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Guidelines and clinical pathways. Is there really a difference?

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A B S T R A C T

Quality Design Activities of Good Clinical Practice guidelines or protocols and clinical pathways (CP) include those clinical plans intended for the patients with a particular disease. They must be based on the clinical evidence, the analysis of the process, and the consensus of the professionals involved in the care of the patient.

When these are introduced to surgical professionals, they usually say that they do not understand the the difference between CP and protocols or guidelines. In fact we are speaking quality design activities with the same objectives of decreasing the unjustified variability and helping in the decision making on a specific clinical problem.

In this work we attempt to show the differences by defining what is understood by a clinical pathway and protocol or guideline.

Guías y vías clínicas, ¿existe realmente diferencia?

Palabras clave:
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Guía de práctica clínica
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R E S U M E N

Las actividades de diseño de la calidad de guías de práctica clínica (GPC) o protocolos y vías clínicas (VC) comprenden aquellos planes asistenciales previstos para los pacientes con una determinada enfermedad. Se deben basar en la evidencia científica, en el análisis del proceso y en el consenso de los profesionales que participan en la atención del paciente.

Es habitual cuando se plantea a los profesionales de la cirugía introducirse en esta problemática que afirmen que no entienden cuál es la diferencia entre VC y protocolos o GPC. De hecho, estamos hablando de actividades de diseño de calidad con los mismos objetivos de disminuir la variabilidad injustificada y ayudar en la toma de decisiones sobre un problema clínico concreto.

En este trabajo vamos a tratar de establecer diferencias y definir qué se entiende por VC y por protocolo o GPC.

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One of the main problems characterising our health systems is the great variability of clinical practice in the care provided to the population. The variability of clinical practice means that patients with a similar clinical condition receive different care. There are also inexplicable differences both in terms of hospital stay and of diagnostic and therapeutic procedures. This raises concern among managers, health professionals and patients, and it questions the fact that clinical practice is based on scientific knowledge and that the use of medical resources is determined by the patients' actual needs.

To minimise variability, quality design tools have been created which, ultimately, aim to avoid possible problems and to ensure a predetermined outcome.

The special nature of surgical practice means that professionals, even when working in teams, should act almost continuously with full autonomy and responsibility. However, standardisation of procedures should be carried out in order to allow team members to coordinate. However complex, this standardisation of the professional work can be so complete that in repeated surgical practice it can lead to a certain degree of automation. This behaviour allows a process to unfold in stages, which could be formalised in the form of clinical pathways (CP) or clinical practice guidelines (CPG).

The quality design practices (CP or CPG) include those care plans provided for patients with a certain disease. They should be based on research-based scientific evidence, on the analysis of the process to identify its weaknesses and on the consensus of the professionals involved in patient care for all such organisational aspects.

Various terms exist in the medical literature, which are commonly used as synonyms (CPG, clinical protocols, procedure manuals, quality standards, etc.). They all have in common a set of principles or recommendations, created to provide patients and professionals the appropriate decision-making powers in specific clinical situations.

When surgery professionals are asked to familiarise themselves with this issue, they usually state that they do not understand the difference between CP, protocols and CPG. In fact, we are talking about quality design practices with the same goals, i.e. reducing unjustified variability and helping in the decision-making of a particular clinical problem.[1]

We shall try to differentiate and define what is meant by CP, protocol and CPG.

Clinical protocols or practice guidelines

CPG (clinical practice guidelines)[2] is the more general term proposed by the Institute of Medicine (IOM), and is increasingly coming into use. The terms set out explicitly as synonyms for CPG are "protocols", "practice parameters", "algorithms" and "descriptive tools", or a set of related criteria. CPG is gradually replacing these and other terms, although they still coexist. The reason we often use the term "protocol" is that it is still the best known and most traditional among Spanish health professionals.[3]

It is a statement of systematically developed principles or recommendations to facilitate appropriate decision-making in patient care in specific clinical situations.

When designing a CPG, it is necessary to describe in detail the health problem for which a protocol will be created. Thus, among other aspects, the protocol's choice of subject can be based on the most prevalent disease, on the disease that demands more services and on previously identified problems concerning care variability. An example is the survey on the status of diagnosis and treatment of colorectal cancer performed in public hospitals in the Valencian Community as a step towards the implementation of CPG, which was created by the Valencian Society of Surgery[4,5] for this disease.

Once the process to be formalised has been identified, as a general rule, we first need to carry out the process of search, assessment and practical translation of the evidence for each of the decisions ("clinical questions", according to the EBM) that we wish to include in the protocol.[3]

In laying down its definition of CPG, the IOM identifies eight attributes with which all CPG must comply with. Four of these attributes refer to development: *1) clarity in the text; 2) explicit documentation and methodology; 3) multidisciplinary development; and 4) periodic updating*. The other four attributes refer to the guide's contents: *1) validity of the guide's recommendations; 2) applicability to patients; 3) flexibility based on guidelines that avoid unjustifiable dogmas; and 4) reliability and reproducibility*.[6]

Of these, the most important attribute is "validity". Its presence indicates that when the protocol is applied there is a high probability of achieving the intended results. Validity is verified by assessing the scientific evidence that justify the recommendations. The method used to identify and review the scientific evidence on which the method is based should be specified. The information sources used should be included, and there should be a relationship between evidence and recommendations. Finally, recommendations should take into account benefits, risks and costs, in light of scientific evidence.[3]

The presence of these eight attributes in a CPG would lend much credibility to its recommendations and its possible use, which would mean the achievement of the desired clinical results.

The best assessment of a CPG is, ultimately, to ensure that its use produces the desired effect, i.e. an assessment of its effectiveness. For this, we would need to choose appropriate indicators in relation to the results that we want to optimise (fewer infections, fewer deaths, etc.). Nevertheless, prior to this selection, we should decide whether a CPG is suitable for use in our work. To do this, we need to assess whether a CPG is of reliable quality. Many instruments have been used to assess the quality of CPG. The most significant came from the IOM in 1992,[6] an instrument which is comprehensive but generally difficult to apply in a normal way. For this reason, we have used a subsequent version of a British adaptation within a project funded by the European Union (AGREE project), which has culminated in the creation of a new version with 23 items based on values on a scale of four response options (from "strongly agree" to "strongly disagree") for each item valued. The AGREE tool is available in several

languages, including Spanish, and it can be downloaded at www.agreecollaboration.org.[7,8]

The most important limitations of CPG are, firstly, the fact that they do not generate primary data, as they are developed from knowledge provided by clinical research and studies on the effectiveness of health technologies. Secondly, another significant limitation is the fact that if a document of recommendations changes the actual medical practice, and if it ultimately improves the clinical results of a given surgery, it may be seen as a step too far.[9]

It may seem that creating good clinical protocols is an extremely complex task, which is unlikely to be available to any group of healthcare professionals or small institutions. This has been and still is a very contentious topic. The creation of protocols can indeed be complex and costly, which has led multiple state agencies and professional and scientific associations of all kinds to address its systematic development within the framework of large-scale projects, which is assumed as part of their mission as institutions. The proliferation of CPG has been spectacular. All initiatives are valuable and can be used as a useful reference for their local adaptation. However, experience has so far produced some useful lessons with great practical use. First, the quality of protocols is not strictly dependent on those who develop them, but on the methodological rigour with which they are developed. Unfortunately, if the authors of the protocol are a scientific society or a state agency, this does not necessarily guarantee quality. Second, the use of protocols requires at least one local adaptation. However, we lack a sense of "belonging" that does not support fully developed protocols at higher levels.[3]

In Spain, most of CPG have problems: they do not associate specialised care with primary care; they offer a wide variability in quality, even with contradictory proposals for the same process; they usually only consider the effectiveness and not the cost-effectiveness; and, above all, they do not consider patients' preferences.

Clinical guidelines

Essentially a CP is a comprehensive protocol with all the implications for protocols or CPG we have seen. Zander et al.[10] described CP as "clinical management tools that organise and determine the sequence and duration of all types of interventions of health personnel (surgeons, nurses, administrators) and of departments (surgery, anaesthesia, digestive) for a particular type of case (e.g. surgery)." In addition, other authors have included the case of a disease with a predictable clinical course (e.g. laparoscopic cholecystectomy or thyroidectomy), which can be strategically important as a first approach, although more controversial as an absolute standard.

The process of developing CP does not differ essentially from that of CPG, while the peculiarities of their creation are derived mainly from their comprehensiveness and the need to coordinate all the activities of the entire team, from administration staff and orderlies to the most specialised unit.[11]

Another difference of CP from CPG is that various specific clinical protocols (e.g. protocol for diagnosis and follow-up of colorectal cancer within the CP) should usually be coordinated. In addition, recommendations or requirements should also be included, many of them with any previous evidence. CP should therefore be "created" on the basis of what we know to be happening in a given process (e.g. we decide to start oral tolerance following cholecystectomy at 6 hours after surgery).

The most common form of presentation adopted by CP is that of a temporary array. In the columns, we place time divided into days or even hours and the patient's location. In the rows, we carefully distribute all the actions and interventions (assessments and care, measurements or laboratory tests, medical treatments and nursing care, medication, activity, physiotherapy, diet, information and support given to the patient or their family and hospital admission or discharge criteria). The documents of a CP constitute a temporary array: the information form for the patient or their family, check sheets, the patient satisfaction survey or that of their family, measurement indicators and, optionally, the standard treatment form.

CP contribute a range of benefits, such as integration and coordination of the teams, improved care with increased participation and involvement of the patient in the care received and greater involvement of professionals and organisations in continuous improvement. On the one hand, these benefits serve as a clinical audit through the development of criteria, indicators and standards, and, on the other hand, they function as a teaching and research tool.[12,13]

Setting up a CP depends on the opportunities available in the environment where it will be developed. CP cannot be extrapolated from one context to another. They can only be used as a guideline or guidance for the development of another CP. However, we believe that modifications should always be required to suit the new context.

The assessment of a CP is an indispensable aspect for professionals to be able to improve the process. The assessment should be scheduled accordingly and presented to the department for their knowledge, so that the service members can be involved in the method, monitoring and improvement process of the CP. It is essential that both medical and nursing staff[1] are involved in the assessment. To achieve the ultimate objectives, it is necessary to create some milestones by which indicators can be defined, especially if the results do not conform to the standards or the quality levels that were set previously.

Currently, no one works on CP methodology without the use of computers. This use can range from the simple development of a CP to the level of integration of the documentation with automatic alerts. Between them, there are different levels of complexity of computerisation. In most departments that use CP, at least the development and exploitation of the results of the CP are usually computerised.[1]

Published data on CP show a number of benefits derived from their application: the reduction of hospital stay; reduced costs; reduced admissions to ICU; reduced complications; increased patient satisfaction; reduced readmissions;

reduced invasive tests; reduced laboratory tests; increased outpatient treatment; reduced use of medication and blood products; and reduced operative time. As noted above, efficiency is the key to achieving the best results. However, few studies have been conducted with scientific rigour. This is largely due to the extreme difficulty in assuming that within the same department the control group will not be conditioned by habits secondary to the implementation of the CP. Consequently, almost all published studies use historical series of patients as a control group, leading to the failure to control other factors that could influence various periods of time.[11-13]

We can always argue that all these reviews lack cases where the outcome has been negative, or without any improvement, because they are not published. Nevertheless, positive evidence is now so abundant that there seems to be no doubt in attempting to develop and implement CP.[11]

The implementation of CPG and CP in the context of a surgical department should help to harmonise the criteria to improve results and assess them. This in turn allows for the production of publications and communications with scientific rigour and, at the same time, for the improvement of efficiency with regard to care. These procedures do not increase paperwork nor do they limit the surgeon's clinical performance or reduce the individuality of the clinical work, as they need to be flexible to suit the needs of an individual patient. However, the working groups that want to introduce these guidelines in their work environment should plan this well and should devote the necessary time. Finally, before attempting to implement any of these procedures, these groups should decide whether they are worth the effort.[14]

Conflict of interest

The authors affirm that they have no conflicts of interest.

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