Evidence-based medicine: Development and implementation of guidelines in oncology

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What are evidence-based clinical practice guidelines?

Clinical practice guidelines (CPGs) are defined as "*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances*" [1]. CPGs are a tool for transferring evidence from clinical research into practice and for influencing practitioner's attitude.

Evidence-based CPGs are intended to: (a) assist practitioners in appropriate clinical decision making, (b) improve quality of healthcare and outcomes for patients and (c) influence national policies for efficient allocation of resources and for better delivery systems [2]. In other words, to provide the right care, at the right time, for the right person and in the right way [3].

Worldwide, professional associations, institutions or other scientific bodies are developing CPGs in oncology at an international, national or regional level. Such groups intend to provide vital networks for CPG dissemination, implementation and evaluation.

CPGs should follow several pivotal steps in order to be of high-quality, methodologically correct and adequately implemented. This strategy includes the evidence-based development of CPGs, the reporting, the assessment, the adaptation and the implementation/dissemination process.

How are clinical practice guidelines developed?

The development process of CPGs is not identical among the existing guidelines. The differences are based on methodological issues i.e. multidisciplinarity, structure systematic review of evidence, production process, public consultation and validation phase.

Not all CPGs follow a systematic review of evidence by using an explicit search strategy and online databases. Some CPGs are produced through a narrative literature search not fulfilling the systematic review process [4].

Concerning the systematic review of evidence, this is performed through the following steps: (a) formulation of clinical question/problem, (b) support staff performs initial search, identifies relevant papers, discards irrelevant or duplicate papers and obtains full-texts, (c) expert taskforce then identifies relevant papers, (d) expert taskforce and methodological experts tabulate and synthesise the evidence and (e) expert taskforce proceeds to GL drafting. To fulfill this process administrative personal, such as support staff, statisticians, IT experts and methodological experts, have frequent meetings with the expert task force, and a time period of 2–3 years is required.

How are clinical practice guidelines disseminated and implemented?

Implementation of CPGs by simple passive dissemination is largely ineffective.

CPGs should be properly and effectively implemented so that they will be adequately incorporated into routine clinical practice. The implementation of evidence-based CPGs facilitates knowledge uptake, critical for practice change, and ultimately leads to better patient-focused care.

One way to make implementation easier is through computerised and visualised activities such as direct mailing, publication in journals or newsletters, organisation or sponsoring of conferences, workshops or consensus processes, training by opinion leaders, publicising to patients or the public, integration in recertification or licensing examinations, promotion in peer reviews and use of computer technology or marketing [4,5].

How can clinical practice guidelines be assessed?

Sometimes, existing CPGs may vary with regard to the methodology, dissemination and implementation,

leading to inconsistencies and practitioner or patient confusion. Therefore, a framework providing quality assessment is very important, taking into account the benefits, harm, costs and practicalities of CPGs.

The AGREE Instrument (Appraisal of Guidelines Research and Evaluation), established in 1998, evaluates the predicted validity of CPGs by assessing the quality of the process of development and reporting.

The principles of the AGREE Instrument are to: (a) develop compatible approaches for the creation of clinical guidelines, (b) establish a structure for the appraisal and monitoring of clinical guidelines, (c) define quality criteria relevant to guidelines and (d) promote and encourage the diffusion of these criteria through international exchanges and collaborative links.

The instrument contains 23 items grouped into six domains (scope and purpose, stakeholder involvement, rigor of development, clarity and presentation, applicability, and editorial independence [6].

Can clinical practice guidelines be adapted?

Since a large number of organisations worldwide produce CPGs on similar or the same topics, it has been proposed that unnecessary duplication of CPGs could be anticipated if existing guidelines were adapted rather than developed *de novo*.

Taking into consideration that both cultural and organisational differences could exist among countries, a "*trans-contextual adaptation*" strategy has been suggested by the ADAPTE framework.

The ADAPTE framework "*provides a systematic approach for the adaptation of CPGs produced in one setting to be used in a different cultural and organisational context*". The ADAPTE collaboration "*is an international collaboration of researchers, guideline developers, and guideline implementers who aim to promote the development and use of CPGs through the adaptation of existing guidelines. The group's main endeavour is to develop and validate a generic adaptation process that will foster valid and high-quality adapted guidelines as well as the users' sense of ownership of the adapted guideline*" [7].

Clinical practice guidelines in oncology

Up til now a considerable number of oncology practice guidelines were developed worldwide either as drug or practice related. In Europe, during the last two decades, both governmental and professional derived guideline programmes have been produced, sometimes leading to duplication of effort. In 2006, the CoCanCPG (Coordination of Cancer Clinical Practice Guidelines), an EU programme, was launched as a Coordination Action under the ERA-NET scheme to reduce duplication and fragmentation in cancer guideline development and research [8].

An international assessment of 32 oncology guidelines among 100 CPGs from 13 counties, using the AGREE Instrument, has shown that oncology CPGs were of better quality than others. More specifically, oncology guidelines had significantly higher scores on rigor of development [9].

In a membership survey of 1500 ASCO members and 131 Health Maintenance Organisations (HMOs) on the value and implementation of ASCO guidelines, it was demonstrated that ASCO guidelines are generally highly supported by physicians and HMOs [10].

From the evaluation of dissemination of ESMO Clinical Recommendations during the last 8 years it has been observed that: (a) in the 6 month period (May 2008-October 2008) the downloads of Oxford Journals (Annals of Oncology Supplement) totalled 60,330 and (b) the average evaluation scoring from the last five ESMO Congress interactive sessions increased from 3.78 to 4.48 (rating 1–5). Also, data from the questionnaire analysis of an electronic survey of more than 1500 ESMO members during the last four ESMO or ECLU Congresses demonstrated that 71–90.7% of ESMO members think ESMO CRs are a helpful source of advice, 72–90.4% believe they are good educational tools, 84–94.1% believe they intended to improve quality of care and 59.2–74.3% think they are not actually reducing physicians autonomy [11].

In a recent article, however, it was reported that the quality of some systematic reviews used to build guidelines were of poor underlying documents. A QUOROM-based check list was applied to the systematic reviews cited in a sample of guidelines on breast and colon cancer prevention and therapy used by the 11 main European and non-European institutions (NHMRC, CCOPGI, NCCN, SIGN, ASCO, ESMO, ACG, NCI, RCSE, RCRCOIN and COR-CPO). From the 80 evaluated reviews, 29% did not match the definition of systematic review, 21% had unclear searching methods, 50% were systematic and 70% were of low or very low quality. The authors conclude that oncologists should be aware that some CPGs, due to methodological problems, could be based on non-high quality literature sources [12].

Heterogeneity in the development methodology, structure, content, implementation and dissemination of cancer guidelines is a vital issue. In another prominent paper, nine well known CPGs were selected (ASCO, ESMO, NICE, SIGH, START, NHMRC, NCI,

NCCN and CCO) and three tumours (advanced breast, lung and colon cancer) were scrutinised. Analysis of the data showed diverse heterogeneity in development, structure, target user and end points among the nine examined CPGs [4].

Although there are different needs to be met by oncology CPGs in various health systems and societies, among health professionals, patients or organisational structures, there is no doubt that the end point should focus on the development and implementation of high quality CPGs, probably through an international collaborative scientific process.

Conflict of interest statement

None declared.

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