Background Internationally multiple initiatives are under way (e.g. Germany, Switzerland, UK) to recommend "Clinical Ethics Consultation" and "Clinical Ethics Committees" (CECs) in guidelines.

Objectives These aim to improve ethical discourse and decision making in medicine.

Methods Appraisal of available evidence and literature [1].

Results For CE-Consultation, mostly CECs are implemented. Empirically their acceptance is poor, despite a large "demand". Historically this international paradox is stable ("failure to thrive phenomenon"). Repeated initiatives and "re-brandings" can be identified. They made no tangible difference. Theories and methods are heterogeneous, patchy and contradictory. Their efficacy is unproven. A multitude of issues concerning quality, competence, qualifications, relevance, transparency, independence, conflicts of interests and legitimacy are unresolved.

Discussion From the perspective of clinically and scientifically oriented Ethics in Medicine, present CE-Consultation represents a "cluster" of highly "experimental" tools, techniques and methods. The available evidence consistently suggests grave deficits. In developing medical guidelines and recommendations, professional bodies are duty-bound to adhere to robust, evidence-based processes. Applying such criteria, CE-Consultation and CECs fail to meet all requirements. The apparent intention to apply a "double-standard" to promote a "laudable" medico-"ethical" intention raises grave (not least ethical and scientific) concerns. These are presented and discussed in detail.

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011

METHODOLOGICAL ISSUES RELATED TO MANDATORY COVERAGE POLICIES OF THE BRAZILIAN REGULATORY AGENCY (ANS) TO BE FOLLOWED BY BRAZILIAN PRIVATE HEALTH PLANS (BPHP)

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Context Brazilian private health plans (BPHP) are regulated by ANS mainly through a list of procedures for mandated coverage, some of which are supported by guidelines formulated by Medical Societies. Where guidelines exist quality varies widely. Penalties imposed on BPHP by ANS have frequently involved coverage mandates not supported by guidelines. An example is treadmill testing, which is ordered more often than can be administered to patients due to lack of providers. A dialogue for collaboration on specific issues between Brazil's largest health plan and the regulatory agency started in 2012.

Description of Best Practice Four areas of interest were selected based on 1)high economic impact; and 2) utilisation issues: cardiovascular and genetic testing, neurosurgery and oncologic procedures. ANS interest focuses on new technologies to be addressed in the upcoming revision of the mandatory coverage list. We used the AGREE II instrument to identify inconsistencies in the ANS guidelines. Most weaknesses related to "Rigour of development" issues.

Lessons for Guideline Developers, Adaptors, Implementers, and/or Users Brazilian regulators currently seek improved criteria for regulation of health technologies. Independently developed guidelines are sparsely used by regulators in Brazil. We initiated a public-private partnership which brings methodological

standards to the table such that scientifically sound guidelines may play an enhanced role in Brazilian regulatory policy. Such a step may increase appropriate utilisation of resources and diminish penalties applied by ANS due to requests not supported by scientific- evidence. Full development of the partnership will require participation of the medical societies.

012

DEVELOPMENT OF AN ANALYTIC FRAMEWORK FOR MAKING EVIDENCE-BASED COVERAGE POLICY DECISIONS

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Background Comprehensive health reform legislation in 2009 directed a US state to develop processes by which evidence can be translated into coverage guidance, and be applied rapidly and uniformly across public and private settings.

Context Topics for development of coverage guidance were chosen if they represented a significant burden of disease, had important uncertainty with regard to efficacy or harms, had important variation or controversy in clinical care, significant economic impact and/or were of high public interest.

Description of Best Practice A list of evidence sources was developed and vetted through the Governor-appointed committee that manages the state Medicaid benefit package. An analytic framework algorithm was developed to guide coverage decisions that consider six stepwise decision points: sufficiency of evidence; effectiveness of the treatment and availability of alternatives; treatment risk; cost; prevalence of treatment and feasibility of clinical research studies. The GRADE process was also used to specify the addition of patient values and preferences as a factor. The algorithm allows the committee to determine whether a service is recommended or not, with two levels of strength of recommendation (strong and weak). Using a public process, the committee has reviewed the evidence and has made coverage policy recommendations for 15 topics, to date. Decisions have been applied to Medicaid, and are also made available to other public and private payers.

Lessons for Guideline Developers, Adaptors, Implementers, and/or Users Use of a discreet analytic framework can aid in the development of coverage decisions, and may accelerate the dissemination of research evidence into clinical practice.

013

CASES FOR ACTION: A NEW APPROACH TO ADDRESSING GAPS BETWEEN RESEARCH EVIDENCE AND HEALTH POLICY AND PRACTICE IN AUSTRALIA

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Background In 2012, Australia's peak body for supporting health and medical research established a Research Translation Faculty of 2,500 researchers to address challenges of translating research evidence into policy/practice. The initial focus of the Faculty is developing Cases for Action to address Australia's major health issues through high-level advocacy.

Abstracts

Objectives To work collaboratively with senior researchers to develop compelling cases for actions that could be taken to address the most significant gaps between research evidence and health policy/practice in Australia.

Methods Faculty members will search literature, consult with stakeholder networks and debate issues in developing a paper of published evidence, recommending actions to address each prioritised gap and providing the rationale for prioritisation. Steering Groups will oversee the development of each Case for Action.

Results This presentation will share the experiences and lessons learnt to-date in developing Cases for Action.

Discussion There is a gap between what we know and what we do. Cases for Action will draw on the combined expertise of researchers to systematically consider and prioritise actions to best address these gaps. Possible actions that could be proposed include advice to government about health policy, clinical or public health guidelines, or opportunities to collaborate with strategic partners to leverage investment in health or to provide support in the implementation of heath strategies.

Implications for Guideline Developers/Users The lessons learnt from the Cases for Action process will benefit attendees who are considering how to focus their effort to ensure that healthcare policy and practice best reflects available evidence.

014

CAN HEALTH CARE NETWORKS DEVELOP AUTONOMY OVER DEVELOPMENT AND IMPLEMENTATION OF GUIDANCE WITHIN AN ENVIRONMENT SHAPED BY ACCREDITATION STANDARDS?

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Background Standards for clinical practice enacted by external accreditation organisations can limit the ability of health care organisations to develop and implement evidence-based guidance to improve clinical practice and health system efficiency, and reduce unnecessary testing.

Context As part of a system-wide effort to improve patient quality and access, medical specialists in a large group practice sought to determine whether standard bilateral venous duplex ultrasound (VDUS) scans were medically necessary in patients with unilateral signs and symptoms of deep vein thrombosis (DVT). Typically these patients receive bilateral exams; however, the high number of negative test results in non-symptomatic legs suggested bilateral testing may not be necessary.

Description of Best Practice An evidence review was conducted to evaluate whether unilateral VDUS scanning accurately identifies patients who can safely undergo unilateral VDUS exams in the symptomatic limb without missing a DVT in the unscanned, asymptomatic limb. The evidence review concluded that the number of undetected DVTs in the unscreened asymptomatic limb was very low, suggesting that unilateral VDUS screening in lower-risk patients (i.e., outpatients and patients without malignancy) could be safely performed. Accreditation standards, however, require bilateral screening in all patients, regardless of DVT risk status.

Lessons for Guideline Developers, Adaptors, Implementers, and/or Users Accreditation standards can hinder practice change and limit research for more effective and efficient practices. Some accrediting organisations accept feedback and adjust

standards as new data emerges. Providing evidence-based information to these organisations may initiate changes in standards.

015

TRACKING THE IMPACT OF THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY'S (AHRQ) EFFECTIVE HEALTH CARE PROGRAM THROUGH UPTAKE BY CLINICAL PRACTICE GUIDELINE AND QUALITY MEASURE DEVELOPERS

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Background Public and private funders evaluate health care investments in terms of outcomes and accountability. Citation analysis can approximate the dissemination and impact of funded research outputs.

Objectives Use references in guidelines and measures represented in the National Guideline Clearinghouse (NGC) and National Quality Measures Clearinghouse (NQMC) to track the uptake of AHRQ Effective Health Care (EHC) programme outputs.

Methods 442 EHC-related titles were searched against the full-text corpus of the Clearinghouses. Documents that cited the titles were examined for the context of the citations. References were considered strong when tied to a specific metric or recommendation or noted as important to the guideline's methodology; moderate if discussed in the body of the citing document; and weak if they appeared only in the reference list.

Results 174 individual guidelines and measures cited EHC-related titles (n=341). 50% of the guideline references were strong, 28% moderate and the remainder weak or undetermined (22%). All measure references were strong.

Discussion This analysis has been done annually since 2010 with the numbers of detected citations increasing each year. The method used not only assesses whether a work was referenced in a guideline or measure, but its relative importance to the guideline or measure providing evidence of impact of the EHC programme.

Implications Systematic reviews and other research published through the EHC programme are being used to develop guidelines and measures that meet inclusion criteria for NGC and NQMC. EHC reports may be downloaded and topics nominated at www.effectivehealthcare.ahrq.gov

016

RETIREMENT OF PERFORMANCE MEASURES IN A NATIONAL PAY FOR PERFORMANCE (P4P) SCHEME

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Background P4P schemes, providing financial incentives across a range of improvement indicators, are widely used and can improve health outcomes. These systems can work at different levels, including at the national level. It is important that performance measures (PMs) used in such systems have a robust and up-to-date evidence base to support continued use and they remain fit for purpose; this involves selecting PMs for 'retirement'

Objectives To: i) describe methods used in selecting PMs for retirement, ii) present alternative methods for selecting PMs for retirement.