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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10:1136/bmjqs-2013-002293.42

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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10:1136/bmjqs-2013-002293.43

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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10:1136/bmjqs-2013-002293.44

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.