Background Despite the availability of clinical practice guidelines (CPGs) on the management of diabetes mellitus type 2 (DMT2), optimal control is not achieved in many parts of the world.

Objectives To assess whether recent nationally-endorsed DMT2 CPGs refer to Cochrane reviews that relate to the recommendations of these CPGs.

Methods MEDLINE, EMBASE, guideline agency websites and Google were searched for CPGs written in English on the management of DMT2 in any practice setting published between Jan 2008 – Jan 2013. Four raters independently appraised each CPG using the AGREE-II instrument. The Cochrane Library (CL) was searched for published reviews using ‘Diabetes mellitus, Type 2 ’ [MeSH]. Reviews published one year prior to the CPG’s publication date were considered ‘available’ reviews. Two reviewers independently assessed their relevance for the CPGs’ recommendations.

Results Five CPGs were identified. The highest scores were for ‘clarity-of-presentation’ and the lowest were for ‘applicability’. The CL search retrieved 45 reviews; 7 of them were assessed as irrelevant. The Canadian-2008, the Australian-2009 and the UK-NICE-2008/2009 guidance referred respectively to 80%, 85.7% and 93.8% of “potential” Cochrane reviews. The American-Diabetes-Association Standards of Medical Care in Diabetes 2013 cited 9/38 and the Malaysian 1/18 recent review.

Implications for Guideline Developers, Adaptors, Implementers, and/or Users Despite the increased production of Cochrane reviews, guidelines developers do not consistently refer to them. These documents represent an idealised approach to guideline development. The Council of Medical Specialty Societies (CMSS) was challenged to provide leadership on a pragmatic pathway for developing “Trustworthy” guidelines. CMSS principles include areas that a specialty society should, must or may consider in developing their own guidelines development methodology.

Discussion: Useful instrument for the evaluation of ethical principles in guidelines. Reconciling and applying these standards is challenging for specialty societies who by their very nature may be insular and sometime resource limited.

**CLINICAL ETHICS COMMITTEES (CECs) IN MEDICINE: ENTIRELY EXPERIMENTAL AND NOT YET “FIT FOR PURPOSE”**

**BACKGROUND**

Several national guidelines now recommend or mandate the involvement of CECs in health-care organizations. The extent to which this is actually practiced is unknown. A specific aim of the study was to determine the current role and activity of CECs.

**METHODS**

A national survey was conducted of CECs in England. The questionnaire was based on a model developed by the International Network for Bioethics (INBio) and ethical principles in guidelines and developed an instrument for evaluation of ethical principles in guidelines based on the AGREE II instrument.

**RESULTS**

The survey was completed by 144 responses representing a range of hospitals, universities, military medical services and the NHS. The results indicated that there was considerable variation in the involvement and activity of CECs. Many CECs reported that they were not actively involved in the development of guidelines and that they were not consulted or involved in the implementation of guidelines. A significant number of CECs reported that they were not involved in the evaluation of ethical dilemmas. A pilot version of case reports for some domains was developed. The questionnaire covered a range of ethical dilemmas. New domain on equity was added. A pilot version of case reports for some domains was developed. The questionnaire covered a range of ethical dilemmas. New domain on equity was added.

**DISCUSSION**

The results of this survey indicate that there is considerable variation in the involvement and activity of CECs. Many CECs reported that they were not actively involved in the development of guidelines and that they were not consulted or involved in the implementation of guidelines. A significant number of CECs reported that they were not involved in the evaluation of ethical dilemmas. New domain on equity was added. A pilot version of case reports for some domains was developed. The questionnaire covered a range of ethical dilemmas. New domain on equity was added.
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.

REFERENCE

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

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 discrete analytic framework can aid in the development of coverage decisions, and may accelerate the dissemination of research evidence into clinical practice.

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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Background 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. Penalities 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 translated into coverage guidance, and be applied rapidly and uniformly across public and private settings.

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.