

THE SIGNIFICANCE OF CLINICAL PROTOCOLS IN SURGICAL DISCIPLINES

Georgios I. Tagarakis^{1,2} Costas Dikeos¹, Fani Tsolaki², Marios Daskalopoulos², Petros Bougioukakis³, Nikolaos Tsilimingas², Nikolaos Polyzos¹

1-Department of Social Administration and Political Science, Democritus University of Thrace

2-Department of Cardiovascular and Thoracic Surgery, University of Thessaly, Larissa, Greece

3-Department of Cardiac Surgery, Bad Neustadt a.d. Saale, Germany

Corresponding author: GI Tagarakis, MD, MSc, PhD, tel-+306970806717, e-mail: gtagarakis@gmail.com

Abstract. In the current article we aim to describe and show the significance of evidence-based medicine (EBM) in surgical disciplines, as this is expressed through the application of clinical protocols and clinical indicators of quality and outcome. We also probe the questions of clinical protocols assisting in hospital management, and moreover of the political and political-ethical issues for the implementation of clinical protocols in the pursuit of better hospital management. Clinical protocols are guidelines with broader scientific acceptance, helping physicians, surgeons and health staff in general, to perform a procedure or combination of procedures with the best possible results at the lowest possible cost. Clinical indicators are implemented in order to assess the achieved results; such indicators are in-hospital mortality, frequency of adverse events such as stroke or venous thromboembolism, duration of hospitalization, incidence of reoperation, incidence of re-admittance etc. The article also includes, for reasons of better understanding, two examples of clinical protocols (coronary artery surgery and total hip arthroplasty).



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INTRODUCTION

The improvement of quality in medical services and the constant need for better clinical results with lower expenses have led since about the mid-1980s to the genesis of evidence-based medicine (EBM). This term corresponds to the performance of medical or surgical procedures under widely accepted standard conditions, and in such a way, that the best possible results with the lower possible costs can be predicted and thus, guaranteed [1-7].

In this sense protocols become less of a medical and more of a managerial tool, whereas management of health services provision, becomes in its turn an important element of health care policy. Prior to any discussion about protocols, we should therefore access both key terms in this approach, i.e. management and health policy (and indeed its goals that have political and political-ethical dimensions within the state-society-citizen relation) as well as assess their relation. In a nutshell management can be taken as the use of (limited) resources (human; material: either durable or consumable; intangible: energy, other services etc) as to achieve certain goals, within a given timetable, alongside a possible accountability for this endeavour. It thus encompasses issues such as cost-benefit analysis and approaches, input-output comparisons and certainly processes like: planning, organizing, directing (and in cases commanding), leading, administering, controlling (and as far as expenses is under question controlling) etc. and moreover the combination and merging of these functions, actions, activities within an organization and indeed phases within a project [8-15]. The article is thus divided into three sections, the first dealing with political, political-ethical (subsection 1a), and managerial (subsection 1b) aspects of clinical protocols; the second examining clinical protocols themselves via a general overview (2a), a discussion of outcomes and of relation to Diagnosis Related Groups (2b), and a presentation of clinical protocols examples for certain operations (2c); and a short third section discussing the arguments bringing medicine, management and political arguments together.

1. POLITICAL, POLITICAL-ETHICAL AND MANAGERIAL ASPECTS OF IMPEMENTING CLINICAL PROTOCOLS.

Returning our focus upon health-care provision and the use of protocols, we can observe that they can also assist in, (apart of planning and directing), one of the key aspects of controlling, that is assessing of procedures. Therefore they can assist in the efficiency of services offered, viz. better management, a question to be probed in subsection 1b. Having said this, it needs to be mentioned that it seems that at least in the past, Greek doctors were overlooking issues of management in the application of their tasks [16-18].

On the other hand, the interests of patients should not be overlooked, since they are the weaker and more vulnerable part in the entire systems of health-care provision [19], that should be protected within the state-society-citizen relation a question to be briefly probed in the following subsection 1a.

1a. Political and Political-Ethical Aspects; a brief overview.

The question set above turns our interest to a political aspect that is not just the significance of protocols in health-care provision and its efficiency, but the issue of (efficient) health-care provision as part of the state-society-citizen relationship. Such an approach would and should commence by reminding of the WHO definition of health [20] and also its 'widening' by Üstün & Jakob [21] who relate health to a sound, dynamic condition providing humans with potential, factors elevating health and health-care provision indeed, to a human right by itself, or to a facilitator of human liberty, dignity and wellbeing. Therefore, clinical protocols should be seen as a tool to assist doctors not just in their day-to-day activities and duties, but also to the betterment of health-care provision overall in order to enhance human welfare. In other words, healthcare provision and its priorities are based upon substantive judgments, that in their turn are based upon values, such as social justice and other "wider social objectives" as Biron et al set it [22] asking "what are the relevant goods to attend to when setting priorities in healthcare?".

Approaching such a question can be assisted inter alia by the work of Vic George on key welfare theorists [23] that is ranging from Epicourian 'pleasure', to Hobbesian 'safety'; and from Payne's radical demands for universal coverage of needs, to Green's 'positive liberty', an idea taken also be I. Berlin in his 'Two Concepts of Liberty'. Such an understanding of 'positive liberty' can be claimed that is closely related to J. S. Mill's concepts of 'utility', 'happiness' that is "the absence of pain", a "thing[] desirable as end",, to which health-care contributes since "the medical art is proved to be good by conducing to health; but how is it possible to prove that health is good?" since health is an "ultimate end", 'liberty' and mainly 'dignity' being damaged by 'calamities' such a 'disease' that harms lives [24]. Additional arguments in this line can be sought in the work of Aristotle on the construction of political society towards the goal of 'good-life' [25], or Rousseau on preservation of the members of the 'social contract' through the implementation of the 'general will' being its (the social contract's) ultimate goal [26]. Protocols therefore, further to their therapeutic (giving 'good' results such as shorter in hospital stay, less re-admissions) and managerial usefulness, (cost reduction, non-duplication of services), can also be seen as means towards ethical-political ends that (at least should) direct modern states, whereas protocols can also assist in cost reduction, viz. re-allocating limited resources towards other goals.

1b. Managerial Aspects; a brief overview.

Whatever the aim of their designers and implementers (medical, managerial or other), or analysis of aiming and reasoning by commentators (managerial, political-ethical or other) the application of EBM and protocols has been gaining ground in all fields of medicine (possibly giving medical processes a project management profile), despite the biological diversity that makes standardization and prediction difficult. It should be however emphasized that herein lies a difference between



project management, that plans and implements the use of materials and resources in a certain usually strictly binding time-schedule (that can reduce costs and enhance control) on the one hand; and EBM and medical protocols that have to do with the said diversities, on the other, therefore more flexibility is vital in the latter case. Nevertheless, this difference does not fully annul the importance and validity of using protocols in a pursuit of better health-care management. In other words, clinical protocols may be more or less binding, and they may have institutional, local, national or international validity. They often have the form of a checklist, containing steps that have to be followed in order to secure the proper performance of a medical procedure [8, 9].

This is the case especially in surgical disciplines, where the aggressive form and the definitive nature of treatment need to be controlled and standardized. A characteristic example of EBM with augmented applications in clinical medicine consist the clinical protocols, whose significance and details are analyzed in the following paragraphs.

2. CLINICAL PROTOCOLS

The structure, aims, significance and contribution of clinical protocols is approached by a general overview (subsection 2a), a discussion of their relation to performance outcomes alongside their relation to Diagnosis Related Groups (subsection 2b), and a presentation of examples of clinical protocols (subsection 2c).

2a Clinical Protocols; an overview

Clinical protocols consist guidelines regarding and aiming at the "lege artis" performance of a diagnostic or therapeutic procedure or series of procedures that may be combined in order to reach a diagnosis or achieve treatment of the patient [8, 9]. "Lege artis" has the meaning of the avoidance of errors, complications and unjustified variations in the final result as well as of the avoidance of unnecessary expenses. Clinical protocols may be more or less binding, and they may have institutional, local, national or international validity. They often have the form of a checklist, containing steps that have to be followed in order to secure the proper performance of a medical procedure. The clinical protocols are based on widely accepted principles, which could be result of: i) randomized controlled trials or meta-analyses (level of evidence la), ii) at least one randomized controlled trial (level of evidence lb), iii) evidence from at least one well designed not randomized controlled trial (level of evidence lla), iv) at least one well designed experimental trial (llb), v) evidence from case, correlation, and comparative studies (III), vi) evidence from a panel of experts (IV).

We should at this point emphasize the fact that a weaker level of evidence, for example IV, does not necessarily mean that the related guideline is not secure enough. For example, the treatment of a microbial infection with antibiotics is based on experts' opinion, because it would be impossible to leave a group of patients without treatment as a part of a doubleblind randomized study, due to ethical reasons.

2b. Clinical Indicators/Outcomes of Quality and Performance

The implementation of clinical protocols has begun during the 1990's in the United States and has rapidly spread to Europe and to the rest of the world. Clinical protocols are planned to involve not only the activities of physicians, but also of other health-related professionals, such as nurses and physical therapists [8-12]. Each clinical protocol is tightly related to clinical indexes of quality and performance, which are parameters that are used in practice in order to evaluate the results of implementation of the protocols [13-15]. Such indicators can be, according to the kind of procedure: mortality, incidence of adverse events, such as preoperative myocardial infarct, stroke or pulmonary embolism, duration of hospitalization, incidence of reoperation for surgical procedures or readmittance to the hospital after the initial discharge, etc [13-15].

The application of a clinical protocol and the related clinical indicators is also tightly connected to the Diagnosis Related Groups (DRG's). These were for the first time introduced by Roger Fetter and John Thomson of the University of Yale in the 1980's. They were applied for the first time in the State of New Jersey and later on spread to the rest of the U.S. and to the other countries [16-19]. Each DRG includes a number of closely related procedures, corresponding to closely related diseases as the latter are described by the ICD list of the World Health Organization [20]. The DRGs aim at the systemization of medical procedures, so as to make the billing and logistics of health-related activity more practical to calculate and easier to administer. The DRG's are nowadays the basis of the billing system in hospitals throughout Europe, eg. in France, Germany, Denmark, Portugal and Greece [18, 19].

2c. Examples of Clinical Protocols

We herein present two clinical protocols regarding coronary artery bypass operation (CAB) and total hip arthroplasty (THA)- (Tables 1 and 2). They have a form of checklist, and include all important points that need to be followed and cannot be forgotten prior, during and after the operation and until discharge. The physician/surgeon, or other members of the staff, responsible are also stated as a guarantee that all procedures will be kept according to the plan. The significance of the protocol can be made evident through some simple examples: if the preoperative interruption of aspirin treatment prior to CAB does not take place, significant perioperative bleeding with augmented need for transfusion and a higher incidence of reoperation may occur [21, 22, 23]. If, on the contrary, aspirin treatment is forgotten and not reinstated after surgery, significant increase in the incidence occlusion may occur, as aspirin is the main antiplatelet agent used for the secondary prevention after CAB [24, 25].

Similarly, if prophylactic treatment [26, 27, 28] against venous thromboembolism (VTE) is not administered after THA, significant increase in the risk for such and pulmonary embolism will occur. The incidence of VTE varies even with adequate treatment between 1-1.5% [29].



Such errors can easily occur, especially in departments and hospitals that have an overload of work and are understaffed, this practically means everywhere! The clinical protocol does not intend to teach the physician/surgeon his/her job; it aims at guiding him/her securely through the accepted paths of the undertaken procedure. The related indexes of outcome can in addition function as a quality control of the performed procedure.

3. DISCUSSION; Bringing the Political, Managerial and Medical Arguments Together.

The quality of medical and especially surgical services has been steadily improving during the last decades, partially also due to the standardization of medical procedures, often in the form of clinical protocols. What the protocols really offer in the everyday routine, is the step by step order of interventions/procedures within a greater surgical procedure, so that manoeuvres important for the patient are not forgotten, something that can quite easily occur in hospitals with overload of work, hospital that are also frequently understaffed, as it is common in the global financial crisis era [30]. Clinical protocols and clinical indexes of outcome and performance are an extra guarantee for the well being of the patient besides the medical expertise and experience of the attending team, and therefore may have dual (positive) repercussions both in hospital management, and in enhancing the state-society-citizen relation through offering 'positive freedom', 'dignity', 'well-being' etc., via better medical attendance. Hopefully, the implementation of clinical protocols and evidence-based medicine will further expand, always for the sake of our patients.

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Table 1. CLINICAL PROTOCOL FOR CORONARY ARTERY BYPASS SURGERY

Responsible staff and their approval with signatures: S: member of the surgical team, A: anaesthesiologist, DN: department nurse, AN: anesthesiology nurse, ON: operating room nurse, Ph: physical therapist

Preoperatively:

-Is full lab control available? (blood count, biochemical control, X-Ray, cardiac echo, coronary angiography, carotid arteries triplex) S

-Is written informed consent available? S

-Control of surgical indication S

-Is antiplatelet/anticoagulant therapy properly interrupted? S

-Does the patient have any allergies? S

-Preoperative preparation: bath, shave, etc. S, DN

-Is the patient a diabetic? Proper adjustment of treatment S

-Are there any other special problems (thyroid disease)? Adjustment of treatment- related consultation S

Operation day (prior to the procedure)

-Patient identity control S, DN, AN, ON

-Confirmation of type of procedure S, A

-Removal of false teeth, rings, other metallic objects DN, AN

-Availability control for blood products S, A

-Special preparation-augmented vigilance in patients with reported difficulties in intubation A

Postoperatively

Operation day

-Can the patient follow a fast track extubation procedure? S, A

-Continuous monitoring, regulation of fluid/electrolytic balance, antibiotic treatment/analgesia, b-blockers/antiarrhythmic drugs, augmented level of clinical suspicion for ischemia and tamponade S

-1st postoperative day- removal of chest drainage, transport to the department or high dependency unit-removal of bladder catheter-light alimentation S-the patient should seat on the side of the bed/ stand Ph

-Initiation of treatment with low molecular weight heparin, initiation of treatment with antiplatelet agents (Salospir-Plavix)progressive adjustment of treatment per os S

-2nd postoperative day-mobilization, respiratory gymnastics Ph

-4th postoperative day- removal of central venous lines S

-6th postoperative day removal of epicardial electrodes S

6 th -8th postoperative day discharge S

Complications – Special Remarks



Relevant Clinical Indexes

In-hospital mortality, perioperative Myocardial Infarct, perioperative Stroke, duration of treatment, incidence of reoperation, incidence of readmission

Table 2. CLINICAL PROTOCOL OF HIP REPLACEMENT

Responsible staff and their approval with signatures: S: member of the surgical team, A: anaesthesiologist, DN: department nurse, AN: anesthesiology nurse, ON: operating room nurse, Ph: physical therapist

- Preoperatively:

- -Is full lab control available? (blood count, biochemical control, X-Rays) S
- -Is written informed consent available? S
- -Control of surgical indication S
- -Is antiplatelet/anticoagulant therapy properly interrupted? S
- -Does the patient have any allergies? S
- -Preoperative preparation: bath, shave etc. S, DN
- -Is the patient a diabetic? Proper adjustment of treatment S
- -Are there any other special problems (thyroid disease)? Adjustment of treatment related consultation S
- Are orthopedic hip prostheses available? S

Operation day (prior to the procedure)

-Patient identity control S, DN, AN, ON

-Confirmation of type of procedure S, A

- -Removal of false teeth, rings, other metallic objects DN, AN
- -Availability control for blood products S, A
- -Special preparation-augmented vigilance in patients with reported difficulties in intubation A

Postoperatively

Operation day

-Can the patient follow a fast track extubation procedure? S, A

-Monitoring of vital signs-Regulation of electrolytic-fluid balance, antibiotic overage, analgesic regimen, high protein concentration diet, administration of vitamin C-augmented clinical suspicion for postoperative hemorrhage S. The patient must be informed that he can not cross his legs or bring them in internal rotation S, Ph

1st postoperative day: change/enhancement of bandages, drainage control-removal S –Initiation of treatment with low molecular weight heparin, initiation of treatment with antiplatelet drugs (aspirin and clopidogrel), if indicated

Next postoperative days and until discharge: Initiation of intensive physical therapy, training programmes for standing, walking, sitting in a chair/toilette, climbing of stairs etc Ph

Prior to discharge: Information to patient and relatives and programming of further physical treatment S, Ph

Complications-Special Remarks

Related clinical indexes: in-hospital mortality, incidence of venous thromboembolism, duration of treatment, incidence of reoperation, incidence of readmission