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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. This variation in the uptake of relevant Cochrane reviews was not directly related to the rigour-of-development domain score.

Implications for Guideline Developers, Adaptors, Implementers, and/or Users Despite the increased production of Cochrane reviews, guidelines developers do not consistently refer to them. This needs to be explored and the practical means for maximising their uptake should be entertained.

008 PRINCIPLES FOR THE DEVELOPMENT OF SPECIALTY SOCIETY CLINICAL GUIDELINES

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Background In 2011 the Institute of Medicine (IOM) issued a report “Clinical Practice Guidelines We Can Trust” and “Standards for Systematic Reviews”. 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 representing 38 societies and the Clinical Practice Guideline (CPG) group is the largest of nine component groups.

Context The IOM Trustworthy report contains 20 standards addressing transparency, conflict of interest and other recommendations. Guidelines International Network (GIN) published a set of 11 key components for high quality and trustworthy

guidelines. Reconciling and applying these standards is challenging for specialty societies who by their very nature may be insular and sometime resource limited.

Description of Best Practice The CPG writing group including representatives from AAD, AAFP, AANS AAP, ACC, ACP, ACOEM and SCCM developed a set of 80 principles that were approved as policy by the CMSS Board in late 2012. These Principles include areas that a specialty society should, must or may consider in developing their own guidelines development methodology.

Lessons for Guideline Developers, Adaptors, Implementers, and/or Users These areas correspond to those outlined by the IOM and GIN but are intended to detail more specific issues that specialty societies are confronted by such as balancing panel expertise and potential bias. The overriding CMSS concepts include a practice approach to extensive evidence review, transparent conflict of interest management and broad stakeholder involvement. The CMSS Principles are intended to be interpreted transparently by member societies developing clinical practice guidelines.

009 ETHICAL PRINCIPLES IN GUIDELINES, IT IS NEVER ENDING STORY

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Background Bioethical principles should be an integral part of all guidelines. Recently, there has been a movement towards ethical principles to be explicit in guidelines. They should be systematically evaluated.

Objectives We have done a systematic review on ethical principles in guidelines and developed an instrument for evaluation of ethical principles in guidelines based on the AGREE II instrument.

Methods The Questionnaire and User’s guide have been developed and tested. The questionnaire covers basic ethical principles, i.e. respect for autonomy, beneficence, non-maleficence and justice, as well as other very important issues such as health professional-patient relationship and inter-professional collaboration. The last question is whether a particular CPG contains examples of ethical dilemmas. New domain on equity was added. A pilot version of case reports for some domains was developed. The instrument will be disseminated, implemented, evaluated and updated if needed.

Results Instrument for evaluation of ethical principles in guidelines.

Discussion: Useful instrument for the evaluation of ethical principles in guidelines has been developing.

Implications for Guideline Developers/Users The instrument can be used during guideline development process as well as during implementation and for evaluation of the quality.

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

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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

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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.