

### 1. Does Personalised Genetic-Risk Information Impact Decision-Making for Colorectal Cancer Screening? A Systematic Literature Review

Ashley Duenas Katriina Heikkilä, PhD

London School of Hygiene and Tropical Medicine, London, United Kingdom

**Objectives:** The emergence of genetic and genomic testing has led to an era of precision medicine, particularly within developed countries. Predictive genetic testing is a primary prevention method that uses high-susceptibility gene variants to flag certain cancers for rapid intervention, thereby reducing mortality and morbidity. Such tests have potential to help patients make better healthcare decisions. Although predictive genetic testing is available in clinical settings for patients with family history of CRC, it is less clear how results will improve patient screening behaviour.

This systematic literature review aimed to synthesise evidence to assess the impact of personalised genetic risk information on decisions to undergo colorectal cancer screening in asymptomatic adults.

**Method:** MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials, PsychINFO, and ProQuest (Health and Medicine) databases were systematically reviewed. NHS Evidence and Clinical trials.gov websites were also searched, whilst Clinical Genetics, Journal of Genetic Counseling, Medical Decision Making, and Public Health Genomics journals were hand searched for relevant articles. Studies were selected on inclusion/exclusion criteria. Critical appraisal methods were used to critique the quality of eligible studies, followed by a descriptive and narrative synthesis to synthesise evidence.

**Results:** 3,843 studies were screened by title and abstract, followed by full-text screening of 27 potential studies. This review identified 12 studies that addressed the research question and met inclusion/exclusion criteria. Studies were heterogeneous in study design and focused on different population groups that were either high-risk or average risk. Overall, high-risk asymptomatic individuals that received genetic testing and counselling followed CRC screening recommendations after receiving positive test results.

This review identified several gaps related to research design, standardisation of reporting, and public health issues. Secondary exploratory findings from the review identified important patterns regarding the prevention paradox, patient decision-making, doctor-patient relationship, and equity.

**Conclusions:** The enthusiasm for precision medicine has led to the rapid implementation of genetic testing for preventative purposes. It is important to understand the harms and benefits of these tests to improve informed patient decision-making.

Currently, there is limited evidence to support how predictive testing can reduce CRC at the population level. Although there appears to be benefit for a selected high-risk group testing for MMR mutations, it is difficult to advocate for PGT with the quality of measures included in this review.

## 2. Are manufacturers' product claims supported by clinical evidence? An objective systematic evaluation of coronary stent product claims.

Mateusz Panasiuk<sup>1</sup>, Dariusz Iwanow<sup>2</sup>, Karolina Pietryńczak<sup>2</sup>, Katarzyna Grodzka<sup>2</sup>, Mateusz Ollik<sup>2</sup>, Gina D'Agostino<sup>3</sup>, Ray Liu<sup>4</sup>

<sup>1</sup>Owned Outcomes, Las Vegas, USA. <sup>2</sup>Owned Outcomes, Bialystok, Poland. <sup>3</sup>Yale New Haven Health, New Haven, USA. <sup>4</sup>Ediom, Las Vegas, USA

**Objectives:** With new product releases, manufacturers commonly use claims to promote the benefits of their products. In this case study, we take a systematic objective approach to evaluating the validity of these claims for the coronary stent market. By testing the claims found on manufacturers' official websites against the published clinical evidence on each stent reviewed, we take an evidence-based approach to assess whether the claims are, in fact, supported by clinical outcomes. Can manufacturers' claims be trusted in helping clinicians make informed choices on products, or must health systems beware and perform their own evidence-based due-diligence to make the most appropriate product formulary decisions?

**Method:** Coronary stents introduced and approved by the FDA from 2014 to present (January 2018) were identified for analysis. The product claims for each were determined from the respective manufacturers' official websites. These claims were then investigated by researching relevant published papers in medical databases and search engines including PubMed, Google Scholar, ResearchGate, and Cochrane Library. With the support of a machine-assisted tool called EvidenceEngine™, each paper was classified with an Evidence Quality score and Evidence Direction score. The Evidence Quality is determined based on the paper's study design, population size, publication date, peer-review status, and potential for conflict of interest. The Evidence Direction is determined based on a sentiment analysis of the study's conclusion relative to the claim being tested. The overall results are compiled using the Evidence Quality as a weighting factor.

**Results:** Thirty (30) claims were identified for the five (5) coronary stents released between January 2014 and January 2018. The search revealed 67 unique studies relevant to the claims. A potential conflict of interest between the author and the manufacturer (either direct or indirect) was declared in about half of these studies (37). Of the 30 claims, 50% (15) are supported by published evidence, with 26.67% (8) supported by clinical studies and 23.33% (7) by non-clinical studies. For 23.33% (7) of the claims, the evidence actually refutes the claim. For the remaining 26.67% (8) claims, no relevant published data could be identified, with five of these claims being too general or imprecise to be verifiable.

**Conclusions:** The results of the comparative analysis conclude that manufacturers' claims about their products cannot be accepted at face value. An evidence-based approach is necessary to properly evaluate the validity of such claims. In the coronary stent market for new products introduced since 2014, only half of the manufacturers' claims were found to be sufficiently supported by the published evidence. Approximately a quarter of these claims actually are refuted by the clinical evidence. With the use of a systematic approach to evaluating the claims based on evidence, health systems can make more informed and clinically sound decisions regarding medical device utilization.

### **3. Application of virtual reality in health professional education: an evidence synthesis-informed conceptual framework**

Lorraine Tudor Car

Lee Kong Chian School of Medicine, NTU, Singapore, Singapore

**Objectives:** Building on our systematic review and a broader review of the virtual reality (VR) literature, we propose a conceptual framework on different applications of VR for health professional education.

**Method:** VR, a fast-developing technology used in different fields, is increasingly employed in health professional education. In our recent systematic review on VR for health professional education, we encountered various methodological and conceptual challenges. Most importantly, there is a lack of relevant conceptual framework that would capture the diversity of VR applications in healthcare education and inform pertinent research in this area. We address the lack of conceptual clarity around VR usage by exploring how VR is applied in the area of health professional education.

**Results:** Focusing primarily on the type and scope of educational content, we see all VR content as being crudely categorised into VR focusing on space, individuals, objects, structure or their combination. We differentiate macro, meso and micro VR and examine how different VR features and health professional education areas match these three VR types. Macro VR consists of educational resources focusing on environment and human interaction. Meso VR comprises of educational content on the anatomy of the human body. Micro VR includes educational resources on miniscule objects including microscopic anatomical structures, tissues, cells, molecules and atoms. The available literature predominantly focuses on meso VR and anatomy training.

**Conclusions:** There is scope for further exploration on the application of macro and micro VR content, as well as a combination of all three, in health professional education, in particular for development of non-technical competencies in healthcare professionals.

### **4. Using deliberative priority-setting to improve gestational diabetes education**

Rose Yeung, Jamie Boisvenue, Padma Kaul, Edmond Ryan

University of Alberta, Edmonton, Canada

**Objectives:** Gestational diabetes mellitus (GDM) education is an important component of GDM management. While pregnancy is thought to be a generally positive experience for women, those with GDM are asked to manage their pregnancy under constant self-discipline to avoid pregnancy complications from hyperglycemia. For many with GDM, this experience is overwhelming. The guidance provided by a multidisciplinary health care team in delivering gestational diabetes education and acknowledging the emotional impact of a diagnosis has shown to improve self-care behaviors and subsequent birth outcomes. This study aims to explore GDM education and care experiences amongst

women diagnosed with GDM attending publicly provided education classes at diabetes clinics in Edmonton, Alberta, Canada.

**Method:** Deliberative priority-setting was the methodology used as described by the Canadian Institute of Health Research (CIHR) to establish a dialogue throughout six working sessions with 5 women with GDM and 7 diabetes health care providers. Iterative working sessions assessed opinions on educational material provided in classes, feelings and emotions surrounding GDM, and how the healthcare system can improve to better meet their needs. Each session was transcribed and a priority-setting and website assessment surveys were conducted.

**Results:** We identified twelve priorities from the priority-setting survey that women wanted to be addressed beyond the existing GDM classes. These include future impacts of GDM on mother and child, blood glucose number interpretation; insulin administration instruction; GDM pathophysiology; how to manage GDM when basic necessities and support are unavailable; language and culture-specific materials; mental health and emotional management and ensuring consistent communication and messaging from health care providers. The working sessions also revealed that the *www.diabetes-pregnancy.ca* website is a commonly used resource across clinics in this region, however, not all clinicians provided or recommended women visit this site. Through the website assessment survey, women identified inconsistencies within content compared to what was delivered in class and were more interested in having access to site content that focus on patient narrative through text and videos that is relatable to with practical advice that can be applied to daily self-management.

**Conclusions:** A priority-setting partnership between women with GDM, healthcare providers, and researchers allowed for honest dialogue on issues relevant to health care providers and women living with GDM. This identified issues that were not adequately addressed in the existing standard GDM education. Women with GDM and health care providers identified the need for consistent and readily accessible information and determined a priority list of items that they would find most helpful. The use of an online resource that women can access before and after attending a GDM education class may help solidify learning and improve self-care behaviors.

## **5. Do robotic-supported prostatectomies provide superior clinical outcomes over traditional techniques? Application of a novel, quantitative approach for evaluating clinical evidence.**

Michal Rutkowski<sup>1</sup>, Dariusz Jasonek<sup>1</sup>, Agnieszka Kalinowska<sup>1</sup>, Eryk Cekala<sup>1</sup>, Dariusz Iwanow<sup>1</sup>, Gina D'Agostino<sup>2</sup>, Ray Liu<sup>3</sup>

<sup>1</sup>Owned Outcomes, Bialystok, Poland. <sup>2</sup>Yale New Haven Health, New Haven, USA. <sup>3</sup>Ediom, Las Vegas, USA

**Objectives:** Robotic surgeries have the potential to reduce the difficulty of complex laparoscopic procedures by providing more precise dissections, leading to better preservation of functional structures and therefore better outcomes. While a robotic approach is said to be beneficial, its actual performance requires a scientific evidence-based evaluation. In this analysis, we explore all relevant studies comparing robotic-assisted radical and simple prostatectomies (RARP and RASP, respectively) to laparoscopic radical

and simple prostatectomies (LRP and LSP) and traditional open radical and simple prostatectomies (ORP and OSP). The numerous published studies on these comparisons reach conflicting conclusions regarding the benefit of robotic-assisted surgeries. Therefore, it is essential to apply a systematic approach that uses quantified objective measures to evaluate the entire landscape of evidence.

**Method:** A comprehensive literature search of multiple databases was performed for digitally accessible full-text articles and abstracts published between 2011 and 2018. Studies comparing directly robotic-assisted prostatectomies with laparoscopic and/or open surgeries were included. With the support of a tool called EvidenceEngine™, the studies were collected and analyzed based on their directional conclusions and level of merit. This level of merit is quantified into a score based on the factors of study design, population size, potential conflict of interest, publication date and peer review status. An analysis of the clinical outcomes results was then performed considering following head-to-head comparisons: RARP vs. LRP, RARP vs. ORP, RASP vs. LSP and RASP vs. OSP. Their results were then compiled with each study's conclusion weighted by its merit to arrive at an Overall Score (OS) for each head-to-head comparison.

**Results:** The evidence comparing RARP and LRP resulted in an OS of 4.2/10 in support of the robotic technique, with benefits that include functional outcomes (higher urinary continence and potency), lower blood loss and transfusion rate, and shorter length of hospital stay (LOS). In the comparison between RARP and ORP, the OS was 2.7/10 in weak support of the robotic technique, with benefits of lower blood loss and transfusion rates, shorter LOS, and faster recovery of functional outcomes, but longer operation times. In the comparison between RASP and LSP, the OS of 0.1/10 in opposition to the robotic technique reveals that there is no meaningful difference between the two approaches. Finally, the evidence on RASP vs. OSP concluded an OS of 4.0/10 in support of the robotic-assisted approach, with lower transfusion prevalence and shorter LOS, but longer operation times.

**Conclusions:** In the case of radical and simple prostatectomies, the analysis concludes that the robotic-assisted approach for radical prostatectomies can be beneficial over conventional techniques. On the other hand, for simple prostatectomies, the robotic-assisted approach is favorable to OSP but showed no difference in outcomes in comparison to LSP. While robotic-assisted surgeries have numerous potential benefits over traditional approaches, a systematic, quantified evaluation of the evidence surrounding these surgeries may reveal unique insights that are very valuable for health system decision-making.

## 6. Community health: Public libraries and their role in health and well-being

Caroline De Brún

Public Health England, London, United Kingdom

**Objectives:** To make informed decisions, people need to have the skills to find the right information for their needs. Evidence-based practice has been embedded in clinical practice since the early 90s, and there are many resources available to help health professionals make evidence-informed decisions, including clinical databases, point of care tools, journals, and medical librarians to help them retrieve and appraise

the information that they need. The general public does not explicitly have this support. There are specialist websites available, such as NHS Choices, The Information Standard, Patient.co.uk, etc. but the general public may not know how to use them, or may not even be aware of them. This is where public and NHS librarians can help, as they can act as signposts to the information that empowers people to be active participants in their health and well-being.

**Method:** Public Health England, the Society of Chief Librarians, Health Education England, the Chartered Institute for Library and Information Professionals, and the Patient Information Forum, have been working together to build links between NHS and public librarians, so that HIL and access to good quality consumer health information can be improved for the general public. A series of workshops was delivered to public and NHS librarians in England, to inform them about the importance of HIL in health and well-being, the impact of low levels of HIL, good quality, consumer health information sources, and give them the opportunity to identify ways to work together to support people looking for health information.

**Results:** In 2012, The Reading Agency said that “public library staff are second only to doctors in terms of the trust placed in them.” They have an integral part to play in shared decision-making and health information literacy (HIL). They possess the required skills, and are uniquely positioned in the community, to provide information support to the general public, particularly to those people who are harder for health and social care services to reach. People with low health literacy are more likely to experience poorer health outcomes, because they do not understand how to manage their health, and/or may have difficulties navigating the health system.

**Conclusions:** This poster highlights the key evidence behind consumer health information, and describes the consequences of poor health information literacy, the content of the workshops and the partners involved in moving this initiative forward.

## **7. Does testosterone shorten life? Triangulation of a much-debated association**

Robin Haring

Monash University, School of Public Health and Preventive Medicine, Melbourne, Australia

**Objectives:** Conflicting data about the association between testosterone (T) and mortality risk in men has fuelled intense public controversy, including regulatory actions. Given the lack of definite evidence, the integration of results from several different methodological approaches might strengthen the conclusions about the potential causal influence of T on male mortality risk.

**Method:** The present triangulation approach was constructed in accordance with suggested criteria for triangulation in aetiological epidemiology, including: (1) the comparison of results from two or more different approaches, (2) addressing the same underlying causal question, (3) with key sources of bias and their expected direction explicitly acknowledged.

Individual knowledge of literature was combined with a PubMed search to identify relevant studies. Risk estimates from four different methodological approaches addressing the association between T and

mortality were integrated: (1) the largest prospective cohort study, (2) meta-analyses of prospective cohort studies, (3) genetic Mendelian randomization (MR), and (4) meta-analyses of RCTs. Based on the expected direction of potential bias sources, stronger effects in the prospective cohort study and their meta-analyses (residual confounding likely), compared to the MR approach and meta-analyses of RCTs (major bias unlikely) were anticipated.

**Results:** Observational evidence from the largest cohort study (N = 2,639), as well as the meta-analysis of 11 cohort studies (N=16,184) suggests an inverse association between exogenous T and mortality (hazard ratio: 1.65, 95% confidence interval (95% CI): 1.29 – 2.12) and relative risk (RR): 1.35, 95% CI: 1.13 – 1.62, respectively). Mendelian randomization analysis reported a non-significant association between T and mortality (RR: 1.23, 95% CI: 0.40 – 3.82). Finally, the meta-analysis of 20 RCTs showed no association between endogenous T and mortality in men (odds ratio: 0.88, 95% CI: 0.55 – 1.42). Plotting the different risk estimates against their potential risk of bias yielded a graded decrease in magnitude of effect and significance level (Figure 1).

Varying durations of exposure across the different approaches, ranging from weeks (RCT), to years (cohort studies) and lifetime exposure (MR), are suspected to explain the differences in magnitude of effect only to a small degree.

**Conclusions:** Integrating evidence from four different methodological approaches, the present triangulation provides little support for a causal association between T and mortality risk in men. As the triangulation approach provides a qualitative assessment of the strength of evidence, further quantitative research would strengthen this conclusion and establish stronger evidence.

## 8. Cochrane Rehabilitation E-Book: a knowledge translation project in rehabilitation

Chiara Arienti<sup>1</sup>, Francesca Gimigliano<sup>2</sup>, Carlotte Kiekens<sup>3</sup>, Stefano Negrini<sup>4</sup>

<sup>1</sup>IRCCS Don Gnocchi Foundation, Milan, Italy. <sup>2</sup>Department of Mental and Physical Health and Preventive Medicine, University of Campania "Luigi Vanvitelli", Napoli, Italy. <sup>3</sup>Physical & Rehabilitation Medicine, University Hospitals Leuven, Leuven, Belgium. <sup>4</sup>Clinical and Experimental Sciences Department, University of Brescia, Brescia, Italy

**Objectives:** Knowledge Translation (KT) is a dynamic and interactive process that includes the synthesis and dissemination of knowledge to improve health, the first task of Cochrane Fields.

Evidence is considered scarce in the world of Rehabilitation and this has a great impact at political, organizational and consumer levels. The main European stakeholders of Physical and Rehabilitation Medicine (PRM), the medical specialty dealing with rehabilitation, called European PRM Bodies, started an effort that gave rise to Cochrane Rehabilitation with the scope to improve evidence production and related KT in this area.

Cochrane Rehabilitation, in collaboration with the European PRM Bodies, has recently decided to engage in the production of an e-book including all relevant Cochrane Systematic Reviews (CSR) in order to facilitate the dissemination of evidence to all the different audiences described in the Cochrane KT

Strategy.

The aim of this work is to describe this KT effort.

**Method:** An editorial group has been set up. To offer a systematic and comprehensible reading, the e-book will have an index and each CSR would be related to one or more indexed topics. Each CSR will be presented with the original abstracts and plain language summary, plus 4 different summaries directed to convey the evidence to 4 different audiences (clinicians, students, policy makers and consumers). The e-book summaries will be initially produced by trainees in PRM of an Italian University and revised by the e-book editors, to be finally approved and released by the European PRM Bodies.

**Results:** A first draft of the e-book was created, which will have to be approved by the European Bodies. A pilot was performed and guidelines to facilitate the summaries production were defined. The clinical summary is meant for all clinicians and health professionals and should highlight the main results of the CSR. The educational summary is meant for medical or other health professional students, reinforcing all basic concepts. The political summary is addressed to policy decision makers and rehabilitation administrators; the text should be very concise and simple to understand. The consumer summary is meant for patients and caregivers and should be written in a clear and simple language as to explain to a patient his/her clinical condition and possible treatments.

**Conclusions:** The e-book project is an important part of the Cochrane Rehabilitation KT Strategy as it would be a useful product to: 1. inform all rehabilitation health professionals on existing evidence; 2. educate students to achieve updated knowledge and learn how to select the best sources of scientific information, learning from the actual best evidence; 3. support political actions toward policymakers, consumers and other stakeholders to effectively organize service delivery, allocate resources, and allow persons experiencing disability to benefit from the best available rehabilitation interventions; and 4. identify unmet needs of evidence synthesis and prioritize Cochrane future work.

## **9. Living FRiendly Summary of the Body of Evidence using Epistemonikos (FRISBEEs) in *Medwave* – a Chilean experience of summarizing the existing body of evidence on a specific clinical question**

Vivienne C Bachelet<sup>1</sup>, Gabriel Rada<sup>2</sup>

<sup>1</sup>Medwave; Facultad de Ciencias Médicas, Universidad de Santiago de Chile, Santiago, Chile. <sup>2</sup>Proyecto Epistemonikos; Facultad de Medicina, Pontificia Universidad Católica de Chile, Santiago, Chile

**Objectives:** To communicate the experience of a partnership between Epistemonikos, a collaborative database of health evidence that contains the largest source of systematic reviews relevant for decision-making, and *Medwave*, an international peer-reviewed general medical journal that publishes in Spanish and English, in the development and dissemination of a new evidence format that balances methodological rigor and much shorter output times than those needed for most existing evidence summaries and, more importantly, that keeps them up to date.



**Method:** The Epistemonikos database is used to develop the evidence summaries. Epistemonikos is a maintained through evidence searches on 30 databases and is continuously updated with the help of increasingly sophisticated software and the contribution of over 600 collaborators world-wide, which now contains more than 200,000 systematic reviews. Based on a focused clinical question, authors select the body of evidence by creating an online evidence matrix that is then meta-analyzed using the included primary studies. A summary of findings table using the GRADE method is also reported. Subsequently, the summary is drafted, peer-reviewed and published in *Medwave*. Already published reviews can be updated when new evidence appears. The articles are version-controlled in MEDLINE. *Medwave* is the editorial dissemination arm of these rapid evidence summaries because of short editorial times, technical editing, bibliographical reference standardization, bilingual publication (Spanish, English), open access, and a carefully designed and responsive website.

**Results:** The partnership began in 2014, when the first evidence summary using the Epistemonikos database was published in *Medwave*. Since then and to date, 144 FRISBEEs have been published, including several updates. A thematic collection of 14 articles is being published on the effectiveness of cannabinoid use in different medical conditions. Authors include last-year medical students from several Chilean universities who engage and learn with an evidence-based approach to clinical decision making as well as becoming familiarized with GRADE early on in their career training. Methodologically supported by the Epistemonikos team, the clinical study groups include over 100 novel researchers and clinical experts.

**Conclusions:** Collaboration between Epistemonikos and *Medwave* has been enduring, productive and mutually rewarding. Formulating a clinical question, quickly finding the body of the evidence of systematic reviews with their included primary studies, and critically appraising the evidence with the GRADE approach, leads to an in-depth engagement with evidence-based medicine. The drafting, submitting and peer-reviewing of the resulting manuscripts, contributes to a comprehensive learning experience for medical students and senior clinicians, as well as helping to disseminate the results to a broad and international audience.

## 10. The HIFA LIS Project: Exploring the role of libraries in times of crisis

Caroline De Brún<sup>1</sup>, Neil Pakenham-Walsh<sup>2</sup>

<sup>1</sup>Public Health England, London, United Kingdom. <sup>2</sup>Global Healthcare Information Network, Oxford, United Kingdom

**Objectives:** HIFA (Healthcare Information For All - [www.hifa.org/](http://www.hifa.org/)) is a global health movement working in collaboration with more than 300 other health and development organisations worldwide, to ensure every person has access to the information they need to protect their own health and the health of others. There are more than 17,000 HIFA members, including health workers, librarians, publishers, researchers, and policymakers.

In March 2017, HIFA joined forces with Public Health England and Evidence Aid to launch a project on the role of Library and Information Services (LIS) in times of crisis. The aim was to leverage the individual and collective HIFA membership to support communication, understanding and advocacy for library and

information services as they relate to global public health and evidence-informed decision making by health professionals, citizens, and policymakers. The project's focus is global health, population health, and preparedness for and response to emergency situations.

**Method:** To help achieve this, an evidence briefing and thematic discussions were carried out, and this poster summarises the findings from these outputs.

The literature review generated a preliminary evidence briefing (EB), which focused on emergencies and disasters, both natural and man-made (tsunamis, storms, floods, earthquakes, off-shore oil drilling, wars, civil unrest, terrorism, disease outbreaks, etc.).

To build on the EB, a thematic discussion took place on the HIFA Forum, between 17<sup>th</sup> July and 18<sup>th</sup> August 2017. Having looked at the published evidence, the purpose of the discussion was to find out more about librarian activity in areas of crisis and disaster.

In October 2017, a second thematic discussion was held, bringing together humanitarians and library and information professionals, looking at ways to improve the quality, usefulness, availability and use of healthcare information for humanitarian action.

**Results:** Sixty-eight papers were included in the EB, and organised into five categories: access to information; knowledge management; existing programmes/resources; roles of libraries, librarians, and knowledge brokers; and social media. The findings showed that library and information centres have a very important role to play in terms of providing support during, and after disasters. They provide a safe place for rescued citizens, and also support disaster teams, providing them with the best evidence to inform decision-making, and acting as knowledge brokers to ensure relevant knowledge and information is shared effectively. Libraries can demonstrate their position as a primary and valuable source of trustworthy information and support, by providing quick and easy access to those looking for reliable information in times of crisis.

**Conclusions:** The thematic discussions concurred with the evidence in the briefing, demonstrating that libraries and librarians have a very important role to play in terms of providing support during, and after disasters.

## **11. The basis of evidence-informed policymaking: communicating the potential impacts of policies**

Cameron Brick<sup>1</sup>, [Alexandra Freeman](#)<sup>1</sup>, Steven Wooding<sup>2</sup>, William Skylark<sup>1</sup>, Theresa Marteau<sup>3</sup>, David Spiegelhalter<sup>1</sup>

<sup>1</sup>The Winton Centre for Risk & Evidence Communication, University of Cambridge, Cambridge, United Kingdom. <sup>2</sup>the Centre for Science & Policy, University of Cambridge, Cambridge, United Kingdom.

<sup>3</sup>Behaviour & Health Research Unit, Cambridge, United Kingdom

**Objectives:** We call for a new research area on the effective communication of policy options to support evidence-informed policy making.

It is critical to communicate the evidence of potential impacts of different policy options in such a way

that individuals can understand them, and then apply their own values and goals in their policy decisions. There has been much research done on how to convey numbers and evidence for individual decisions about, for example, health or finances. In recent decades, communications providing options for individuals have increasingly moved towards showing both potential harms and benefits of options, using principles of clear communication that have been tested empirically.

We set out to review communications around policy options - whether by governments, businesses or NGOs - to see whether the same principles were being, or could be, applied.

**Method:** We carried out reviews of existing policy option communications from a wide range of domains and sources, of current guidelines for evidence summaries (such as governmental guidelines, and from organisations such as Cochrane), and of empirical studies of effectiveness of such communications in aiding comprehension.

**Results:** We identified very little empirical evidence on how policy options are best communicated. However, we did identify some key challenges that we believe makes policy-level communication more complex than individual-level communication:

- Policies usually have heterogeneous effects across a population which a decision-maker will need to bear in mind (there are winners and losers). The need to display these differential effects in such a way to allow comparison adds complexity
- Policy outcomes are often measured across many different domains (eg. health, environmental, financial), each with different metrics
- Policies often have effects over long time periods, and these effects may be variable.
- The evidence for potential policy impacts often has very large uncertainties around it

Although all of these apply to individual-level communication too, we believe that policy-level communication suffers even more greatly, and there is a bigger trade-off to be made between making communications comprehensive and comprehensible.

**Conclusions:** In our review we identified examples of formats attempting to summarise policy-level evidence in an 'at a glance' summary. However, none of them appear to have been empirically tested on their target audiences. Equally, few organisational guidelines on how to present this kind of evidence cite any empirical research.

We suggest that the field of policy-level communication is recognised as having a distinct set of challenges. We also suggest that empirical studies are called for in order to identify which lessons from individual-level communication research can be carried over, and how the specific challenges of policy-level communication are best met.

## **12. Wikipedia culture and usage: A survey of first year medical students to determine barriers and facilitators**

Melanie Walker<sup>1</sup>, Heather Murray<sup>1</sup>, Jennifer Dawson<sup>2</sup>, Lauren Maggio<sup>3</sup>

<sup>1</sup>Queen's University, Kingston, Canada. <sup>2</sup>University of Ottawa, Ottawa, Canada. <sup>3</sup>Uniformed Services University of the Health Sciences, Bethesda, USA

**Objectives:** Wikipedia is the sixth most trafficked website globally and used heavily by individuals seeking health information. For example, Wikipedia's pneumonia entry is, on average, viewed daily over 10,000 times. Unsurprisingly, researchers have identified medical students among Wikipedia users. Medical students are trained to practice evidence-based medicine (EBM) that requires accessing and critically appraising information from a variety of sources. While researchers have investigated use of information resources (e.g., MEDLINE, UpToDate, BMJ Best Practice) as evidence dissemination tools, there is limited information in relation to Wikipedia. This project examined medical student perceptions of Wikipedia use by medical practitioners and the public, and in ongoing student training.

**Method:** In Fall 2017, 101 first-year medical students at Queen's University, Canada participated in a longitudinal project to learn how to contribute to a medical page in Wikipedia. This was part of their critical appraisal, research and lifelong learning course which is a mandatory component of the students' EBM training. Based on their engagement with Wikipedia pages and the Wikipedia community, the students were required to complete a survey at project end that sought their feedback on: (1) whether and how the project changed their opinion of Wikipedia as a medical resource for the public; (2) their views on Wikipedia as a resource for medical practitioners, and (3) their prediction on future Wikipedia usage going forward in medical school or as a resident. Two members of the research team who were not involved in marking student assessments reviewed survey responses and, using thematic analysis, identified salient themes.

**Results:** Students recognized Wikipedia as a useful health information resource for the public. Students also described an increased appreciation of the Wikipedia editing and citation process and assurance with the oversight and engagement provided by the Wikipedia community. Conversely, perceived barriers to recommending Wikipedia to the public included concerns about Wikipedia editors' lack of content expertise, unreliability of information and outdated information compared with other evidence-based resources. With respect to their opinion of Wikipedia as a resource for medical practitioners, student opinions were more divided with concerns raised regarding the depth, comprehensiveness and reliability/accuracy of information provided compared to other resources. However, despite these reservations, the large majority of respondents indicated they will use Wikipedia going forward in medical school and as a resident. Students attributed Wikipedia's utility to its' ease of access, usefulness as a 'refresher' on background information and its use as a springboard to more evidence-based resources.

**Conclusions:** Medical students reported appreciation for Wikipedia as a useful health information resource given their enhanced understanding of the editing and oversight processes. Students cited Wikipedia as a resource they would recommend to the public and that they will continue to use owing to its ease and speed of access to background information on health topics. Concerns about reliability, accuracy and currency of information were barriers identified in recommending Wikipedia to medical practitioners. There is an opportunity for medical schools and educators to develop a health advocacy partnership with the Wikipedia community to improve evidence-based content.

### 13. Key Concepts for Assessing Treatment Claims: A Blog Series by Students 4 Best Evidence

Emma Carter, Selena Ryan-Vig

Students 4 Best Evidence, Oxford, United Kingdom

**Objectives:** Students 4 Best Evidence (S4BE) objectives were: to raise awareness of key concepts designed to help people assess claims about the effects of treatments; to encourage students to write blogs, providing an alternative platform for learning; and to promote critical thinking and discussion of the numerous treatment claims seen and heard every day.

In 2013, an Informed Health Choices (IHC) project team published a list of 33 'Key Concepts'. The list was designed to be a starting point from which teachers and other intermediaries could develop resources to help people understand and apply the concepts. It is a 'living' document, subject to yearly review, which as at September 2017 lists 36 concepts.

The overall aim was to produce a key resource which sought to help in the understanding and dissemination of these concepts.

**Method:** We invited the S4BE community (via our monthly newsletter, social media and whilst on student electives at Cochrane UK) to write an explanatory blog on one of the 36 'Key Concepts'. Bloggers were encouraged to use 2 key sources for researching content for their blog: Testing Treatments interactive (TTi) which provides explanatory and illustrative resources linked to each key concept and the James Lind Library.

Each of the blogs were then reviewed by Iain Chalmers of TTI, who provided support and feedback, assisting us in producing 'quality assured' blogs. Short videos explaining the concept were embedded into the blog, together with clear signposting to further learning resources.

The blogs were published on the Students 4 Best Evidence (S4BE) website, promoted amongst our partners, highlighted in our monthly newsletter and disseminated via social media.

**Results:** 19 students have written a total of 36 blogs, explaining each of the key concepts. As at 28 February 2018, 25 of these blogs have been published on the S4BE website, with a combined total of 62,635 views. Further information relating to the reach and commentary on social media platforms will be published in the final poster.

An unanticipated result of this project was the engagement of several organizations wanting to translate the blogs and/or short videos. Translation into Portuguese, Spanish and German has all begun, with further enquiries from Croatian and Dutch groups.

**Conclusions:** The remaining 11 blogs are due to be published prior to Evidence Live 2018, at which time further analysis will be carried out of the reach of the blogs/videos. The unintended result of generating interest in countries outside of the UK has been an encouraging development.

Further discussion about disseminating the full series will be key to its continued reach, as well as ensuring the blogs are updated as the 'living' document is revised.

## 14. Assessment of methodological quality of animal and human studies of a blockbuster immunotherapy drug Ipilimumab: a systematic review

Lindsay Bock, Frost Mackenzi, Andrew Lai, Samantha Slattery, Srinivas Bharadwaj, [Rahul Mhaskar](#)

University of South Florida, Tampa, USA

**Objectives:** Up to 85% of biomedical research investment is lost and majority of the waste can be attributed to inadequate study methodology. The lack reproducibility of studies especially animal studies is worrisome and may add to research waste. Ipilimumab is a human monoclonal antibody that targets cytotoxic T-lymphocyte antigen-4 (CTLA-4) to promote T-cell mediated anti-tumor responses. It was approved for the treatment of metastatic melanoma by the Food and Drug Administration (FDA) and European Medicines Agency (EMA) in 2011. Many studies have evaluated the safety and efficacy of Ipilimumab in the treatment of melanoma and other cancers. Optimally, the implicit quality of these studies would ensure patient safety, enhance the soundness of clinical knowledge and practice, and reduce research waste. In this systematic review, we evaluated the methodological quality of animal and human trials investigating efficacy or toxicity of a successful immunotherapeutic drug: Ipilimumab.

**Method:** All randomized clinical trials studies investigating Ipilimumab/anti-CTLA4 in human or animal models of any cancer type with primary outcomes of efficacy or safety were included. A comprehensive literature search first via PubMed, EMBASE, and the CENTRAL databases and then using snow ball strategy was conducted. No time or language limits were used. The methodological quality of human studies was investigated using the Cochrane Risk of Bias assessment and methodological quality of animal studies was assessed employing the ARRIVE guidelines. Each domain in the ARRIVE guideline was also categorized as high versus low versus unclear risk of bias.

**Results:** 29 studies (15 animal and 14 human) were included. Among animal studies categories that exhibited high risk of bias due to lack of reporting were: baseline data (15/15), description of methods of allocating animals to experimental groups and order in which the animals in the different experimental groups were treated (12/15), and description of adverse events and resulting modifications to protocol (11/15). Categories with unclear risk of bias were: experimental procedures (15/15), experimental animals (details of the animals used, including species, strain, sex, developmental stage and weight), study design (13/15) each, outcomes and estimation; study title (11/15) each, abstract, background (9/15) each, and objectives (8/15). In human studies categories with high risk of bias were: incomplete outcome data (4/14) and other sources of biases (3/14). Categories with unclear risk of bias were: random sequence generation (10/14), allocation concealment, blinding of participants and personnel, and blinding of outcome assessment (9/14) each.

**Conclusions:** Our study clearly highlights low to poor methodological quality of both animal and human studies used in investigating efficacy and safety of blockbuster drug Ipilimumab, including those studies used in FDA and EMA approval processes. The observed low/poor quality may lead to research waste and can be avoided in part by modest and reasonable methodological adjustments during study design phase. Clear, comprehensive reporting especially of animal studies could decrease waste of research and foster evidence-based clinical practice including replication of experiments leading to robust evidence base.

## 15. Barriers and facilitators to successful hospital mergers: a systematic review

Martin Keane, Louise Farragher

Health Research Board, Dublin, Ireland

**Primary objective:** What are the barriers to and facilitators of, the successful implementation of hospital mergers reported in the research literature?

### **Secondary objectives:**

1. How are successful mergers between hospitals defined and evaluated in the research literature?
2. What are the barriers to, and facilitators of, implementing hospital mergers reported in the research literature?
3. Are there particular interventions reported in the literature that facilitate a hospital merger?
4. What is the quality of the available research to inform success in hospital mergers?

**Method:** We undertook a search of Medline and CINAHL from January 1996 to February 2015. We also undertook reference chasing from identified relevant literature. We included 31 quantitative studies and 18 qualitative studies. We undertook a thematic synthesis of the qualitative data using line by line coding, developing descriptive and analytical themes. We undertook a narrative synthesis of the quantitative data. Finally, we integrated both the qualitative and quantitative data to develop a set of overarching themes. We undertook a quality appraisal of all the included studies.

**Results:** Hospital staff involved in mergers experienced a sense of loss for their former institution, an erosion of professional status and loss of autonomy, high levels of stress due to job insecurity, job pressure or work overload and lack of role clarity. Staff expressed a wish for involvement, empowerment and participation during the merger process.

The implementation of hospital mergers is *hindered* when hospital staff are excluded from active participation and dialogue, are distanced from decision-making relating to the merger, when the emotional and professional pressures on hospital staff threaten their professional identity and when parties to the merger fail to bridge the cultural divide.

The implementation of hospital mergers are *facilitated* when there is participatory dialogue between hospital staff and senior management, when senior management are less remote from hospital staff and when the primacy of patient care is emphasised and hospital staff can reclaim their professional caregiver status.

**Conclusions:** Our overall conclusion suggests the distance between senior management and hospital staff is a greater threat to a hospital merger than cultural differences between merging institutions. This distance is characterised by minimal dialogue between senior management and hospital staff and little opportunity for staff to influence decisions pertaining to their role or their responsibility for patient care. At best, hospital staff is afforded degrees of partial participation, which excludes them from influencing

decisions. Hospital staff feels disrespected and not trusted by senior management which heightens their anxiety and uncertainty about their role in the merger and threatens their professional autonomy.

## **16. Early detection of bowel problems in the community**

Dr Ramakrishnagupta Mudalagiri

Shotton Medical Practice, Peterlee, United Kingdom

**Objectives:** Early detection of bowel problems in the community.

**Method:** Requested the patients to record early morning temperature continuously for 7 days as soon as they woke up from sleep in morning. If the temperature below normal 37.4 degrees C these patients were found to have GastroIntestinal disorders or going to develop gastrointestinal disorders

**Results:** About 50 patients were requested to record the early morning temperature for 7 days. 50% of them were found to have a low temperature.

All those were found to have bowel dysfunction, constipation, and not able to open bowel every day. Some developed colitis, ulcerative colitis, and one developed cancer bowel.

**Conclusions:** It is possible to predict the Bowel problems in the community by recording early morning temperatures for 7 days and if the temperature is low or very low those patients could be investigated further for Bowel problems.

## **17. Implementation: the missing link in the stroke rehabilitation research pipeline**

Louise Connell<sup>1</sup>, Brigit Chesworth<sup>1</sup>, Elizabeth Lynch<sup>2</sup>

<sup>1</sup>University of Central Lancashire, Preston, United Kingdom. <sup>2</sup>Florey Institute of Neuroscience and Mental Health, Melbourne, Australia

**Objectives:** Despite the exponential growth in the evidence base for stroke rehabilitation, there is still a paucity of knowledge about how to consistently and sustainably deliver evidence-based stroke rehabilitation therapies in clinical practice. This means that people with stroke will not consistently benefit from research breakthroughs, simply because clinicians do not always have the skills, authority, knowledge or resources to be able to translate the findings from a research trial and apply these in clinical practice.

The objective of this review was to establish the amount of available evidence within leading stroke rehabilitation journals to guide the translation of evidence to practice.

**Method:** Leading journals within stroke rehabilitation were pragmatically identified by reviewing the 15 highest impact journals listed in the Thomson Reuters 2015 Journal Citation Reports in the Rehabilitation category, as well as the specialty journals Stroke and Lancet Neurology. Journals were included if they



published articles pertaining to clinical care or rehabilitation for people with stroke.

All research articles were independently reviewed by two reviewers to determine the type of clinical stroke research that was published in 2016.

Articles were excluded if the participants were not humans with stroke, if the studies were undertaken post-mortem, or if the research was investigating solely pharmacological or surgical interventions.

Included articles were categorised according to the Knowledge to Action framework as: 'Knowledge Inquiry', 'Knowledge Synthesis' and 'Implementation and Evaluation', plus an additional category of 'Non-intervention studies'.

**Results:** Eight journals were included in our final review, with 1047 research articles published between January and December 2016. 763 of these articles were excluded.

The included 284 articles were categorised as follows: 185 non-intervention studies (65.1% of included studies), 70 knowledge inquiry studies (24.6%), 22 knowledge syntheses (7.7%) and 7 implementation or evaluation studies (2.5%).

Of the seven articles which presented implementation or evaluation of non-pharmacological, non-surgical management after stroke, three presented findings regarding delivery of rehabilitation services, whereas the remaining four articles presented findings regarding quality of care in the acute post-stroke period. One rehabilitation study evaluated the real world implementation of early supported discharge, and the other two rehabilitation studies examined physical therapists' self-reported adherence with recommendations from clinical guidelines (electrical stimulation and provision of education about community-based exercise).

**Conclusions:** This review highlights in a striking fashion the lack of focus within the academic community on the implementation of evidence-based interventions within stroke rehabilitation practice, with less than 3% of stroke rehabilitation research published in the leading stroke rehabilitation journals addressing implementation or evaluation. Given the ongoing need for rehabilitation after stroke, it is imperative that a greater focus on implementation is shown by researchers, publishers, funders and professional bodies in order for people with stroke to benefit from the best possible evidence-based care.

## **18. Trials and tribulations of establishing treatment effectiveness in addiction research**

Brittany Dennis<sup>1</sup>, Monica Bawor<sup>2</sup>, Leen Naji<sup>3</sup>, Ashley Boner<sup>3</sup>, Pavel Roshanov<sup>3</sup>, James Paul<sup>3</sup>, Andrew Worster<sup>3</sup>, David C Marsh<sup>4</sup>, Michael Varenbut<sup>5</sup>, Jeff Daiter<sup>5</sup>, Carolyn Plater<sup>5</sup>, Dipika Desai<sup>3</sup>, Guillaume Pare<sup>3</sup>, Lehana Thabane<sup>3</sup>, Zainab Samaan<sup>3</sup>

<sup>1</sup>St. George's University of London, London, Canada. <sup>2</sup>St. George's University of London, London, United Kingdom. <sup>3</sup>McMaster University, Hamilton, Canada. <sup>4</sup>Northern Ontario School of Medicine, Sudbury, Canada. <sup>5</sup>Canadian Addiction Treatment Centres, Richmond Hill, Canada

**Objectives:** Without treatment opioid addiction can incur a substantial increase in mortality and risk for serious comorbidities such as HIV and hepatitis. Opioid substitution and antagonistic therapies (OSATs) are front-line treatments for opioid addiction. The emergence of multiple OSATs renders traditional meta-

analysis of direct evidence from randomized trials inadequate to provide hierarchical estimates of the best available treatment. Utilizing systematic review methods, we provide the first multiple treatments comparison and network meta-analysis to combine evidence from all trials examining OSAT with the aim of distinguishing the most effective treatments for opioid addiction.

Our secondary aims were to assess the quality of the evidence as well as examine how this evidence is incorporated into clinical practice guidelines.

**Method:** We searched nine databases from inception to January 1, 2014 to identify randomized controlled trials assessing the effectiveness OSATs for opioid addiction. The primary outcome was treatment retention. We also evaluated the eligibility criteria used across trials. To quantify the effect of trials' eligibility criteria on generalizability, we applied these criteria to data from an observational study of opioid-dependent patients (n=298). We then accessed the Canadian, American, and British OSAT guidelines to evaluate how evidence is used in the recommendations.

**Results:** We identified 60 trials eligible for inclusion and among those, 28 trials testing 16 interventions in a total of 3342 participants were included in the network meta-analysis assessing treatment retention. In comparison to all other OSATs, heroin consistently ranked highest for increasing the odds of remaining in treatment. A representative number of trials exclude patients with psychiatric (60%, k=36) and physical comorbidity (51.7%, k=31), current alcohol/substance-use problems (31.7%, k=19), or patients taking psychotropic medications (48.3%, k=29). These criteria were restrictive and in some cases rendered 70% of the observational sample of 298 general methadone patients ineligible for inclusion. OSAT guidelines made strong recommendations supported by evidence with poor generalizability.

**Conclusions:** Among patients treated with OSATs, those randomized to heroin-assisted treatment or high-dose methadone were more likely to remain in therapy. There was insufficient evidence to confidently rank the remaining treatments. Trials assessing OSATs' often exclude patients with concurrent disorders. Eligibility criteria that result in the exclusion of a substantial number of patients from randomized trials jeopardize the generalizability of treatment effect to much of the clinical population. If the excluded patients respond differently to treatment, results from these trials are likely to overestimate the true effectiveness of OSATs. North American guidelines should consider these limitations when drafting clinical recommendations.

## **19. A personalized approach to obesity consultations: patient perspective and impacts**

Thea Luig<sup>1</sup>, Robin Anderson<sup>2</sup>, Arya Sharma<sup>1</sup>, Denise Campbell-Scherer<sup>1</sup>

<sup>1</sup>University of Alberta, Edmonton, Canada. <sup>2</sup>Edmonton Southside Primary Care Network, Edmonton, Canada

**Objectives:** Previous research revealed people living with obesity want substantive conversations, personalized assessments and plans. Together with patients and interdisciplinary primary care providers we have created a model for personalized obesity consultations that integrates the 5As of obesity management with the collaborative deliberation model for care.

To do this, we used in-depth qualitative methods to examine how people perceive the interpersonal work and content of the consultation; and how this experience impacts their ability to make changes in everyday life to improve their health.

**Method:** We recruited 20 people living with obesity through purposeful sampling to ensure a diversity of patient contexts. Video-recorded one-on-one interventions with a primary care clinician, loosely structured, conversational interviews (patient and clinician) following the consultation, and documentation of intervention impact on patients' self-management through diaries and two follow-up interviews over the course of 6-8 weeks. Thematic analysis using inductive and deductive coding managed in NVIVO11.

**Results:** From the patient perspective an impactful personalized obesity consultation is anchored in the patient's story and a comprehensive root cause assessment, and guided by a whole-person health approach and an orientation on patients' strengths and resources. Using collaborative communication, the care planning focuses on strengthening the patient's capacity to engage in health promoting strategies that fit with the context and fundamental goals of their lives. Impacts that patients experienced include (1) increased confidence, hope, and self-compassion; (2) activation and increased activity levels; (3) increased insight into own barriers and improved coping.

**Conclusions:** We examined patient experiences of the obesity consultation and their everyday life experience of effecting change to improving health and used results to develop a model for a personalized obesity consultation approach. Findings suggest that interpersonal processes that shift the patient towards focusing on whole-person health goals and towards a strength-based, compassionate view of self, effectively support patient activation and self-efficacy for improving health outcomes.

## **20. Methods of mobilizing collective intelligence through crowdsourcing in research: a scoping review**

Thu Van Nguyen<sup>1</sup>, Mehdi Benchoufi<sup>1</sup>, Bridget Young<sup>2</sup>, Lina El Chall<sup>1</sup>, Philippe Ravaud<sup>1</sup>, Isabelle Boutron<sup>1</sup>

<sup>1</sup>INSERM, U1153 Epidemiology and Biostatistics Sorbonne Paris Cité Research Center (CRESS), Methods of Therapeutic Evaluation of Chronic Diseases Team (METHODS), Paris, France. <sup>2</sup>Department of Psychological Sciences, Institute of Psychology, Health and Society, University of Liverpool, Liverpool, United Kingdom

**Objectives:** Collective intelligence (CI), which is defined as shared intelligence emerging from a group of people when they work on the same tasks, is a cornerstone of science where researchers interact and collaborate with each other. However, a new kind of CI through crowdsourcing is emerging by inclusively mobilizing people who are not usually involved in research to conduct more innovative research which address the needs of the community. Climate CoLab, an initiative experimenting new ideas to tackle climate change, has mobilized more than 90,000 people to develop and implement more than 2000 research proposals within 7 years since its creation.

To determine whether CI through crowdsourcing could change how research is performed, we

systematically reviewed methods of mobilizing CI through crowdsourcing across different fields of research.

**Method:** We searched PubMed, Web of Science, Scopus, EBSCO Business Source Premier, EBSCO Academic Source Premier, Google scholar and resources of the Centre for Collective Intelligence Massachusetts Institute of Technology for all reports describing a research project that had applied methods of CI through crowdsourcing defined as shared intelligence emerging when mobilizing people who are usually not involved in the research process to work on a specific task (e.g., solving a problem, generating ideas).

We extracted information on the following domains: (1) purposes of using CI, (2) type of participants and methods to recruit participants, (3) motivation, (4) type of participants' contribution to the project, (5) type of interaction between participants, (6) methods to evaluate participants' contribution and decision making process, (7) challenges and drawbacks of CI reported by authors and authors' satisfaction with participants' contributions. We applied content analysis to inductively develop themes and categories for each domain.

**Results:** We identified 141 reports. CI was mobilized to generate ideas, to evaluate ideas/work, to solve problem (e.g., diagnose disease, analyze and interpret data), or to create intellectual products. Most research projects (76%) were open to the public without restriction to the expertise of participants. Incentives to participants and intrinsic motivation were reported in 74% of articles. Of those reported, 38% were financial incentives, followed by recognition from the network (8%), access to data (2%). Independent contribution (i.e., no interaction with other participants) (37%), collaboration (31%), competitions (26%), and playing games (11%) were the methods by which participants contributed to projects. 61% of articles reported methods of evaluation of participants' contribution and decision-making process with 43% of projects using an independent panel of experts and 18% involving end-users in evaluation and decision making. Some challenges in implementation and sustainability of collective intelligence were reported.

**Conclusions:** Our results provide an in-depth description of methods for mobilizing collective intelligence and we propose a framework to facilitate its use in research. However, more research is needed to understand the conditions which enable and constrain the success of collective intelligence.

## **21. The Impact of Applying both a Critical Statistical and a Critical Clinical Appraisal to the Randomized Trials that form the Cardiology Revascularization Guidelines: Implications for Clinical Practice**

David Dobies<sup>1</sup>, Kimberly Barber<sup>2</sup>

<sup>1</sup>Regional Cardiology Associates, Grand Blanc, USA. <sup>2</sup>Genesys Office of Research, Grand Blanc, USA

**Objectives:** Randomized trials and guidelines are used by physicians, administrators, patients, and policy makers to make medical decisions. The assumption is that the randomized trial conclusions and the guideline recommendations are accurate and have been properly vetted. Furthermore, the randomized

trial conclusions and guideline recommendations are used for certification examinations. Therefore, a critical appraisal should be performed. Both a critical statistical and a critical clinical evaluation should be performed.

**Method:** The 5 Year Syntax and the Freedom Trials were evaluated. These trials compared percutaneous coronary artery intervention (PCI) utilizing drug eluting stents to coronary artery bypass (CABG). In both trials patients with multi-vessel coronary disease were studied. These two trials form the basis on the cardiology guidelines. Both trials reported a highly significant result favoring CABG over PCI for patients with mult-vessel coronary artery disease.

Both a critical statistical and a critical clinical evaluation of these two trials was performed. From a statistical standpoint, a sensitivity analysis was performed that included Forest plots. Also, the number needed to treat vs the number needed to harm was calculated. From a clinical standpoint, the definition of a myocardial infarction was evaluated along with the clinical impact. Both trials had significant limitations due to missing data.

**Results:** The actual statistical findings of both the 5 Year Syntax Trial and the Freedom Trial demonstrated no difference in major adverse cardiovascular and cerebrovascular events (MACCE). The critical statistical analysis of the Syntax Trial differed significantly from the reported trial results because the effect of missing data was accounted for. The reported results counted all missing data as non-events. The missing data was calculated as non-events, study event average, and as having events. The clinical evaluation focused on the definition of a myocardial infarction that was the biggest component of the MACCE rate. The definition was different for the CABG patients compared to the PCI patients.

The Freedom Trial reported results were severely limited by the calculation of ratio at risk, a high differential loss, and a high overall attrition rate. When these limitations are corrected for the actual results show no difference between PCI and CABG.

**Conclusions:** The reported results of both the 5 Year Syntax Trial and The Freedom Trial differed significantly from the actual trial findings since either subjects were excluded or missing data was only calculated as non-events. Both trial conclusions were severely compromised. From a clinical standpoint, the definition of a myocardial infarction was study dependent, a newer generation of stents are used which are safer, and newer and more effective anti-platelet medications are used in current practice.

Given the concern over the accuracy of reported conclusions of randomized trials, guideline committees should utilize independent statisticians for accurate analysis.

## **22. Imprecise evidence based guidelines and issues for decision-makers - an example of severe chronic plaque psoriasis in Australia**

Martin Downes

Centre for Applied Health Economics, Griffith University, Brisbane, Australia

**Objectives:** Plaque psoriasis occurs in 90% of psoriasis sufferers and has characteristic thick, sharply edged (marginated), red scaly lesions, most commonly on the elbows, knees, lower back and scalp.

Psoriasis can affect the emotional and social wellbeing of the affected person. Biologicals are used to treat severe chronic plaque psoriasis (sCPP) which is subsidised for certain patients in Australia. There was a request from stakeholders to the Australian government to widen the population eligible to receive subsidised biologics for sCPP in Australia to align with Australian clinical guidelines. The Australian Department of Health initiated a post market review. The objective of the review was to align access to biologics in sCPP in Australia to clinical guidelines and clinical evidence to ensure equitable access to cost effective treatments.

**Method:** The Australian government conducted a three-stage review of current evidence, as follows:

1) a review of clinical guidelines and access.

A systematic review was conducted to identify clinical guidelines for the treatment for psoriasis. In the absence of evidence-based Australian guidelines, the search also included international guidance. We assessed guidelines using AGREE II.

We reviewed the requirements for access to subsidised biologicals.

2) a systematic review of the clinical effectiveness evidence for biologics in sCPP.

A systematic review was conducted to identify RCTs that evaluated the efficacy and safety of Australian subsidised biologics for the treatment of sCPP.

3) a review of epidemiological evidence of sCPP in Australia.

A systematic review was conducted to identify estimates of the incidence and prevalence of severe CPP in Australia or estimates that may be applicable to the Australian context e.g. New Zealand, United Kingdom, United States of America, Canada, and Europe.

**Results:** Biologicals are used to treat sCPP and in Australia, subsidised access is restricted to those with a Psoriasis Area and Severity Index (PASI) score of  $>15$  as this was the value that was historically deemed cost effective. All clinical effectiveness (RCT) evidence for the use of biologicals in sCPP were for patients with a PASI  $\geq 12$ .

Evidence based guidelines advise that a PASI  $\geq 10$  and DLQI  $>10$  (NICE) or no numerical cut off (Canada) should be used to allow patients access to biologicals.

An estimated 19,000 people have a PASI  $\geq 15$  in Australia. We estimated that there is 16,000 people with a PASI of 12 to 15 and 15,000 with a PASI of 10 to 12. Current expenditure is ~\$121 million. Increasing the subsidised population could lead to increasing expenditure by ~\$91 million (PASI  $\geq 12$ ) and ~\$180 million (PASI  $\geq 10$ ).

**Conclusions:** There were inconsistencies identified between the population that was used to assess clinical evidence of biologics and the clinical guidelines for the treatment of sCPP. These inconsistencies has led to confusion for clinicians, patients and decision makers. The inconsistencies identified makes the decision to reimburse even more complicated. There is a need for clinical guidelines (especially those that are evidence based) to be consistent and truly reliant on the evidence that is available as without this decisions can be made that result in patients being exposed to adverse events at substantial cost without evidence of efficacy.

## 23. Therapeutic Nipple-sparing versus Skin-sparing Mastectomy: A Systematic Review

Riaz Agha<sup>1</sup>, Yasser Al Omran<sup>2</sup>, Georgina Wellstead<sup>3</sup>, Charmilie Chandrakumar<sup>3</sup>, Harkiran Sagoo<sup>4</sup>, Ishani Barai<sup>5</sup>, Shivanchan Rajmohan<sup>5</sup>, Mimi Borrelli<sup>6</sup>, Martinique Vella-Baldacchino<sup>2</sup>, Dennis Orgill<sup>7</sup>, Jennifer Rusby<sup>8</sup>

<sup>1</sup>Department of Plastic Surgery, Queen Victoria Hospital,, East Grinstead, United Kingdom. <sup>2</sup>Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom. <sup>3</sup>Barts and The London School of Medicine and Dentistry, Queen Mary University of London, London, United Kingdom. <sup>4</sup>GKT School of Medical Education, King's College London,, London, United Kingdom. <sup>5</sup>- Imperial College School of Medicine, London, United Kingdom. <sup>6</sup>Division of Plastic Surgery - Stanford University, Stanford, USA. <sup>7</sup>Division of Plastic Surgery, Brigham and Women's Hospital, Boston, USA. <sup>8</sup>The Royal Marsden NHS Foundation Trust, London, United Kingdom

**Objectives:** Breast cancer has a lifetime incidence of 1 in 8 women. Over the last three decades there has been a move towards breast conservation and a focus on aesthetic outcomes whilst maintaining oncological safety. When mastectomy is required, use of nipple-sparing mastectomy (NSM) is increasing, despite unproven oncological safety in the therapeutic setting, and the benefits and indications have not been clearly identified. The objective of this systematic review was to determine the safety and efficacy of NSM as compared with skin-sparing mastectomy (SSM).

**Method:** All original comparative studies including randomised controlled trials, cohort studies and case-control studies comparing women undergoing therapeutic NSM or SSM for breast cancer were included. Primary outcomes were oncological outcomes and secondary were clinical, aesthetic, patient-reported and quality of life outcomes. A comprehensive electronic literature search, designed by a search specialist, was undertaken. Grey literature searches were also conducted. Eligibility assessment occurred in two stages; title and abstract screening and then full text assessment. Each step was conducted by two trained teams acting independently. Data were then extracted and stored in a database with standardised extraction fields to facilitate easy and consistent data entry. Data analysis was undertaken to explore the relationship between NSM and SSM, and pre-selected outcomes. Heterogeneity was assessed using the Cochrane Tests.

**Results:** Our searches identified 690 articles, of which 14 were included in this review. These 14 studies included 3,015 patients, of which there were 1419 NSMs and 1596 SSMs with follow-up ranging from 18 to 101 months. There was no statistically significant difference 5-year disease free survival and mortality for NSM and SSM groups where data was available. Local recurrence rates were also similar between NSM (3.9%) and SSM (3.3%) groups with no significant difference ( $p=0.75$ ). NSM does have a partial or complete nipple necrosis rate of 15%, and a higher complication rate than SSM (23.5% vs 13.1%). The higher overall complication rate is due to nipple necrosis and a higher rate of mastectomy skin flap necrosis rate (4.7% vs 3.9% for SSM).

**Conclusions:** In carefully selected cases, NSM is a viable choice for women with breast cancer needing to undergo mastectomy. This is the most comprehensive and up to date systematic review providing guidance on indications and outcomes for this procedure although methodological and reporting quality

were significant limitations. More research is needed to help further refine the evidence on which surgical approaches to NSM optimise outcomes.

### **23a. Which medicines do we need? Development of an outcomes-based approach to essential medicines lists**

Authors: Nav Persaud, Jeffrey Aronson, Carl Heneghan

**Objectives:** To develop an approach to creating and updating essential medicines lists based on information about how effectively each medicine is known to achieve desired outcomes (e.g. preventing strokes). This could help the 134 countries with essential medicines lists choose medicines most important for their 5.8 billion residents.

**Methods:** We will seek input on the best ways to inform countries that have essential medicines lists about the importance of each medicine.

**Results:** The current plan is to conduct a consensus process to determine which information about each medicine is most important. Then the literature will be systematically reviewed to determine which medicines are most effective and achieving desired outcomes. Network meta-analyses may be employed. The information about each medicine will be provided in a searchable online database and presented to interested countries.

**Conclusions:** An outcomes-based approach to essential medicines lists has the potential to promote access to medicines that achieve desired outcomes.

### **24. Metabolic monitoring of youth prescribed antipsychotics: the evidence gap widens in failing to provide reasonable standard of physical healthcare**

Nisreen Aouira<sup>1</sup>, [Sohil Khan](#)<sup>2</sup>, Helen Heussler<sup>3</sup>, Brett McDermott<sup>4</sup>, Alison Haywood<sup>5</sup>, William Bor<sup>3</sup>

<sup>1</sup>School of Pharmacy and Pharmacology, Griffith University, Gold Coast, Australia. <sup>2</sup>School of Pharmacy and Pharmacology, Griffith University; Mater Research Institute - The University of Queensland, South Brisbane; Manipal University, Manipal, Gold Coast, Australia. <sup>3</sup>Children's Health Queensland Hospital and Health Service, South Brisbane; Mater Research Institute - The University of Queensland, South Brisbane, South Brisbane, Australia. <sup>4</sup>College of Medicine and Dentistry, James Cook University, Townsville, Australia. <sup>5</sup>School of Pharmacy and Pharmacology, Griffith University; Mater Research Institute - The University of Queensland, South Brisbane, Gold Coast, Australia

**Objectives:** Prescription of second-generation antipsychotics (also called atypical antipsychotics) in youth and young people is rapidly increasing globally, despite the potential for significant adverse effects (metabolic syndrome, MS) and long-term health consequences. The adverse effects of atypical antipsychotics are more severe in youth and young people than in adults (in particular, obesity and diabetes). They can gain a significant amount of weight after taking antipsychotics even for a short period



(weight gain observed within 8-12 weeks). Evidence suggests that screening strategies for MS are not effective and that implementation of guidelines and health policies is falling short of acceptable standards of care as a component of pharmacovigilance. There is significant evidence gap on monitoring strategies among youth and young people. Present research examined these factors through assessment of intervention studies that aimed at improving the rate of metabolic monitoring in this target population.

**Method:** A systematic review was conducted using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) protocol. Studies were identified through Medline/PubMed, EMBASE and CINAHL abstract databases from 2000 to December 2017. Search terms included *metabolic monitoring, children, atypical antipsychotics, mental health, diabetes, adherence, barriers and facilitators.*

Experimental (randomised, quasi-randomised trials); and observational (cross-sectional clinical audits, drug utilisation evaluation studies) studies conducted among youth/young people (10-24 years of age) were included. Key outcome measures were the most and least likely strategies to improve the rate of metabolic monitoring and the barriers to monitoring. The strategies were then ranked based on the Strength of evidence recommendation taxonomy (SORT) ratings.

**Results:** A total of 7 studies met the inclusion criteria and were analysed. The studies primarily targeted adherence to metabolic monitoring by practitioners. Four studies included patients and/or carers. Barrier analysis identified prescriber related factors affecting poor rate. The common prescriber targeted intervention included behavioural change strategies such as PDSA (plan, do study, act) quality improvement framework, education (e.g. periodic seminars, workshop, drop-in sessions) and reminders (e.g. physical health check reminder card, one page monitoring chart embedded in the patient file). Patient focused strategies were limited to diabetes education and management assessing the feasibility of point-of-care testing for metabolic monitoring of antipsychotics. Consumer related barriers to metabolic monitoring include stigma to undergo monitoring, challenging and vulnerable age group with severe mental illness, troubled family/carers and lack of knowledge to undergo monitoring. A modest improvement in glucose testing monitoring was observed but couldn't meet the guidelines recommendation.

**Conclusions:** This is one of the first studies that evaluated intervention studies to improve metabolic monitoring of youth/young people prescribed antipsychotics. The clinical audits targeted prescriber related factors. Patient and health service factors remains understudied. Significant evidence gaps exist on what youth and carers feel about medication reviews including potential regular blood tests, physical examination and remedial action to counter the effects of obesity. Reform of practice and health service monitoring behaviour needs to work in parallel with changes in consumer behaviour. Significant service gap exists in the physical care of mentally ill youth/young people on antipsychotic medication.

## **25. Factors and variation driving inappropriate opioid analgesic prescribing in the community: a systematic review protocol**

Georgia Richards, Kamal Mahtani, Ben Goldacre, Carl Heneghan

University of Oxford, Oxford, United Kingdom

**Objectives:** The prescription of opioid analgesics is rising in communities of high-income countries. Some of this increase may be appropriately addressing the growing number of people living with pain. Yet, the inappropriate prescribing of opioids (i.e. prescribing that deviates from evidence-based guidelines) may be causing more harms than potential benefits. Previous studies have focused disproportionately on demonstrating the increases in opioid prescribing without understanding what is driving the increase in prescribing. Therefore, We aim to systematically review the literature to establish what factors are driving inappropriate opioid prescribing and potential variation in opioid prescribing practices in high-income countries.

**Method:** We searched MEDLINE, EMBASE and Web of Science using “primary care”, “factors”, “variation”, “opioid”, “prescribing” and derivatives of these. No language, date or additional limits were applied. The search was completed on 12 February 2018 and is registered on PROSPERO [CRD42018088057]. Studies are being reviewed by two authors who will independently select the eligible articles, extract the data, assess the risk of bias using ROBINS-I (Sterne et al. 2016) and quality of the evidence using GRADE. Relevant internet proceedings, reference lists of included studies and review articles will be examined. Inclusion criteria includes: observational studies, adults (aged  $\geq 18$ ) recruited in communities of high-income countries, a measurement of opioid prescribing, factors that explain prescribing and/or a measure of variation in prescribing practices. Inpatients or patients admitted to hospital (unless followed up in the community), patients with a pre-existing opioid-use disorder or addiction and case studies will be excluded.

**Results:** We identified 3,950 records to be reviewed for inclusion or exclusion after 4,421 duplicates were removed. We anticipate a range of patient-, practitioner- and system-level factors to be found that explain inappropriate opioid analgesic prescribing in the community. Variation is expected to be found across countries, on the indication for prescription and type of opioid prescribed.

**Conclusions:** The prescription of opioid analgesics is continuing to rise. Identifying potential patient-, prescriber- and system-level factors associated with opioid prescribing will be the first step in understanding the drivers of prescription and address unwarranted variation in the treatment of pain. This study will provide a framework for a primary database study to be designed that will develop our understanding of the growing treatment needs for people living with persistent pain.

## **26. The Swedish version of the Normalization Process Theory Measure S-NoMAD: Translation, adaptation and pilot testing**

Anna Cristina Åberg<sup>1</sup>, Marie Elf<sup>1</sup>, Sofie Nordmark<sup>2</sup>, Johan Lyhagen<sup>3</sup>, Inger Lindberg<sup>2</sup>, Tracy Finch<sup>4</sup>

<sup>1</sup>School of Education, Health and Social Studies, Dalarna University, Falun, Sweden. <sup>2</sup>Department of Health Sciences, Luleå University University of Technology, Luleå, Sweden. <sup>3</sup>Department of Statistics, Uppsala University, Uppsala, Sweden. <sup>4</sup>Department of Nursing, Midwifery & Health, Northumbria University, Newcastle, United Kingdom

**Objectives** To: **i)** Translate and adapt the original British instrument the Normalization Process Theory Measure (NoMAD) into the Swedish version S-NoMAD, and **ii)** Evaluate its basic psychometric properties, including pilot-testing for validity in a health care context including in-hospital, primary, and community care in a region of northern Sweden.

The NoMAD instrument is based on Normalization Process Theory, and its four core constructs: Coherence, Cognitive Participation, Collective Action and Reflexive Monitoring. They represent ways of thinking about implementation and are focused on how interventions can become part of everyday practice and how different groups of people need to work together to achieve it.

**Method:** A systematic approach with a four step process was utilized, including forward and backward translation and expert reviews for the test and improvement of content validity of the S-NoMAD in different stages of development. The final S-NoMAD version was then used for process evaluation in a pilot study aimed at implementation of a new working method for individualized and coordinated care planning. The pilot was executed in a county council and fourteen municipalities, and supported by a specifically designed IT-solution. The S-NoMAD pilot results were analysed for validity by the use of confirmatory factor analysis, i.e. a one factor model fitted for each of the four constructs of the NoMAD. Cronbach's alpha was used to ascertain the internal consistency reliability

**Results:** In the pilot study S-NoMAD data were collected from 144 individuals of different health care professions as well as managers, working at in-hospital, primary and community care. The initial factor analysis model showed very good fit for two of the constructs (Coherence and Cognitive Participation) and unsatisfactory fit for the remaining two (Collective Action and Reflexive Monitoring) due to three problematic items. Deleting those items from the model yielded a very good fit. Then the internal consistency reliability was shown to be good (alphas between 0.78 and 0.83). However, estimation of correlations between the factors showed that the factor Reflexive Monitoring was highly correlated (around 0.9) with the factors Coherence and Collective Action.

**Conclusions:** Careful translation and adaptation in several steps is essential for the maintenance of psychometric qualities. Still cultural (language) differences may have caused poor fit for three items of the S-NoMAD, indicating low construct validity. After deleting these items, a good fit was obtained and overall good factor reliability was shown. Still, high correlation between constructs (factors) may indicate a psychometric problem, but may also be due to a small sample size. More extensive studies in different health care contexts are needed for further evaluation and development of the S-NoMAD.

## **27. Improving the reporting of medical risks and benefits in the media: The Press Alert App**

Alexandra Freeman, Leila Finikarides, Mike Pearson, David Spiegelhalter

Winton Centre for Risk & Evidence Communication, Cambridge, United Kingdom

**Objectives:** Papers, press releases and headlines very commonly still cite relative risks only, leading to headlines such as a drug or behaviour “halves your risk of” or “doubles your risk” of an effect. These headlines sound dramatic, but leave the reader none the wiser of the actual magnitude of either the risk

or the effect. This is despite the fact that many journals now require authors to give the numbers for absolute as well as relative risks (or benefits).

The reasons for this failure to use absolute risks are often that they are not available, or that journalists and press officers lack the confidence to convert the numbers they have been given to the numbers they wish to report.

We are designing and currently user-testing an App to represent the findings of research clearly and accurately, for use by journalists and publishers.

**Method:** Registered press officers will have password-protected access to a web front-end allowing them to create a press alert via the App. The interface will help them input correct absolute risk data from the research paper (or, with the authors, source it externally). They will also be include a link to their full press release.

When a press alert has been completed, the App will push a notification to the phones of all registered journalists who have it (pre-embargo). The App will display the results of the study in terms of absolute and relative risks as well as 'number needed to treat' in various graphical, numerical and verbal formats. Journalists can use these directly in their publications and stories, and follow the link to the full press release.

We aim to evaluate the App's effects, monitoring story uptake volume, reporting of absolute risks and proportion of stories including caveats about interpretation.

**Conclusions:** This App could form an efficient conduit between academics (and their press officers) and journalists, carrying accurate and automated graphics/phrases designed to clearly represent their results. The advantages to press officers and authors is instant access to the phones of relevant journalists. The advantages to journalists is instant push-notification of new press releases alongside easily re-used phrases, numbers and graphics for their stories.

Our evaluation will determine how being explicit about absolute risks changes reporting emphasis. Other work we are currently undertaking on the effect of absolute risks on public perception of a story will be complementary to this.

## **29. Do dose expansion cohorts impact surrogate benefit in pediatric Phase I trials in oncology?**

Marcin Waligora<sup>1</sup>, Malgorzata M Bala<sup>2</sup>, Magdalena Koperny<sup>3</sup>, Mateusz T Wasylewski<sup>1</sup>, Karolina Strzebonska<sup>1</sup>, Rafał R Jaeschke<sup>4</sup>, Agnieszka Wozniak<sup>5</sup>, Jan Piasecki<sup>1</sup>, Agnieszka Sliwka<sup>6</sup>, Jerzy W Mitus<sup>7</sup>, Maciej Polak<sup>8</sup>, Dominika Nowis<sup>9</sup>, Dean Fergusson<sup>10</sup>, Jonathan Kimmelman<sup>11</sup>

<sup>1</sup>REMEDY, Research Ethics in Medicine Study Group, Dept. of Philosophy and Bioethics, Jagiellonian University Medical College, Krakow, Poland. <sup>2</sup>Dept. of Hygiene and Dietetics, Chair of Epidemiology and Preventive Medicine, Jagiellonian University Medical College, Krakow, Poland. <sup>3</sup>Dept. of Public Health and

Health Promotion, Regional Sanitary-Epidemiological Station in Krakow, Krakow, Poland. <sup>4</sup>Section of Affective Disorders, Dept. of Psychiatry, Jagiellonian University Medical College, Krakow, Poland. <sup>5</sup>The Agency for Health Technology Assessment and Tariff System, Warsaw, Poland. <sup>6</sup>Dept. of Rehabilitation in Internal Diseases, Jagiellonian University Medical College, Krakow, Poland. <sup>7</sup>Dept. of Surgical Oncology, Maria Skłodowska-Curie Memorial Cancer Center and Institute of Oncology, Krakow, Poland. <sup>8</sup>Dept. of Epidemiology and Population Studies, Jagiellonian University Medical College, Krakow, Poland. <sup>9</sup>Dept. of Immunology, Medical University of Warsaw, Warsaw, Poland. <sup>10</sup>Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada. <sup>11</sup>Studies of Translation, Ethics and Medicine (STREAM), Biomedical Ethics Unit, McGill University, Montreal, Canada

**Objectives:** Phase I cancer clinical trials aim to determine the safety of a new drug, and present a high risk of serious adverse events with limited prospect of therapeutic benefit. Such trials can include a dose-escalation phase that determines the maximum tolerated dose (MTD), followed by a dose-expansion phase to determine the recommended dose. Little is known about the level of risk and benefit in pediatric Phase I trials in oncology. Our aim was to establish the benefit associated with pediatric Phase I studies in oncology and compare it between studies with and without dose expansion cohorts.

**Method:** We systematically searched Embase and PubMed for pediatric Phase I cancer studies published between 1 January 2004 and 1 March 2015. We defined the objective response rate as the proportion of participants with partial or complete response as defined by authors of the included studies. For acute leukemia, we did not count partial responses in our assessment of objective responses, since anything short of a complete response is not considered a benefit for these malignancies. We defined the dose expansion cohort (DEC) as enrollment of at least 3 additional patients after determining the MTD for further evaluation of toxicities.

**Results:** We identified 170 studies with 4,604 patients meeting eligibility criteria. Only 43 of these trials involved dose expansion cohorts. The pooled overall objective response rate for all studies was 10.29% (95% CI 8.33% to 12.25%), with a response rate of 3.17% (95% CI 2.62% to 3.72%) for solid tumors and 27.90% (95% CI 20.53% to 35.27%) for hematological malignancies. The overall response rate for trials with DEC was 7.26% (95% CI 4.46% to 10.06%), and for trials without DEC was 10.74% (95% CI 8.42% to 13.05%). Response rates in studies with DEC did not differ from those not having dose expansion cohorts ( $p = 0.10$ ), nor did we observe an obvious relationship between higher response rate and higher number of patients in expansion cohorts (Spearman's rank correlation coefficient  $R = -0.08$ ,  $p = 0.7$ ).

**Conclusions:** Our aggregate objective response estimate for pediatric studies does not appear to have been driven by a small number of Phase I trials with large dose expansion cohorts.

### **30. Evaluating the effect of the Practical Approach to Care Kit on teaching medical students primary care:Quasi-experimental study**

Robert Mash<sup>1</sup>, Michael Pather<sup>1</sup>, Hilary Rhode<sup>1</sup>, Lara Fairall<sup>2</sup>

<sup>1</sup>Stellenbosch University, Cape Town, South Africa. <sup>2</sup>Knowledge Translation Unit University of Cape Town, Cape Town, South Africa

**Objectives:** This study aimed to evaluate the effect on student performance of the Practical Approach to Care Kit (PACK) (an integrated decision-making tool for adult primary care) during the final phase of medical student training in family medicine and primary care at Stellenbosch University.

**Method:** A quasi-experimental study comparing student performance in those with and without exposure to the PACK as well as a phenomenological approach to explore the students' experience and perceptions of using PACK.

All 190 interns in their sixth year of study in 2014 were invited to participate in the study.

The students' scores in the end-of-rotation MCQ exam were used to assess their application of knowledge to clinical decision-making in primary care. Thirty MCQs were randomly selected from a bank of 60 MCQs. The OSCE required the students to demonstrate their competency at assessing common presentations or managing common conditions in primary care.

Data were analysed using SPSS version 24. The MCQ data were compared using an independent samples t test and the OSCE data with the Mann–Whitney U test as the data were not normally distributed.

Qualitative data were analysed with the help of Atlas-ti using the framework method.

**Results:** Student performance in examinations was significantly better in those exposed to the PACK. Students varied from using the PACK overtly or covertly during the consultation to checking up on decisions made after the consultation. Some felt that the PACK was more suitable for nurses or junior students.

In the MCQ examination, 50 students from the first semester were compared to 83 students in the second semester (rotations six to nine). The mean grade for the MCQ examination was significantly better ( $p = 0.03$ ) in those with the PACK (72.3%, SD 8.6) compared to those without (68.8%, SD 9.6).

In the OSCE examination, 75 students in the first semester examination were compared with 83 students in the second semester examination (rotations six to nine). The mean grade for the OSCE was significantly better ( $p < 0.001$ ) in those with the PACK (64.4%, SD 7.0) compared to those without (58.8%, SD 10.9).

**Conclusions:** The performance of undergraduate students in primary care improved following the introduction of the PACK in their final phase using an inter-professional model of training. The PACK should be used going forward, but introduced in the early phase of undergraduate training. Supervisors should be trained further in how to incorporate use of the PACK in their practice and educational conversations.

## **32. Using human-centred design to better support primary care obesity management: 5As Team at Home.**

Guillermina Noël, Thea Luig, Denise Campbell-Scherrer

University of Alberta, Edmonton, Canada

**Objectives:** The WHO has issued a call to implement *people-centred* strategies to health services. This makes personalized care a priority. Obesity management in primary care is often embedded in other clinical presentations, like diabetes or osteoarthritis. Achieving collaborative encounters in primary care

obesity management is difficult. *The challenge is how to support constructive engagement to address the unique needs of each individual.* To overcome this, it is indispensable to apply a human-centred approach to meet patients' needs and values. The objective of this project was to collaboratively identify patients' needs and expectations about tools for obesity management. Also, to co-design with patients and care teams 4 tools to support patient-physician collaborative engagement to identify health goals and create personalized care plans to manage obesity using a human-centred design approach. Human-centred design puts people at the centre.

**Method:** We developed three co-design workshops: we used personas, role playing, dialogue prompters, and prototypes to foster collaboration and good communication between patients, health professionals and researchers. Five patients participated in the first workshop to identify their needs and expectations about tools to achieve meaningful obesity conversations. This workshop helped develop a list of goals the tools needed to fulfill and create a first prototype. Ten patients and ten healthcare providers participated in the other two co-creation workshops to tailor the tools to the needs of patients and health professionals. Eight videos of obesity encounters helped develop 3 personas. The personas were used to help participants situate themselves in the story of a "constructed" patient. The personas help patients and health professionals to role play a weight management conversation while using the first prototypes. Dialogue prompters were used to collect participants ideas about what worked, why and how to change it.

**Results:** Diverse communication needs emerged between patients and healthcare professionals. Patients found the first prototype too medical and technical not helping to address their overall health. Health professionals needed the tool to cover more mental health and functional aspects. The co-creation clarified that we needed to differentiate between what the tool should do from what the health professional should do. For example, the tool should *support the identification* of patients' strengths, but it is the *health professional who should identify* patients' strengths (such as overcoming depression or emotional eating) throughout the patients' story. This requires professional training. We learned that the steps to guide patients to plan action needed to be simple and straightforward to avoid overwhelming them. If the tool to plan action was overwhelming, it affected the patients' capacity and confidence to plan and implement future actions. Overall the tool promoted conversation, but it needed clear instructions.

**Conclusions:** This study shows the value of human-centred design to achieve collaboration and partnership between patients, health professionals and researchers. Co-creating not only helps investigate how to achieve a deeper understanding of one another's needs, values and perspectives, but also to get ideas none of these 3 stakeholders: researchers, patients and health professionals would ever conceive alone. This collective aspect of design, is starting to be seeing as an asset. The adoption of human-centred design can help patients and physicians to collaboratively design better healthcare approaches, re-configure the patient-physician relationship, and help provide more suitable weight management conversations.

### 33. Empirical evidence against placebo controls

Sadhvi Batra<sup>1</sup>, Jeremy Howick<sup>2</sup>

<sup>1</sup>University of Alabama at Birmingham School of Medicine, Birmingham, USA. <sup>2</sup>University of Oxford, Oxford, United Kingdom

**Objectives:** The revised Declaration of Helsinki allows placebo-controlled trials to be used even when there is an established therapy, provided there are adequate 'methodological' reasons for doing so. This seems to violate the principle of beneficence: where there is an established therapy, physicians treating patients with a placebo are withholding a known effective therapy. Because of this problem, we hypothesised that clinical researchers may be unwilling to risk violating the principle of beneficence and employ placebo-controlled trials in cases where there is an established therapy.

**Method:** In this paper, we began to investigate this hypothesis. After summarising the arguments for and against using placebo controls in clinical practice, we explored the extent to which placebo-controlled trials are used in cases where there is an established therapy. To do this, we conducted a systematic search for all placebo-controlled trials published in 2015 in the five highest impact general medical journals.

**Results:** We identified 70 placebo-controlled trials. Of these, 66 were for indications where there was no established effective therapy. Only four used a placebo control in spite of there being an available effective therapy.

**Conclusions:** The infrequent use of placebo controlled trials where established therapy exists highlights a seeming discrepancy between what the Declaration of Helsinki allows and what clinical investigators believe to be ethically acceptable. The evidence presented in this paper suggests that the Declaration of Helsinki be reconsidered, and perhaps revised, in light of actual practice.

### **34. A Nationwide Survey of the Attitudes of Doctors and Dentists in Training Towards the Use of Evidence-Based Practice**

Bosun Hong, Christopher Jones, Cochrane UK & Ireland Trainees Advisory Group .

Cochrane UK, Oxford, United Kingdom

**Objectives:** The use of best evidence is vital to improving patient outcomes. Whilst organizational adherence to the evidence-base has previously been studied, the extent to which trainee clinicians engage with evidence-base practice is unclear. We outline here the results of a national survey of medical and dental trainees from across the United Kingdom (UK) and the Republic of Ireland (RoI) that sought to determine the extent to which doctors and dentists in training use the evidence base in everyday clinical practice, and to evaluate barriers to further engagement.

**Method:** A nationwide survey of medicine and dentistry trainees within the UK and RoI was undertaken by the Cochrane UK & Ireland Trainees Advisory group. An online questionnaire was developed using the SurveyMonkey cloud-based online survey programme and adapted following a pilot study of 16 trainees



from a range of medical and dental specialties. The questionnaire was distributed to trainees across the UK and RoI via two routes between 19 September 2017 and 8 November 2017. Firstly, an online and social media strategy was employed to raise awareness of the survey. Secondly, the survey was highlighted to specialty and deanery-specific organisations who were asked to distribute it to trainees via mailing lists or ePortfolio accounts, including for instance the Foundation Programme national bulletin. Doctors and dentists were eligible for participation if they held a recognised UK or RoI training post at the time of survey completion.

**Results:** The survey yielded 243 responses from 30 medical/surgical specialties and seven dental specialties. Approximately half (52.0%) of the respondents reported they referred to the literature at least weekly to determine the evidence base for a clinical decision. The foremost two barriers to evidence-based practice were insufficient time (54.6%) and tendency to follow the generally accepted clinical practice in their department (41.7%). In addition, 22.3% reported they would feel comfortable querying a colleague's management based on their understanding of relevant evidence only if that colleague was more junior/ less experienced than them. The motivators to evidence-based practice included the desire to better understand how clinical decisions are made (61.6%) and senior encouragement (38.9%). When asked how they could be encouraged to draw more on the evidence base by Cochrane UK, the respondents expressed most interest in receiving email updates on evidence-based practice (53.7%) or participating in online journal clubs (47.3%).

**Conclusions:** A lack of time, a reluctance to challenge colleague's management and the influence of established departmental practice are key inhibitors to the wider adoption of evidence-based practice by medical and dental trainees. Further work will be undertaken by the Cochrane UK & Ireland Trainees Advisory Group to challenge these barriers and improve trainee engagement with the evidence base.

### **35. EBP related self-efficacy among healthcare and social care professionals: a systematic review**

Peter Hoegen<sup>1</sup>, Cindy De Bot<sup>1</sup>, Michael Ehteld<sup>1</sup>, Hester Vermeulen<sup>2</sup>

<sup>1</sup>Avans University of Applied Science, Expertise Centre Caring Society, Breda, Netherlands. <sup>2</sup>Radboud University Medical Center, Radboud Institute for Health Sciences, Nijmegen, Netherlands

**Objectives:** Evidence-based practice (EBP) has obtained a well-established position in healthcare. However, actual EBP-behaviour among all healthcare professionals in daily practice is still a challenge. In the quest to identify and subsequently address barriers for EBP-behaviour, EBP related self-efficacy (SE) of healthcare professionals appears to be underexposed. A better understanding of underlying problems to build SE and thus the influence on actual EBP-behaviour of healthcare professionals is needed. With this knowledge we can optimise education and enrich training for healthcare professionals. Therefore we undertook this systematic review of both quantitative and qualitative studies.

**Method:** MEDLINE (through PubMed), EMBASE, Cochrane, CINAHL and PsycINFO were searched up to December 2017. Additional records were identified by snowballing. No date limitations nor language

restrictions where applied. Study selection, quality assessment, data extraction and thematic synthesis were conducted by two authors independently. Original studies, either quantitative, qualitative or mixed methods designs were included. Therefore, quality was assessed in accordance to the Mixed Methods Appraisal Tool (MMAT), version 2011. Data was extracted systematically, crosschecked and discussed by two authors. Qualitative analysis was performed, following the Guidance on the conduct of Narrative Synthesis in Systematic Reviews to identify underlying themes and gain understanding of SE and EBP-behaviour.

**Results:** We included 40 studies. Half of the studies included (student-)nurses, the other half healthcare- or social care professionals. The methodological quality was reasonable as the MMAT Scores were above 50% for half of the studies.

Thematic data analysis resulted in five themes “behaviour”, “competence”, “authority”, “autonomy” and “support”. Positive attitudes were supportive as starting point for development of knowledge, skills, SE and subsequently EBP-behaviour. Perceived barriers for EBP-behaviour are especially lacking knowledge, skills and confidence to appraise research articles or interpret statistical matter. In case of educational strategies, knowledge improved, but confidence for EBP-behaviour and change patient procedures stayed behind. Especially nurses were hampered in their EBP-behaviour by low recognition of their profession as an autonomous, academic profession which is based on research, both within their own and other healthcare disciplines. Support and encouragement from managers and mentoring by peers and experienced colleagues is missed to build SE.

**Conclusions:** SE has attention but its influence on actual EBP behaviour of healthcare professionals in daily practice seems to be underestimated. Studies on barriers for EBP implementation often do not mention SE. Future education, training and implementation projects should include specific components designed to develop SE in each of the EBP steps. In accordance with known learning strategies, positive experiences, exemplary behaviour from experienced colleagues and peers and encouragement from relevant parties such as the senior management, are indispensable. To evaluate the effect of interventions which improve SE, measurement instruments should be developed and evaluated on validity, reliability and responsiveness.

### **36. Methods for Teaching Evidence-Based Practice: A Scoping Review**

Anne Seneca Terkelsen\*<sup>1</sup>, Anne-Marie Fiala Carlsen<sup>2</sup>, Camilla Marie Larsen<sup>1,3,5</sup>, Poul Bruun<sup>1</sup>, Hanne Kaae Kristensen<sup>1,4</sup>

<sup>1</sup> Health Sciences Research Centre, University College Lillebaelt, Odense, Denmark

<sup>2</sup> UCL Library in Odense, University College Lillebaelt, Odense, Denmark

<sup>3</sup> Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark

<sup>4</sup> Department of Clinical Research, University of Southern Denmark, Odense, Denmark

<sup>5</sup> Department of Physiotherapy, University College Lillebaelt, Odense, Denmark

**Background:** EBP skills are essential requirements in clinical practice among health professionals. Further

knowledge about teaching Professional Bachelor Degree healthcare students evidence-based practice at undergraduate level is however needed. This scoping review aims to gather recommendations for teaching evidence-based practice across Professional Bachelor's Degree healthcare programmes by mapping literature describing teaching methods for undergraduate healthcare students including the five steps suggested by the Sicily Statement.

**Methods:** Three databases covering health, education and grey literature were searched. Full-text articles were screened by four reviewers and data extracted to two data extraction tools: Study characteristics and key methods of teaching evidence-based practice. Study characteristics were described narratively. Thematic analysis identified key methods for teaching evidence-based practice while full-text revisions identified the use of the Sicily Statement's five steps and context.

**Results:** The database search identified 1,908 records. 181 records were eligible for full-text assessment and 73 studies were included. Studies were conducted from 2010-2016. Seven key methods for teaching evidence-based practice were identified. Research courses and workshops, collaboration with clinical practice and IT technology were the key methods most frequently identified. Journal clubs and embedded librarians were referred to the least. The majority of the methods included 2-4 of the Sicily Statement five steps, while few methods referred to all five steps.

**Conclusions:** Collaboration with clinical practice is an advantageous method for teaching undergraduate healthcare students evidence-based practice; incorporating many of the Sicily Statements steps. Journal clubs and embedded librarians should be further investigated as methods to fortify existing methods of teaching.