class of recommendation and determined temporal changes in proportion.

**Results:** Out of 52 guidelines, we extracted 4547 recommendations, with 67% being in Class I or III, indicating unequivocal guidance. Regarding the level of evidence for these recommendations, we found that only 18% were class A, indicating high quality evidence, and 50% were class C, indicating consensus opinion or small studies. From 2000-2014, there were minor changes in the proportions of different classes of recommendation and levels of evidence.

**Conclusions:** Medicine is rapidly changing and cardiologists face difficult challenges in the application of a growing number of recommendations of difference evidence level to guide clinical practice. Our analysis highlights that 33% of all guideline statements are in the equivocal class (II), with 82% of guidelines not based upon the highest level of evidence. Over 14 years there have been minimal changes in proportions of class of recommendation and level of evidence. Our findings suggest the need to improve the level of evidence underpinning current guidance to increase the proportion of unequivocal guidance recommendations.

### **0133 - Investigation of the influence of patient decision aids on knowledge and informed decision-making: a systematic review and content analysis**

Jean Ryan, Arlene McCurtin, Amanda Clifford, Fiona Murphy, Cathal Walsh  
*Univeristy of Limerick, Limerick, Ireland*

**Background:** Public interactions with health services is one of the cornerstones of health service research (Clancy 2011). In fact, an increasing commitment to promoting patient engagement and facilitating patient voice is evident within the literature. Engaging users in their own healthcare experience has been demonstrated to manifest in more responsive services and enhanced outcomes (Barello 2012; Mockford 2011). One means of enhancing user involvement is shared decision-making. This involves the patient and healthcare professional engaging in collaborative deliberation regarding health decisions pertaining to the individual involved. However, a fully informed patient is an important prerequisite for this process. Interventions called decision aids can be used to educate patients and promote shared decision-making. Essentially, they synthesise different forms of knowledge or evidence in order to assist patients in making an informed decision. They have been shown to positively affect knowledge, decisional conflict and patient engagement (Stacey 2014). However, less is known regarding the types of knowledge/evidence included in decision aids and their congruence with the evidence based practice model.

**Objectives:** This systematic review aims to explore the types of knowledge used in decision aids and the effect of this information on outcomes of decision making.

**Method:** A comprehensive search of a selection of databases will be conducted in order to retrieve randomised controlled trials of health treatment decision aids. The information included in these aids will be analysed using content analysis. Other primary outcomes include knowledge and informed decision making. These outcomes will be assessed using statistical analyses. Methodological quality of the included studies will be ascertained using The Cochrane Collaboration risk of bias tool. Decision aid quality will be assessed using the International Patient Decision Aid Standards instrument short form (IPDAS-SF).

**Results:** Results of the content analysis will determine the types of knowledge or evidence included in decision aids. A statistical analysis will depict the effect of information within decision aids on patient knowledge and making an informed decision.

**Conclusion:** This systematic review will provide an understanding of the categories of evidence used in patient decision aids and the effect of this on decision-making.

### **0134 - Missing Results for Trials of New Neurological Drugs: A Systematic Analysis**

Amanda Hakala<sup>1</sup>, Dean Fergusson<sup>2</sup>, Jonathan Kimmelman<sup>1</sup>

<sup>1</sup>*McGill University, Montreal, QC, Canada*, <sup>2</sup>*University of Ottawa, Ottawa, ON, Canada*

**Background and aims:** Neurological drug development is one of the most challenging domains of drug development. Trials of products that never receive regulatory licensure provide vital information about theoretical premises driving drug development, and their publication helps redeem the sacrifice of patients who participate in such studies. We systematically assessed the rate of nonpublication of trials testing new neurological drugs. **Methods:** Using a cohort of major neurological drugs that reached phase III clinical testing before 2013, we created a sample of registered trials closing before October 1, 2010 for products receiving licensure and products stalling in development. We determined the publication status of trials using searches of clinicaltrials.gov, Google Scholar, PubMed, Embase, and direct electronic query of trial contacts and sponsors listed in public registries. **Results:** Our searches captured 163 trials of 8 licensed drugs and 203 trials of 28 stalled drugs. The unadjusted proportion of fully published trials of licensed drugs was 55% (90/163), vs. 31% (63/203) for unlicensed drugs. The adjusted hazard ratio for publication was 1.67 (95% confidence interval 1.1 to 2.54) in favour of licensed drugs. No result data was publicly available in any form for 10% (16/163) and 47% (95/203) of trials of licensed and stalled drugs, respectively, representing the unredeemed sacrifices of 2,109 and 22,102 participants, respectively. **Conclusion:** Despite their ethical and practical importance, results of trials of unlicensed drugs are heavily underreported.

**Objectives:** Neurological drug development is one of the most challenging domains of drug development. Trials of products that never receive regulatory licensure provide vital information about theoretical premises driving drug development, and their publication helps redeem the sacrifice of patients who participate in such studies. We systematically assessed the rate of nonpublication of trials testing new neurological drugs.

**Method:** Using a cohort of major neurological drugs that reached phase III clinical testing before 2013, we created a sample of registered trials closing before October 1, 2010 for products receiving licensure and products stalling in development. We determined the publication status of trials using searches of clinicaltrials.gov, Google Scholar, PubMed, Embase, and direct electronic query of trial contacts and sponsors listed in public registries.

**Results:** Our searches captured 163 trials of 8 licensed drugs and 203 trials of 28 stalled drugs. The unadjusted

proportion of fully published trials of licensed drugs was 55% (90/163), vs. 31% (63/203) for unlicensed drugs. The adjusted hazard ratio for publication was 1.67 (95% confidence interval 1.1 to 2.54) in favour of licensed drugs. No result data was publicly available in any form for 10% (16/163) and 47% (95/203) of trials of licensed and stalled drugs, respectively, representing the unredeemed sacrifices of 2,109 and 22,102 participants, respectively.

**Conclusions:** Despite their ethical and practical importance, results of trials of unlicensed drugs are heavily underreported.

### **0136 - Evidence Review Methods to Support Evidence-based Coverage Decisions and the Goldilocks**

#### **Principle: Too Big, Too Small, Just Right?**

Valerie King<sup>1,2</sup>, Adam Obley<sup>1,3</sup>, Cat Livingston<sup>4,2</sup>, Craig Mosbaek<sup>1</sup>, Aasta Thielke<sup>1</sup>, Jason Gingerich<sup>4</sup>, Darren Coffman<sup>4</sup>

<sup>1</sup>Center for Evidence-based Policy, Portland, Oregon, USA, <sup>2</sup>Oregon Health & Science University, Portland, Oregon, USA, <sup>3</sup>Portland Veterans Administration Medical Center, Portland, Oregon, USA, <sup>4</sup>Oregon Health Authority--Health Evidence Review Commission, Salem, Oregon, USA

**Abstract:** A central issue for health policy makers is how much information is "enough" to support decisions, within the constraints of rapid timelines and other resource constraints. After 2009 legislative direction, the U.S. state of Oregon, long known for its Medicaid program's "Prioritized List" of services, has been developing evidence-based coverage standards. These standards, developed by the Health Evidence Review Commission (HERC) are binding for Medicaid and widely used by commercial insurers. This paper examines the evolving evidence review methods used by the HERC and the advantages and disadvantages of these methods for policy development.

Process mapping and key informant interviews were completed to determine quality and efficiency of HERC evidence reviews.

The HERC has developed 46 coverage standards. The first three adopted a clinical practice guideline format, employing the ADAPTE framework and were completed in 13-23 months. The HERC found this process too lengthy and the guidelines too clinically detailed. From 2012 to mid-2014 HERC produced 33 coverage "guidances." Supporting evidence reviews used a core set of 13 trusted SR sources, including Cochrane, AHRQ and NICE. Although timeline goals were 6 months, detailed process mapping found average completion time of 44 (range 10-89) weeks. Two common causes of delay were requests for additional research and evidence identified during public comment. Other common delays related to interim process changes, insufficient staffing and meeting time. In 2015, major methodology changes were initiated to address concerns about quality and timeliness. A rapid review (RR) methodology, including expanded initial scope definition, comprehensive evidence searching and incorporation of GRADE tables was developed. Six guidance topics have used the new RR methodology. One has been completed in less than 5 months, with the remaining on course.

Development of full guidelines, even using abbreviated processes, took too long and resulted in products that were too clinically detailed. Use of only existing SRs missed key newer studies and did not always identify evidence for key comparators or outcomes of interest. Adoption of a RR method appears to have solved these problems and has allowed both higher quality and more timely evidence review production to support coverage policy decisions.

#### **Objectives:**

1. To describe the evolution of evidence review methods used to inform health coverage decisions for the Oregon Health Evidence Review Commission (HERC).
2. To discuss the applicability of rapid review (RR) methods to support coverage policy determinations by the HERC.

**Method:** Process mapping and key informant interviews were completed to determine quality and efficiency of HERC evidence reviews.

**Results:** The first topics adopted a clinical practice guideline format, employing the ADAPTE framework and were completed in 13-23 months. From 2012 to mid-2014, HERC approved 33 coverage "guidances" using a set of 13 SR sources. Process mapping found timelines averaged 44 weeks, 18 over projected. Common delays related to additional research requests and evidence identified during public comment. To address concerns about quality and timeliness, staff developed a rapid review (RR) methodology, including expanded scope definition, comprehensive searching and GRADE tables. Six guidance topics have used the RR methodology. One has been completed under time, with the others on course.

**Conclusions:** Development of full guidelines, even using abbreviated processes, took too long and resulted in products that were too clinically detailed. Use of only existing SRs missed key newer studies and did not always identify evidence for key comparators or outcomes of interest. Adoption of a RR method appears to

have solved these problems and has allowed both higher quality and more timely evidence review production to support coverage policy decisions.

### **0137 - Association between titles of healthcare articles and inclusion in the Altmetric Top 100**

Nicola Di Girolamo<sup>1</sup>, Reint Meursinge Reynders<sup>2</sup>

<sup>1</sup>University of Bologna, Bologna, Italy, <sup>2</sup>University of Amsterdam, Amsterdam, The Netherlands

**Objectives:** The aim of this study was to assess whether title characteristics could influence the likelihood of being included in the "Altmetric Top 100".

**Methods:** We conducted a 1:2 matched case-control study with the cases being the healthcare articles included in the "Altmetric Top 100" lists (2013-2015) matched through a random computerized procedure with 2 healthcare articles published in the same journal and year. For each title we extracted the number of characters in the title, the number of difficult words and whether the title was declarative. Conditional logistic regression was used to estimate odds ratio (OR) with 95% confidence intervals adjusted for a pre-specified baseline confounder (open access).

**Results:** 108 "Medical and health sciences" articles were retrieved in the 2013-2015 "Altmetric Top 100" and matched to 216 control articles. Titles of the "Altmetric Top 100" articles were 102.6 characters ( $\pm 42$ ) long, included 3.4 ( $\pm 2.0$ ) words, and 29.6% (32/108) were 'declarative'. Titles of the matched articles were 109.3 characters ( $\pm 37.1$ ) long, included 4.7 ( $\pm 2.4$ ) words, and 21.8% (47/216) were 'declarative'. After multivariate adjustment, declarative titles with a lower number of difficult words were significantly more represented in the Altmetric list, with declarative titles having 2.8 times the odds of being in the top list (OR: 2.8; 95%CI: 1.2 to 6.4). For each additional difficult word in the title, there was a 1.4 increase in the odds of being a non-Altmetric Top 100 article (1.4; 1.2 to 1.6).

**Conclusion:** An easy-to-understand, informative title may somehow shorten the gap between academic researchers and lay people.

### **0138 - Transforming the Communication of Evidence for Better Health: Improving the availability and use of reliable healthcare information for health professionals, citizens, policymakers and researchers**

Neil Pakenham-Walsh

*Healthcare Information For All, Oxford, UK*

**Abstract:** This presentation will address the elephant in the room that is fundamental to even the most basic notions of evidence-based policy and practice: namely, the availability of reliable healthcare information in the language and format that different users can understand and act upon. Without such access, any attempt to promote evidence-based medicine is a waste of time. The key to improve access is to strengthen the global healthcare information system. The current system is not working for most people in low- and middle-income countries.

Thousands of children and adults die needlessly every day because they do not receive basic life-saving interventions - interventions that are often locally available but are simply not provided due to indecision, delays, misdiagnosis, and incorrect treatment. Many would still be alive today if those responsible for their care had access to basic healthcare information.

Healthcare Information For All (HIFA) is a professional global health network working in collaboration with WHO. HIFA has more than 15,000 health workers, librarians, publishers, researchers and policymakers, committed to accelerate progress towards the HIFA Vision: a world where every person has access to the healthcare information they need to protect their own health and the health of others. One third of members are based in Africa, one-third in Europe, and one-third in the rest of the world. HIFA members represent more than 2500 organisations across 175 countries worldwide, and interact on five global email discussion forums (HIFA Global Forums) in three languages (English, French, Portuguese).

### **0142 - Multi-Perspective Consumer Health Information Search: Making Sense of Conflicting & Confusing Health Information Online**

Satish Rath, Shourya Roy, Sandya Mannarswamy

*Xerox Research Centre India, Bangalore, India*

**Abstract:** Online Health Information Seekers (OHIS) often turn to web to get information on questions for which they cannot find definitive answers from their traditional information sources. With the rise of "Informed Patient" movement, internet is increasingly being used by patients, as an aid for decision making. General

search engines are not effective in addressing complex consumer health queries which do not have a single definitive answer. We use the term "Multi-Perspective Consumer Health Information Search" (MPCHIS) to denote such queries, for which there is "No single Correct Answer", whereas multiple perspectives (and very often contradictory perspectives) are available on the web regarding the query. While it is easy to get a definitive answer to a query such as "what are the symptoms of Diabetes?" from web search engines, a query such as "are statins effective against heart disease?" causes considerable frustration for the patient. Patients find it challenging to synthesize a balanced point of view even at the end of considerable time spent navigating through the mass of results presented for such MPCHIS queries.

MPCHIS requires mining and synthesis of perspectives from multiple sources, which includes data driven medical research evidence and experiential evidence (available from similar patients' narratives, health related content on social media). While medical research evidence is data-driven, patient experience narratives are subjective and anecdotal. Novel techniques are needed to synthesize and grade evidence across these heterogeneous sources of information. MPCHIS also needs to handle phenomena such as medical reversal and source credibility. With concerns of life and death in balance, presentation of "correct" and balanced views (with supporting evidence) becomes crucial. In this paper, we present the challenges associated with MPCHIS, and describe an end to end Natural Language Processing based information extraction system which given any MPCHIS query, can automatically mine information from the web and organize it in the form of a summary of perspectives such that

- (1) supporting and opposing perspectives are clearly distinguished.
- (2) evidence for each perspective is marked out.
- (3) Identification of entities associated with these perspectives and their affiliations
- (4) A timeline based view of the different perspectives.

**Objectives:** Making sense of controversial and subjective health information online becomes a challenging task for patients. MPCHIS queries such as "should I take an aspirin daily for preventing a heart attack?" present the user with hundreds of links, which lay patients need to make sense of, requiring considerable time and effort. Automated tools based on Natural Language Processing (NLP) techniques can help in extracting the various perspectives and supporting evidence associated with their health queries. In this paper, we describe "MPCHIS Evidence Miner", an end to end system for automatically extracting perspective summaries for MPCHIS queries and share initial experimental results.

**Method:** Our system processes the search engine result pages (SERP) for MPCHIS queries to extract Relevant Sentences which are then classified into Supporting/Opposing/Conditionally Supporting/Conditionally Opposing categories using machine learning techniques. Our system employs a pattern based approach for detecting conditional support/opposition statements relevant to the query. Perspectives need to be supported by available evidence. Evidence can be research evidence (clinical trials, studies, reports), expert evidence and personal anecdotal evidence. We use a machine learning based approach to detect and classify evidence sentences for the different perspectives. The output of EvidenceMiner is a summary presenting multiple perspectives along with their evidence supports.

**Results:** We created a sample MPCHIS dataset from queries posted by patients, seeking health information online, which is available at <https://sites.google.com/site/multiperspectivehealthqa/>. Since our full prototype is still under development, our initial experimental evaluation consisted of evaluating the tasks of (i) Support/Oppose classification of relevant sentences (ii) identifying and classifying evidence sentences for MPCHIS queries. The initial results are encouraging with the vanilla EvidenceMiner achieving F1 Score of 0.59 in task(i) and 0.62 in task (ii) compared to the gold standard of manual annotation for our sample dataset. We plan to release the gold standard annotation for our dataset shortly.

**Conclusions:** This poster is intended to bring to the attention of health informatics researchers, the unique challenges involved in MPCHIS. We describe EvidenceMiner, an automatic end-to-end system for extracting perspectives and evidence for MPCHIS queries from internet. Our early experimental evaluation is promising. We also provide a MPCHIS query data set and plan to share the manual annotated gold standard for our sample data set publicly. Our work is aimed at enabling lay patients to make sense of the multiple perspectives and medical evidence available online, relevant to their complex health information queries.

#### **0146 - Practicing Evidence Based Medicine (EBM): A descriptive analysis of medical student whole-task EBM assignments**

Lauren Maggio<sup>1</sup>, Nicole Capdarest-Arest<sup>2</sup>, Keith Posley<sup>3</sup>

<sup>1</sup>Uniformed Services University of the Health Sciences, Bethesda, MD, USA, <sup>2</sup>Stanford University School of Medicine, Stanford, CA, USA, <sup>3</sup>VA Palo Alto Healthcare System, Palo Alto, CA, USA

**Objectives:** Evidence-based medicine (EBM) training is integrated into medical school curriculum using a variety of modalities. Researchers have suggested whole-task learning activities for medical education and specifically to teach EBM, however, limited description exists of their use in EBM curriculum. This session will describe an EBM assignment and presents analysis of students' efforts to identify knowledge gaps, formulate



questions, locate, appraise and apply information and plan for future use of EBM. Findings are considered in light of current educational approaches and suggestions for EBM training proposed.

**Methods:** At Stanford University, 123 students completed a whole-task EBM assignment in their pediatrics clerkship based on an authentic patient interaction. Students submitted the assignment online capturing their efforts to perform the EBM steps plus a description of the patient scenario and strategies for managing future knowledge needs. Assignments were analyzed using descriptive statistics and qualitative description.

**Results:** Students formulated therapy (n=76), prognosis (n=18) diagnosis (n=15), harm (n=9), etiology (n=2) questions and utilized single (n=58) or multiple information resources (n=57). 95 students indicated found evidence would inform future practice while 16 were skeptical of its conclusivity. Sixty-five learners wanted to share evidence with colleagues; 33 with patients. To meet future knowledge needs learners suggested using a structured approach (n=58), reading more literature (n=22), and creating question logs (n=21).

**Conclusion:** This session provides a glimpse into students' EBM process and demonstrates the feasibility of whole-task activities for EBM training. Findings related to information sharing and learner identification with patients raises questions about current coverage of these topics in EBM curricula and suggests further investigation.

### 0147 - EBM for under 18s?

Sarah Pannell<sup>1,2</sup>

<sup>1</sup>Lingfield Notre Dame School, Lingfield, Surrey, UK, <sup>2</sup>Centre for Evidence Based Medicine, Oxford, UK

**Abstract:** The teaching of evidence based medicine is an important aspect of training new medical practitioners, however, given that only a small proportion of the 18 year olds leaving the education system in the UK will pursue careers in this field, should we be introducing EBM to younger audiences?

EBM themes are gradually being brought in to GCSE (public examinations for 16 year olds in England and Wales) and A Level (for 18 year olds) courses, however teachers would benefit from the support of practicing clinicians and researchers in the development of their own subject knowledge as well as new resources to enhance their teaching.

Hear how the CEBM is starting a new project to support teachers in this field and contribute your own ideas to the future of EBM.

**Objectives:** To develop meaningful resources for teachers and students to enhance knowledge of EBM in under 18s.

**Method:** Working with teacher Dr Sarah Pannell, the CEBM has secured funding for this project which will take place over the 2016/17 academic year.

**Results:** None yet! Hopefully engagement with pupils and teachers in pilot workshops with resources created.

**Conclusions:** None yet! Hopefully meaningful resources developed in collaboration between teachers and EBM practitioners.

### 0150 - Assessment of the Reporting Quality of Randomized Controlled Trials articles in the field of diabetes, determine the usage of these RCTs in medical guidelines

Azadeh Aletaha<sup>1</sup>, Hamidreza BARadaran<sup>2</sup>, Akbar Soltani<sup>1</sup>, Amir Ramezani<sup>2</sup>, Ashkan Majedi<sup>3</sup>, Farzaneh Hematian<sup>3</sup>

<sup>1</sup>Endocrinology&Metabolism Research Institute,EBM Group,Tehran University of Medical Sciences, Tehran, Iran, <sup>2</sup>Iran University of Medical Sciences, Tehran, Iran, <sup>3</sup>Tehran University of Medical Sciences, Tehran, Iran

**Objective:** To determine the quality of randomized controlled clinical trial reports in diabetes research in Iran and their presence in domestic and foreign credible guidelines which can imply whether randomized controlled trial articles in the field of diabetes are of good quality or not with respect to their high level of received citations, quality and credibility.

**Method:** We included RCTs conducted on Diabetes mellitus in Iran. Animal studies, educational, interventions, and non-randomized trials were excluded. This was a bibliographic study examining published journal articles involving RCTs in diabetes research from Iranian authors. A systematic search of ten databases were undertaken from July 2004-2014. We excluded duplicated publications reporting the same groups of participants and intervention. Two independent reviewers identify all eligible articles specifically designed data extraction form. Two reviewers assessed the quality of reporting by CONSORT

2010(Consolidated Standards of Reporting Trials) checklist statement and also evaluate each article with Scientometry tools in 260 valid English diabetes guidelines.

**Result:** Overall, we included 185 RCTs on diabetes mellitus, One hundred and eight five (185) studies were included and appraised. Half of them (55.7%) were published in Iranian journals. Most (89.7%) were parallel RCTs, and being performed on type2 diabetic patients (77.8%). Less than half of the CONSORT items (43.2%) were reported in studies, totally. The reporting of randomization and blinding were poor. A few studies 15.1% mentioned the method of random sequence generation and strategy of allocation concealment. And only 34.8% of trials report how blinding was applied. From 185 articles, twelve articles (10%) are presented in 260 Guidelines.

**Conclusion:** The reporting quality of abstracts of RCTs on Diabetes mellitus still should be improved. After the publication of CONSORT for abstracts guideline, the RCT abstracts reporting quality were improvement to some extent. The presence of RCTs on diabetes mellitus in guidelines was poor. This indicates that RCTs on diabetes mellitus need substantial improvement. In order to present an adequate reporting of the randomized controlled trial results, it is necessary that comprehensive information be given about the study's design, implementation, included groups, method of data analysis and interpretation of the results.

### **0151 - Is another validation of a clinical prediction rule necessary? A demonstration of research wastes using recursive cumulative meta-analyses**

Jong-Wook Ban<sup>1, 2</sup>

<sup>1</sup>University of Oxford, Oxford, UK, <sup>2</sup>Providence Health & Services, Olympia, WA, USA

**Objectives:** Although the number of studies validating clinical prediction rules increased dramatically, they have been unevenly focused on a few prediction rules leaving many prediction rules without any external validation. The objective of this study was to demonstrate research wastes related to conducting many validation studies of a clinical prediction rule.

**Method:** Data from validation studies of Pneumonia Severity Index (PSI) and Alvarado Score included in two published meta-analyses were analyzed. From each validation study, the date of publication, total number of subjects, and number of predicted and observed events were recorded. For each prediction rule, a random-effects cumulative meta-analysis of predictive performance (predicted/observed event ratio) was conducted according to the publication date. Then, the trajectory of previous to current cumulative predictive performance ratio over information step (addition of a new validation study) was graphically assessed. The number of validation studies and participants included in the validation studies were calculated before and after the stability of predictive performance is reached.

**Results:** 30 validation studies of Pneumonia Severity Index (PSI) which contained 26563 participants were analyzed. After the data from the 12th validation study was added to the recursive cumulative meta-analysis, the trajectory of cumulative predictive performance became stable (sustained less than 5% fluctuation). Therefore, 19 (63.3%) validation studies and the data from 17443 (65.7%) participants added little value. 34 studies validating Alvarado Score (9778 participants) were included. The trajectory of cumulative predictive performance became stable after the data from the 7th validation study was added to the recursive cumulative meta-analysis. 24 (80%) validation studies and data from 8066 (82.5%) participants included in these validation had little value. Only 1 validation study updated PSI.

**Conclusion:** Substantial degree of research wastes were demonstrated in the validation of Pneumonia Severity Index and Alvarado Score. Before a validation of a clinical prediction rule is carried out, researchers should carefully consider whether it is truly necessary.

### **0152 - Global collaborative networks on Randomized Control Trials (RCTs) on diabetes mellitus Published in impact factor medical journals between 2004-2014: a social network analysis**

Azadeh Aletaha<sup>1</sup>, Amir Ramezani<sup>2</sup>, Hamidreza Baradaran<sup>2</sup>, Akbar Soltani<sup>1</sup>, Maryam Razmgir<sup>2</sup>, Ashkan Majedi<sup>3</sup>

<sup>1</sup>Endocrinology & Metabolism Research Institute, EBM Group, Tehran University of Medical Sciences, Tehran, Iran, <sup>2</sup>Iran University of Medical Sciences, Tehran, Iran, <sup>3</sup>Tehran University of Medical Sciences, Tehran, Iran

**Objective:** The purpose of this research was to describe and characterize the global collaborative patterns in randomized control trials on diabetes mellitus published in impact factor medical journals between 2004-2014

**Method:** This was a cross-sectional, social network analysis. We searched SCOPUS and ISI journals for relevant randomized control trials (RCTs) in diabetes published between July 2004-2014. We selected 184

articles from 269 articles (including randomized control trials on diabetes mellitus as primary evidence source) published in ISI and SCOPUS journals. Gestational Diabetes Mellitus (GDM), animal studies, studies conducted on education in diabetic patients, and other studies with different designs (non-RCTs, duplicated articles, observational studies, follow up studies, animal studies, in vitro studies, case reports, reviews, systematic reviews, meta analysis, cohort studies, editorial and letters, comments, brief communication, Protocols) were excluded. VOS viewer, Pajak and UCI NET softwares were used to show visualization.

**Result:** Overall, we included 184 RCTs on diabetes mellitus in which 15 authors as highly cited papers in Scopus and ISI, 16 institutions, and 15 countries participated. The greatest number of articles (22%) published in 2013 and the least number of articles was (3.5%) in 2006. The growth of publication was (17.8%) between 2004-2014. 15 countries with the highest publication rates were identified. The greatest number of citation (618) in 2013, followed by 2014 (603) and 2012 (448). 10 top journals had co-citation with each other. 10 top authors in ISI had the greatest publications and citations. In Scopus 15 authors were as highly cited papers. 45 top journals per year had the greatest publication from science space report. In most important keywords over time searched were type 2 diabetes (26) and the least were zinc, vitamin d, diabetes mellitus, type 2 pentoxifylline, glycemic, control triamcinolone, macular malondialdehyde laser photocoagulation and acetamide type ii diabetes (4). From 3901 keywords, 80 extracted for visualization. In co-authorship network, from 628 authors, 157 authors were evaluated. The most prolific countries were Iran and United States.

**Conclusion:** Our analysis identified networks of authors, institutions and countries publishing randomized control trials (RCTs) in ISI and SCOPUS journals. This valuable information may be used to strengthen scientific capacity for collaboration and to help to promote a global agenda for future research of excellence.

### **0153 - The New Cochrane Rapid Reviews Methods Group: Development, Goals and Linkages**

Valerie King<sup>1</sup>, Chantelle Garrity<sup>2</sup>, Gerald Gartlehner<sup>3</sup>, Chris Kamel<sup>4</sup>, Julie Polisena<sup>4</sup>, Adrienne Stevens<sup>2</sup>

<sup>1</sup>Center for Evidence-based Policy, Portland, Oregon, USA, <sup>2</sup>Ottawa Hospital Research Institute, Ottawa, Ontario, Canada, <sup>3</sup>Cochrane Austria, Vienna, Austria, <sup>4</sup>Canadian Agency for Drugs and Technologies in Health, Ottawa, Ontario, Canada

**Background:** Cochrane systematic reviews (SRs) are known for their rigor, but the average Cochrane review takes over 2 years to produce. Ensuring the review process is comprehensive and systematic often results in a research product that does not meet the time and resource needs of some users, notably health policy makers. The international knowledge synthesis community has responded by developing rapid reviews (RRs)--knowledge syntheses more systematic than narrative reviews, but completed within a short timeframe. Policymakers are using RRs in their day-to-day decision-making, and are influential in the development of health policy. At least 29 international organizations conduct RRs, and they have become key building blocks for the development of rapid clinical practice guidelines. Cochrane has recently approved a methods group devoted to rapid reviews, with the aim of defining current RR conduct, increasing empirical understanding of the comparative strengths and limitations of RRs, and establishing RR best practices.

**Methods:** Description of the development of the CMRR Group from 2013 to present, using analysis of key documents and key informant interviews. **Results:** The CMRR Group's primary objectives are to provide guidance on RR conduct, inform the empirical evidence for RR methods, and serve as a forum for discussion. The CMRR Group will develop proposals to study RR methods and contribute toward development of sound methodologies guiding best practices. Core functions of the Group are to provide policy advice to Cochrane, including development of a RR methods chapter for the Cochrane Handbook and coordination with other Cochrane Methods Groups; maintain databases of RR publications and persons with interest in RRs; and to link with other organizations and potential commissioners or end-users of RRs.

**Conclusions:** As part of its effort to link to other organizations, researchers, and end-users of RRs, this session seeks to inform attendees about the development and activities of the CMRR Group. The CMRR Group seeks to establish connections with others who are interested in efforts to streamline evidence synthesis while maintaining rigor, reliability and applicability.

#### **Objectives**

1. To describe the development of the newest Cochrane Methods Group: Cochrane Methods -- Rapid Review (CMRR)
2. To discuss the purpose and function of the CMRR Group
3. To describe and offer opportunities for involvement with the CMRR Group

**Method:** Description of the development of the CMRR Group from 2013 to present, using analysis of key documents and key informant interviews.

**Results:** The CMRR Group's primary objectives are to provide guidance on RR conduct, inform the empirical evidence for RR methods, and serve as a forum for discussion. The CMRR Group will develop proposals to

study RR methods and contribute toward development of sound methodologies guiding best practices. Core functions of the Group are to provide policy advice to Cochrane, including development of a RR methods chapter for the Cochrane Handbook and coordination with other Cochrane Methods Groups; maintain databases of RR publications and persons with interest in RRs; and to link with other organizations and potential commissioners or end-users of RRs.

**Conclusions:** As part of its effort to link to other organizations, researchers, and end-users of RRs, this session seeks to inform attendees about the development and activities of the CMRR Group. The CMRR Group seeks to establish connections with others who are interested in efforts to streamline evidence synthesis while maintaining rigor, reliability and applicability.

#### **0154 - Global cardiovascular risk assessment in the primary prevention of cardiovascular disease: overview of systematic reviews**

Dylan Collins, Alice Tompson, Nia Roberts, Alison Ward, Carl Heneghan

University of Oxford, Oxford, UK

**Background:** Global cardiovascular risk assessment is widely recommended in the primary prevention of cardiovascular disease (CVD).

**Objectives:** We conducted an overview of systematic reviews in order to identify, critically appraise, and summarise the existing evidence on the impact of global CVD risk assessment on important patient outcomes: primarily CVD morbidity and CVD or all-cause mortality, secondarily changes in systolic blood pressure, total or LDL cholesterol, and smoking.

**Methods:** We searched The Cochrane Library, EMBASE, MEDLINE, and CINAHL databases, using an *a priori* strategy without language or location restrictions. Title, abstract, and full text screening, in addition to data extraction and quality assessment, was conducted independently by two reviewers.

**Results:** After screening 5,929 titles and abstracts, we reviewed 143 full text articles, ultimately yielding six systematic reviews for inclusion. These reviews collectively reported 18 unique primary studies relevant to our overview. No primary studies reported data on CVD morbidity or CVD or all-cause mortality, 12 reported changes in systolic blood pressure, 14 on LDL or total cholesterol, and 10 on smoking cessation. The quality of included systematic reviews ranged from AMSTAR ratings of 0/11 to 6/11, and the most recent search performed by an included review was in 2013. Further analyses are currently underway to synthesise the data reported by included systematic reviews.

**Conclusions:** This represents the first ever overview on the impact of global cardiovascular risk assessment in the primary prevention of CVD. The quality of existing systematic review evidence is limited. We are therefore supplementing data from systematic reviews by referring to the primary studies in order to more accurately assess the impact of CVD risk scores on important patient outcomes. Upon completion, we will provide meta-analysed data on the impact of global CVD risk assessment on patients' systolic blood pressure, total or LDL cholesterol, and smoking cessation.

#### **0157 - PICO Framework: Two Decades of Variation and Application**

Farhad Shokraneh

Institute of Mental Health, Nottingham, UK

**Abstract:** Although PICO was supposed to be a mnemonic tool for clear presentation of interventional clinical questions, it became a useful tool in designing study question, developing search strategies, coding indexing and retrieving the studies, search tool, summarizing the research, formulating research recommendations, information therapy (Ix), and guideline development. Also it was an inspiration for similar frameworks such as ECLIPSE, SPIDER and SPICE. History of PICO shows a wide variation of this framework to get adapted for the purpose. Some of the variations are PECO, PICOS, PICOT, and PIPOH. Like any other tool, PICO has its own disadvantages. This review is a systematic effort to document the history of PICO.

**Objectives:** To document the history of PICO framework in past two decades

**Method:** This is a systematic literature review.

**Results:** PICO was suggested for clear presentation of interventional questions but its usage got expanded. Its applications could be listed as follow:

- Designing study question
- Developing search strategies (in systematic reviews)
- Coding/indexing the studies (PICO annotator and study-based registers)
- Retrieving the studies (in TRIPDatabase or PICO interface)
- Summarizing the research (BMJ PICO)
- Formulating research recommendations

- Information therapy (Ix)
- Guideline development

There are tens of variations presented for PICO showing its flexibility to be used as research of clinical PICO. The main disadvantage for PICO is the loosing semantics while converting a natural language question into PICO.

**Conclusions:** PICO is a good example of a simple mnemonic tool that because useful in both research and clinic. Its developments in past two decades have not been celebrated while its story could be an idea for developing similar tools in evidence-based medicine. PICO needs more attention as it becomes more involved in daily EBM practice.

**0158 - COMPare (CEBM Outcome Monitoring Project): Tracking switched outcomes in clinical trials. Authors: Henry Drysdale, Ben Goldacre, Carl Heneghan and the COMPare team**

Henry Drysdale, Ben Goldacre, Carl Heneghan, Aaron Dale, Eirion Slade, Philip Hartley, Ioan Milosevic, Kamal Mahtani

*The Centre for Evidence-Based Medicine, University of Oxford, Oxford, UK*

**Abstract:** Outcome switching in clinical trial reports distorts the evidence doctors and patients use to make clinical decisions. Moving on from prevalence studies of the problem, the CEBM Outcome Monitoring Project (COMPare) aimed to find out which specific trials and journals correctly detect and correct misreported outcomes, and which don't. For 6 weeks, we compared all randomised control trials published in 5 top medical journals with the outcomes pre-specified before trial commencement, in order to detect both missing outcomes, and undeclared novel outcomes. For every trial with discrepancies, we submitted a letter to the journal to correct the record, and posted all raw data and results on our website - COMPare-trials.org. We assessed a total of 67 trials, and found that 58 of them (87%) contain misreported outcomes. Of 58 letters sent to journals, 47 have not been published, and the discrepancies outlined remain uncorrected. We have had a range of responses from the journal editors and trial authors: the BMJ has issued a correction on a trial and changed their policy on pre-specification requirements, while Annals of Internal Medicine has demonstrated a fundamental misunderstanding of the problem and resisted public discussion. We will continue to post ongoing results, and to engage with journals in public discussion on this important problem. In doing so, we hope improve understanding and establish new norms in outcome reporting, and to reduce the prevalence of outcome switching in clinical trials.

**Objectives**

1. Determine the proportion of pre-specified outcomes that are correctly reported in the top 5 general medical journals.
1. Determine the prevalence of undeclared, non-pre-specified outcomes reported in these journals.
1. Submit letters to journals setting out the discrepancies, in order to correct the record, and assess whether these are published at all, and in a timely fashion.
1. Share our results openly to increase awareness of the presence of misreported outcomes in specific trials and journals

**Method:** Each week 5 top medical journals were scanned for randomised control trials. The published outcomes were then compared with those pre-specified prior to trial commencement. We recorded whether each outcome was reported in the main trial publication, whether non-prespecified outcomes were added, and whether any discrepancies were declared. Pre-specification and reporting of outcomes was assessed in line with the CONSORT guidelines. For each trial with discrepancies, a letter was written to the journal outlining the errors. These letters were monitored for publication and posted online if unpublished after 4 weeks, along with full results and raw data for every trial.

**Results:** Of the 67 trials assessed during a 6 week period, 58 (87%) contain misreported outcomes. On average, each trial reported 62% of its pre-specified outcomes, and silently added 5.3 novel outcomes. Of 58 correction letters sent to journals, 6 have been published, 16 have been rejected, and 36 remain unpublished.

The BMJ has published a correction on a trial, and changed its pre-specification requirements for authors. Annals of Internal Medicine has published two of our letters. The Lancet has accepted many of our letters for publication, while both NEJM and JAMA have declined to publish our letters.

**Conclusions:** Our results indicate a high overall prevalence of outcome switching in top journals, consistent with previous prevalence studies. We have also highlighted heterogeneity in the nature and degree of outcome switching. However, our most important results so far have been the responses from journal editors and authors: these have shed light on the underlying misunderstandings that drive misreporting of outcomes in top journals, despite apparent endorsement of best practice and guidelines to the contrary. It is only through challenging these misunderstandings and establishing new norms in outcome reporting that this prevalent and important problem can be solved.

## 0160 - Supporting evidence-informed decision making by CCGs: what difference does access to a responsive evidence briefing service make?

Paul Wilson<sup>1</sup>, Kate Farley<sup>2</sup>, Liz Bickerdike<sup>3</sup>, Alison Booth<sup>3</sup>, Carl Thompson<sup>2</sup>, Mark Lambert<sup>5</sup>, Rhiannon Turner<sup>4</sup>, Ian Watt<sup>3</sup>

<sup>1</sup>University of Manchester, Manchester, UK, <sup>2</sup>University of Leeds, Leeds, UK, <sup>3</sup>University of York, York, UK,

<sup>4</sup>Queens University Belfast, Belfast, UK, <sup>5</sup>Public Health England, Newcastle, UK

**Abstract:** The NHS is facing severe funding constraints both now and in the medium term. In challenging times, NHS commissioners have a duty to use research evidence to ensure that the best value health care interventions and service improvements are adopted and that procedures and practices that have been shown to be ineffective are no longer used. This controlled before and after study evaluated whether access to a demand-led evidence briefing service improved the uptake and use of research evidence by NHS commissioners compared with less intensive and less targeted alternatives.

Over the course of the study the evidence briefing service addressed 24 topics raised by CCGs. The majority of requests dealt with options for delivering and reorganising services and were not directly linked to explicit decisions but were to provide knowledge and awareness of possible options for future actions. Requests dealing with explicit decisions were linked to low value procedures and practices of no or low clinical benefit. At one year follow up we found that the evidence briefing service was not associated with increases in CCG capacity to acquire, assess, adapt and apply research evidence in their decision making. Low response rates and missing data limit the reliability of these findings.

**Objectives:** Does access to a demand-led knowledge translation service improve uptake and use of research evidence by NHS commissioners compared with less intensive and less targeted alternatives?

**Method:** Nine CCGs received one of three interventions to support the use of research evidence in their decision-making.. Data for the primary outcome measure was collected at baseline and 12 months post-intervention, using survey instrument devised to assess an organisations' ability to acquire, assess, adapt and apply research evidence to support decision-making. Documentary evidence of the use of the outputs of the service was sought. A process evaluation evaluated the nature and success of the interactions both within the sites and between commissioners and researchers delivering the service.

**Results:** Over the course of the study the evidence briefing service addressed 24 topics raised by participating CCGs. Most of the requests could be categorised as conceptual; not directly linked to discrete decisions or actions but often to provide knowledge and awareness of possible options for future actions. Opportunities to impact on instrumental decision making processes were limited to explicit disinvestment processes. Overall, the evidence briefing service was not associated with increases in CCG capacity to acquire, assess, adapt and apply research evidence to support decision making. Low response rates and missing data limit the reliability of these findings.

**Conclusions:** Access to a demand-led evidence briefing service did not improve the uptake and use of research evidence by NHS commissioners compared with less intensive and less targeted alternatives. Resource intensive approaches to providing evidence may best be employed to support instrumental decision making.

## 0161 - The librarian will see you now: The role of information professionals in shared decision-making

Caroline De Brún<sup>1,2</sup>

<sup>1</sup>Public Health England, London, UK, <sup>2</sup>Coventry University, Coventry, UK

**Background:** With the 2011 Salzburg statement on shared decision-making, and health systems focusing on patient-centred care, patients are being encouraged to participate in the decisions made about their treatments. However, while clinicians have access to clinical decision support tools, evidence summaries, and professionally-staffed medical libraries, support for evidence-based patient choice, in the UK, is sporadic. Online consumer health information seeking is on the rise, yet the level of quality varies greatly, and searching for appropriate content can be problematic. The primary objective of this study was to identify the gaps in consumer health information provision, both on and off-line, and the information skills of health service users, and propose ways in which librarians can work together across sector to provide support.

**Methods:** A mixed-methods study was performed using quantitative and qualitative surveys and a literature review to identify consumer health information experience and needs.

**Findings:** The evidence and the survey results confirmed that people do want to make decisions with their doctor, and that while they do search for information about clinical conditions they do not always find what they are looking for. In the survey, people said that they would value librarian support and information skills training, but would also find an all-encompassing consumer health information web-site useful.

**Discussion:** The expert patient is beneficial for the patient, the carer, and the health service, because well-

informed patients make better decisions, and are more likely to comply with the treatment regime, resulting in a better experience for them, and reduced costs for health services. It is essential that people have the right information at the right time so that they can make the right decisions for their personal circumstances. Librarians are in a key position to support the general public. Medical librarians have the skills to identify and appraise the evidence, while public librarians provide the setting to reach the relevant population. A collaboration between medical and public librarians would enable the support of patients and carers as they search for and appraise information, which can be used by patients to make evidence-based decisions with their clinicians.

**Objectives:** The objectives of this research were to:

- identify gaps and highlight issues in information service provision for the general public.
- map health information needs of the general public.
- propose solutions to improve access to quality consumer health information.

**Method:** A mixed-methods study was performed using quantitative and qualitative surveys and a literature review to identify consumer health information experience and needs.

**Results:** The majority of people do want to make decisions with their doctor, but while they do search for information about clinical conditions they do not always find what they are looking for. People would value librarian support and information skills training, but would also find an all-encompassing consumer health information web-site useful.

**Conclusions:** Librarians are in a key position to support the general public. A collaboration between medical and public librarians would enable the support of patients and carers as they search for and appraise information, which can be used by patients to make evidence-based decisions with their clinicians.

### **0167 - Using Team Based Learning to teach critical evaluation of research studies and clinical practice guidelines in a third year internal medicine clerkship**

Dan Mayer, Joseph Wayne

*Albany Medical College, Albany, New York, USA*

**Abstract:** We are reporting on an educational exercise designed to improve the ability of third-year medical students to use the most current tool to evaluate the quality of clinical research studies (GRADE) and then use a generally validated tool to evaluate the quality of a clinical guideline (AGREE-II). Students read selected studies (harm, diagnosis and therapy) and used the GRADE tool to evaluate the level of evidence and then read a clinical guideline and evaluated it using the AGREE-II tool. These were taught using Team Based Learning as the primary educational process as outlined by Michaelson and Sweet. Each session started by testing the student knowledge of the studies and basic EBM principles using an individual and group Readiness Assurance Tool (IRAT and GRAT). Following a review of the RAT questions with the entire class, the students answered carefully crafted questions about the use of the GRADE tool to evaluate the validity of each study. These questions were evaluated in the Application Facilitation Exercise (AFE). The AFE during the last two sessions taught the process of reviewing a clinical practice guideline using the AGREE-II tool. The student evaluations of this exercise have been excellent and we have made appropriate modifications to improve the exercise. We will present some of the exercises and discuss the use of Team Based Learning to facilitate the educational process in EBM.

**Objectives:** Following the six EBM sessions during the third year internal medicine clerkship students will have:

1. Improve the ability of third-year medical students to evaluate clinical research and clinical practice guidelines.
2. Learn how to use and demonstrate their ability to use the most current critical appraisal tool (GRADE) to evaluate the quality of clinical research studies
3. Learn how to use and demonstrate their use of a generally validated tool (AGREE-II) to evaluate the quality of a published clinical practice guideline

**Methods:** During the six sessions, students rated the level of evidence for clinical research studies using the GRADE tool (4 sessions) and evaluated the validity of a clinical practice guideline (2 sessions) using the AGREE-II tool. Using the traditional model of Team Based Learning (Michaelson & Sweet), students were tested with individual and group Readiness Assurance Tools to assess baseline learning and then answered questions about the use of the GRADE or AGREE II tool in formed Application Facilitation Exercises using principles of significant problem, same question, specific choice and simultaneous reporting.

**Results:** The IRAT quiz grades were significantly lower than the GRAT grades. The overall evaluations given by the students were very positive, with many of them giving this part of the clerkship a high rating (good or excellent) and stating that their skills in EBM have been improved.

**Conclusions:** Team Based Learning can be successfully applied to teach EBM principles during a third year clinical rotation in Internal Medicine

## 0168 - What do researchers understand when they read the report of a systematic review? A mixed methods study.

Elaine Beller<sup>1</sup>, Fiona Alderdice<sup>2</sup>, Mike Clarke<sup>2</sup>, Paul Glasziou<sup>1</sup>, Toby Lasserson<sup>3</sup>, Olinda Santin<sup>2</sup>, Victoria Simms<sup>4</sup>  
<sup>1</sup>Bond University, Gold Coast, QLD, Australia, <sup>2</sup>Queen's University, Belfast, Northern Ireland, UK, <sup>3</sup>Cochrane Central Editorial Unit, London, UK, <sup>4</sup>Ulster University, Belfast, Northern Ireland, UK

**Background:** Healthcare practitioners should use the findings of systematic reviews in their clinical practice and researchers should do likewise when designing projects, in order to justify new studies. Therefore, academic researchers should readily understand journal reports of systematic reviews. They should be able to make their own conclusions from the data presented, given that authors' conclusions may be biased or influenced by 'spin'.

**Objectives:** To make recommendations about the training of researchers and the structure and writing of future systematic review reports, we assessed how much of a systematic review was understood by early career researchers.

**Methods:** We asked twenty early-career academic researchers in health sciences (up to 5 years post-PhD) to use a 'think aloud' protocol whilst reading a systematic review report. The chosen review was about fibre supplementation in irritable bowel syndrome, with the abstract, discussion and conclusions redacted. Participants were instructed to say what they did or did not understand, in preparation for summarising the results to a hypothetical colleague. Eye-gaze and audio data were captured, using the Tobii X2-60 compact eye tracking system. After the 'think out loud' task, participants completed a questionnaire and brief interview about their experience.

We report here preliminary results of areas of misunderstanding or lack of knowledge, and whether participants correctly interpreted the main result of the review.

**Results:** As they were reading the review, many participants stated they did not understand the following important concepts of systematic reviews methodology: publication bias (55%); I<sup>2</sup> (50%); sensitivity analysis (50%); heterogeneity (35%); forest plots (25%); and allocation concealment (20%).

16 (80%) participants concluded that fibre supplementation was beneficial, in agreement with the review authors, but 20% reached other conclusions. However, none mentioned the size of the effect. 14 (70%) were able to interpret the subgroup analysis (soluble vs insoluble fibre), but only 8 (40%) discussed the quality of the evidence or methodology of the review, and 6 (30%) mentioned harms of the intervention.

**Conclusions:** Early career researchers need more training in the interpretation of systematic reviews, and authors need to better explain the importance and meaning of methodology terminology used in review reports.

## 0172 - Technology identities - why evidence is neither sufficient nor necessary for adopting medical devices

Susan Peirce<sup>1</sup>, Alex Faulkner<sup>2</sup>, Selda Ulucanlar<sup>3</sup>

<sup>1</sup>Cardiff University, Cardiff, Wales, UK, <sup>2</sup>University of Sussex, Brighton, Sussex, UK, <sup>3</sup>Aston University, Birmingham, UK

**Abstract:** There is a concept of technology adoption in healthcare being a linear rational process, progressing from development to evidence generation to adoption to diffusion. This process is generally characterised by barriers and gatekeepers versus EBM and other facilitators. However, this simplistic model does not take into account the complexity of factors and processes influencing such decisions regarding device technologies. The decision to take up (or even pilot) a medical device may have more in common with our everyday choices about consumer goods than the highly regulated processes of pharmaceutical evaluation and national guidance.

We looked at real-world decisions about medical technology adoption in the NHS regarding a range of device types. We discovered that personal experience, service models, the material properties of the device and perceptions of risk can be more influential than published evidence. We saw how adoption processes varied according to the type of technology and were strongly influenced by sociopolitical factors. We identified information sources used in these decisions that were much broader than those used



in traditional Health Technology Assessment. We termed this latter 'evidence for confidence', which includes any piece of information that is part of the decision-making process (whether it is publicly acknowledged or not).

We also defined the concept of 'technology identities' to encompass the different device-related factors that determine whether it is considered desirable or not, and to explain how the same device gets different reactions from different people and organisations.

We will present examples from our study to demonstrate how decisions about the adoption of healthcare devices are much more complex and malleable than are provided for in the usual HTA/EBM paradigm.

**Objectives:** To examine the decision-making processes around the adoption of non-pharmaceutical technologies in the NHS. We aimed to provide insights into the underlying mechanisms of adoption, to contribute to defining 'appropriate' technology adoption, and to produce an analysis that could contribute to developing better decision-making for practice and policy.

**Method:** This was a qualitative study using a multiple technology case-study approach and examining naturally-occurring examples of adoption and non-adoption. We interviewed stakeholders regarding technology awareness, use of evidence/evaluations and the people and processes involved in decision-making. Interviews took place between May 2009 and February 2012 and involved clinicians, managers, commissioners, industry representatives and patient groups as appropriate. Interviews were transcribed and analysed alongside other information sources such as websites, conferences and documents. Analysis was based on principles and processes of constructivist grounded theory and informed by structuration and actor-network theories.

**Results:** The study suggests that while adoption decisions are made within healthcare organisations, they are shaped in an 'adoption space' that transcends organisational and geographic boundaries. Industry, healthcare practices, health technology assessment and policy influences interact to produce 'technology identities.' These encompass different aspects of the technology (novelty, effectiveness, utility, risks, requirements) and are malleable and diverse, even for the same technology. The use of published evidence in these decisions (where available) may be foregrounded, but in actuality are often transcended by other considerations.

**Conclusions:** The policy-rational healthcare perspective prevalent in the adoption of pharmaceuticals emphasises decisions based on high-level published effectiveness evidence. In the realm of device technologies this is seen to be inadequate, given the highly socially-mediated, multi-perspective and contingent nature of adoption. Although evidence levels are often poor, simply conducting and publishing more and better clinical studies will not necessarily result in more rational adoption of medical devices.

### 0173 - How can research become truly evidence-based?

Hans Lund<sup>1, 2</sup>, Klara Brunnhuber<sup>3</sup>

<sup>1</sup>University of Southern Denmark, Odense M, Denmark, <sup>2</sup>Bergen University College, Bergen, Norway, <sup>3</sup>BMJ, London, UK

**Abstract:** To embark on a new study without systematically reviewing evidence of what is already known, particularly when the research involves people or animals, is unethical, unscientific, and wasteful. To act in an evidence-based manner researchers should be able to make best use of a current, high-quality systematic review (SR) relevant to their proposed question. This is not as straightforward as it sounds. The skills to identify, appraise and update an existing SR, or to conduct a new one, are not widespread. Secondly, the time used for preparing an SR (especially for a novice) may be perceived as unnecessarily encroaching upon the time available for 'proper' research activities. On the other hand, it would be highly embarrassing to have to defend a study which might have been shown to be redundant had an SR been conducted. Recognizing that there are "users" and "doers" of SRs might be a helpful first step. Indeed, all researchers should be able to use an SR, i.e. to identify relevant SRs, evaluate their methodological quality and use the information in SRs to ensure that their research is justified based on the available evidence: that the study is optimally designed and conducted; and that findings are presented within the context of existing knowledge. Only a small proportion of researchers, however, need to be 'doers': the ones actively preparing and publishing a new SR. A novel flowchart of evidence-based research (EBR) illustrates these two pathways, and demonstrates how an SR, whether self-conducted or commissioned, can become an essential early part of the routine research process. The resulting new or updated SR of the best available evidence base, if available from the early stages of research, can optimally inform funding, ethical approval and publishing decisions, and thereby help to reduce avoidable research waste and the risk of potential harm to research participants through unnecessary or low-quality trials. In our presentation, we will introduce the concept of and need for EBR, its process as outlined in the EBR flowchart, associated challenges and possible solutions for the research community.

**Objectives:** To introduce the concept of and need for Evidence Based Research (EBR), its process as outlined in the EBR flowchart, associated challenges and possible solutions for the research community

**Method:** Discussion of the evidence base for need of Evidence Based Research (EBR) and an EBR flowchart that includes a current, high-quality systematic review as an essential early part of the research process

**Results:** In order to conduct research in a truly evidence-based manner, researchers should be able to make best use of a current, high-quality systematic review (SR) for their proposed question. All researchers should be able to use an SR, i.e. find relevant SRs, evaluate methodological quality and show that, based on the available evidence, their research is justified: the study is optimally designed and conducted; and findings are presented within the context of existing knowledge. Only a small proportion of researchers, however, need to be 'doers': the ones actively preparing and publishing a new SR.

**Conclusions:** Researchers often lack the time or required skills to identify, appraise and update an existing systematic review (SR), or to conduct a new one. A novel flowchart of evidence-based research (EBR) demonstrates how an SR, whether self-conducted or commissioned, can become an essential early part of the routine research process. If available from the early stages of research, a current, high-quality SR can optimally inform funding, ethical approval and publishing decisions, and thereby help to reduce avoidable research waste and the risk of potential harm to research participants through unnecessary or low-quality trials.

### **0174 - An Overview of Systematic Reviews of Interventions to Reduce Unscheduled Hospital Admissions among Adults**

Niklas Bobrovitz<sup>1,3</sup>, Igho Onakpoya<sup>1,3</sup>, Benjamin Fletcher<sup>1</sup>, Dylan Collins<sup>2,3</sup>, Brittney Scott<sup>1</sup>, Alice Tompson<sup>1,3</sup>, Rebecca Fisher<sup>1</sup>, Joseph Lee<sup>1</sup>, Oliver van Hecke<sup>1</sup>, Sarah Stevens<sup>1</sup>, Brian Nicholson<sup>1</sup>, Jack O'Sullivan<sup>1,3</sup>, Kamal Mahtani<sup>1,3</sup>, Carl Heneghan<sup>1,3</sup>

<sup>1</sup>University of Oxford, Oxford, UK, <sup>2</sup>University of Calgary, Calgary, Canada, <sup>3</sup>Centre for Evidence-Based Medicine, Oxford, UK

**Objectives:** Unscheduled hospital admissions are an increasing burden on health systems worldwide. To date, initiatives to reduce admissions have had limited success as it is unclear which strategies effectively reduce admissions and are supported by a strong evidence-base. Therefore, our objective was to conduct an overview to find, assess, and summarize all published peer-reviewed systematic reviews of randomized controlled trials that examine the effect of a health intervention on unplanned admissions among adults (> 16 years old).

**Methods:** Four databases were searched from inception to February 2016: Ovid MEDLINE, Pubmed, Cochrane Database of Systematic Reviews, and the Cochrane Database of Abstracts of Reviews of Effects. To identify additional relevant articles we searched reference lists of included studies, contacted experts, and searched the publication pages of major health research funders, think tanks, and charities in the UK. We only included reviews that identified unscheduled hospitalisations as a pre-specified outcome. We assessed the quality of included reviews and extracted ratings of the quality of evidence from within each review.

**Results:** Two authors independently screened 10575 abstracts and 1290 full text articles. Ultimately, 505 reviews were included in the study. To date, we have identified several interventions that have been shown to significantly reduce unscheduled admissions including medications, monitoring devices, treatment devices, and self-management strategies. Ultimately, we will create a hierarchical list of interventions based on estimates of absolute admission reductions and the quality of the evidence. We will also compare, contrast, and discuss the interventions with consideration given to other relevant factors including the quality of the reviews, and heterogeneity within reviews.

**Conclusions:** We will produce a list of effective, evidence-based interventions to reduce unscheduled hospitalisations. This list will inform research into the current use of the interventions in practice. The results could be used to guide resource allocation decisions and inform local implementation and optimization of interventions. If the results of this overview are translated into changes in patient care and healthcare practices then patients will benefit from the reduced burden of hospitalization either through improved disease treatment and management or better preventative care.

### **0177 - The Evidence of Effects Page: Refinement of a tool for optimising evidence-based informed treatment decisions In Clinical practice (The EEPIC-1 study)**

Nunan D<sup>1</sup>, Williams V<sup>1</sup>, Mahtani KR<sup>1</sup>

<sup>1</sup>University of Oxford, United Kingdom

**Background:** Patients are increasingly expected to be actively involved in their care. Moreover, making evidence-based decisions with patients to aid healthcare and treatment decisions is well recognised. Few

evidence-based communication tools exist that successfully engage and aid consumer understanding in a format that also facilitates evidence-based clinical decisions.

**Objectives:** To develop a tool that presents the best available evidence for treatment effects that enables both patients and clinicians to make better-informed treatment and healthcare decisions.

**Methods:** Using treatment of hypertension with angiotensin converting enzyme inhibitors (ACEi) as an example, we searched the output of the Cochrane Hypertension Review Group for relevant systematic reviews and found one suitable review. We extracted data into Excel on the mean effect (95% confidence limits (CI)) of 14 ACEi on systolic blood pressure (SBP) only. These data were used to create a modified bar chart. Each ACEi was displayed in descending order according to the certainty of effects based on 95% CI. The modified chart was inserted into a table column with the heading 'Blood pressure effect performance'. Other columns included 'Dose', 'Cost', 'Sample size' and 'Duration'. These columns provide data on the dosage of drug for the observed blood pressure effect, the cost on a daily basis based on the dose, the number of studies and participants for the observed effect and the duration of treatment/follow-up of these studies. Individual sections with the headings 'Technical Information', 'Cost information', 'Dose information', 'Quality information' and 'Usage information' are placed under the table and provide clarification and further details of the information contained therein.

**Results:** We present the methods used to derive the first Evidence of Effects Page (EEP) as a new and effective way to present the evidence for treatment effects and plans to refine the tool.

**Conclusions:** EEPs for treatments of most health conditions can now be refined then their efficacy for improving informed and shared-decisions can be assessed in suitable trials.

## **0178 - Fostering evidence diversity in decision aid design: philosophy and process**

Arlene McCurtin, Jean Ryan, Amanda Clifford, Fiona Murphy, Cathal Walsh  
*University of Limerick, Ireland*

**Introduction:** Increasing attention is being paid to promoting patient's active roles in their own healthcare [Barello et al 2012]. Strategies to better engage patients include the use of decision aids. While there is high-quality evidence that decision aids enhance patient's knowledge regarding options, there is low-quality evidence they improve congruence between chosen options and patient values (Stacey et al 2014). Patients need to be enabled to make decisions using relevant information which includes not just research evidence, but also other types of information such as patient evidence. This study sets out to develop a decision aid for the intervention of bolus modification for post-stroke dysphagic patients which includes a range of evidence.

**Aims:** Develop a decision aid for the specified intervention which broadly reflects evidence-based practice incorporating multiple sources of knowledge.

Gather evidence to populate the decision aid, most specifically, clinical guidelines and research, practice and patient evidence

**Method:** Available evidence from systematic reviews of the research evidence will be retrieved. To plug gaps in other evidence a number of strategies will be employed. A systematic review of clinical guidelines will be performed. Focus groups will be conducted with hospital-based dysphagia therapists to obtain practice evidence. Semi-structured interviews will be carried out with dysphagic individuals who have used the intervention accessed through stroke support groups. Thematic analysis will be used to summarise practice and patient data. The summarised data from each component will populate the decision aid.

**Results:** The results from each strand will be summarised and incorporated into the decision aid.

**Conclusions:** The overall philosophy guiding the decision aid development reflects contemporary interpretations of evidence-based practice and a need to represent multiple forms of knowledge in decision aids in order to help service users make fully informed decisions. The process and outcome are outlined in this presentation.