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ORIGINAL ARTICLE

Clinical pathways – the Bulgarian approach

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Abstract
Background Over the past 20 years, the use of clinical pathways has increased rapidly in many countries. The implementation of clinical pathways, i.e., using evidence-based gold standards in diagnostic and treatment algorithms, is aimed at optimising patient care, improving the intermediate and discharge outcomes, as well as reducing the inpatient length of stay and the overall costs. Bulgaria introduced CPs in 2000, but failed to achieve the goals it had initially set. To analyse the potential reasons for this failure, our study aims to describe the approaches used in Bulgaria to develop CPs and the actual application of CPs in Bulgaria.
Methods We analysed Bulgarian literature and official government publications and utilised the author's first-hand experience, working as a consultant to various governmental organisations. To evaluate the Bulgarian CPs we compared the Bulgarian approach with internationally acknowledged methods to devise CPs.
Results In Bulgaria, the requirements for understanding the procedures covered by CPs, for defining the rules of treatment, for monitoring deviations, for refining the rules and ultimately for modifying practice behaviour have not been complied with while developing the clinical pathways. Bulgaria uses CPs as an instrument for resource allocation to inpatient health-care providers rather than as a tool for improving health-care quality.
Conclusions Despite the broad scope of discussion in Bulgaria and the experience and knowledge gained in the past 5 years, the utilisation of clinical pathways for improving the quality of medical care is still unsatisfactory. Bulgarian health decision-makers merely used the title of a tool with proven qualities in managed care and efficient resource utilisation without implementing it according to international standards.

Keywords Clinical pathways · Bulgaria · Application · Resource allocation

Abbreviations

CP	clinical pathway
DRG	diagnosis related groups
LOS	length of stay
MoH	Ministry of Health
NFC	National Framework Contract
NHIF	National Health Insurance Fund

Background

An increase of health-care expenditure has been observed in many countries in recent years. At the same time, social requirements for high quality health services are continuously growing. Therefore, health politicians, funding institutions and medical professionals develop and introduce strategies for optimisation and efficient spending of health-care budgets in order to improve the quality of services provided to the population.

Clinical (or critical) *pathways* (CPs) have been recognised as an instrument appropriate for this purpose in recent years (Chou and Boldi 1999).

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In Bulgaria, CPs were first introduced in 2000, at a time when fundamental health-care reforms were initiated. Public and medical professionals presumed that upon the implementation of CPs, diagnostic and therapeutic guidelines would be established, health-care quality and outcomes would improve and along with that, resource utilisation efficiency would rise. In the meantime, health-care providers and health politicians have determined that the implementation of CPs in Bulgaria did not fulfil the envisioned goals. To analyse potential reasons for that failure, our study describes the Bulgarian model of CPs and compares the approaches used to develop them as well as their actual application in Bulgaria to international standards.

Methods

In order to describe the methods applied for the development and the actual application of CPs in Bulgaria, we analysed existing literature and official government publications as well as utilised the author's first-hand experience, working as a consultant to various governmental organisations. To evaluate the Bulgarian CPs, we compared the Bulgarian approach with internationally acknowledged methods to devise CPs.

Clinical pathways

CPs are management tools, aimed at achieving better quality and outcomes of care, containing inpatient treatment costs and increasing health-care efficiency. Chou and Boldy (1999) defined CPs as "a patient care management plan developed by a multidisciplinary team for patients with a particular diagnosis, procedure, or symptom (...). The major interventions of all disciplines are included in the plan, the timing and sequencing of care are identified, and an expected length of stay is determined by the team".

The potential benefits of using CPs according to key investigators of the subject (Chou and Boldy 1999; Cheah 2000; Ibarra et al. 1996; Lagoe 1998; Lanska 1998; Ramos and Ratliff 1997; Smith and Gow 1999) are:

- sustained or improved quality of care
- reduced variation in management practice
- better collaboration and communication between health-care providers
- lower mortality
- higher patient satisfaction
- improved outcomes
- reduced hospital length of stay (LOS)
- improved health-care efficiency

In order to achieve the indicated outcomes, adherences to the following steps are recommended when devising clinical (critical) pathways (Fleischmann et al. 2002):

- Select a topic – generally high volume and high cost diagnoses and procedures are preferred,
- Select a team – a multidisciplinary approach is crucial to ensuring support and "buy-in" from the personnel involved,
- Evaluate current processes of care – a data-driven review to help identify critical procedures and outcomes,
- Evaluate medical evidence – including the medical literature as well as internal and external data for "benchmarking",
- Select a critical pathway format – simplicity, transparency and ease of documentation for caregivers are particularly important in choosing a format,
- Document and analyse variance – choosing which outcomes and processes to track for assessment, feedback and iterative improvement.

The health-care reform in Bulgaria

In Bulgaria, CP introduction was one of the major steps in health-care reform and was associated with the need for a more efficient management of financial resources.

During the whole period of political, social and economic transition, which for Central and Eastern Europe began in 1989, the Bulgarian health-care system has been reorganised, to some extent, without a clear action plan and without the needed know-how at the decision-making level. The new health policy goals have included, amongst others, high quality of care, improvement of cost efficiency and patient satisfaction (European Commission and WHO Regional Office for Europe 2001).

Since 2000, all Bulgarian citizens are subject to a mandatory insurance plan, covering a specified out- and inpatient package of medical care benefits defined annually by the Ministry of Health (MoH) and paid for by the National Health Insurance Fund (NHIF). Key feature of the new system are the contracts between health-care providers and the NHIF. In compliance with the *Health Insurance Act* and the *Law on the Professional Associations of the Health-care Providers - Physicians and Dentists*, a National Framework Contract (NFC) is signed on an annual basis. The signatories are the NHIF, the Bulgarian Medical Association and the Union of Dentists in Bulgaria. The most important provisions of the NFC are the conditions and procedures of choosing providers with whom the NHIF shall sign an agreement, the types of services and the volume, prices and method of payment for in- and outpatient health-care provision.

Together with the NFC, a trend is established towards strategic purchasing as a way of allocating resources to providers in order to maximise fulfilment of the goals for health system performance. The contracting mechanism and performance-related payment are used as an instrument for influencing providers' behaviour and achieving the health policy objectives.

Clinical pathways in Bulgaria

Until 2000, the health-care system was financed mainly out of general tax revenues from two main sources – the national and the municipal budgets. Hospital budgets were based on the number of patients treated and the number of bed-days provided. Therefore, they did not reflect the whole array of in-hospital activities. Hospitals with high numbers of treated patients and/or high numbers of bed-days received more money, irrespectively of the provided medical services. This was one of the key problems that the health-care reform had to address – ensuring an allocation of resources to inpatient health-care providers according to the services actually provided.

As of 2001, the NHIF began paying for inpatient care on the basis of clinical pathways. While in 2001, the NHIF paid for only 21 CPs (National Framework Contract 2001), this number rose to 30 CPs in 2002 (National Framework Contract 2002), 81 CPs (National Framework Contract 2003) in the years 2003-2004, and to 120 CPs (National Framework Contract 2005) in 2005. For treatment of patients with diagnoses not included in CPs, the hospitals received funds from the MoH based on past budgets. As of 2006, inpatient care in Bulgaria was financed completely by the NHIF. The NHIF currently pays for treatment under 290 CPs, which cover about 7,600 types of diseases (National Framework Contract 2006). According to preliminary estimates, there are six diseases representing the most common causes of hospitalisation (Bucarev 2005).

In Bulgaria, the NFC of 2001 (National Framework Contract 2001) defined the clinical pathways primarily as an integrated approach for behaviour modelling of various medical professionals in the treatment of patients with specified health problems and secondly as a quality management tool. Key elements of the CPs are guidelines for:

- the general practitioner and/or the outpatient care specialist whose job it is to prepare the patient for hospitalisation,
- the hospital diagnosis,
- the consulting specialist with specific hospitalisation indications,
- the hospital medical devices, structural units and staff qualification,
- the clinical behaviour of the medical staff in hospitals,
- the amount paid for treatment according to the respective CP,
- the length of stay.

Evaluation of Bulgarian CPs

By comparing the key steps for devising CPs mentioned above and the approach towards developing CPs in Bulgaria, we can identify the following essential differences between the international standard model for CPs and the Bulgarian model.

Select a topic

Generally, CPs are developed and implemented for patients suffering from specific diseases, associated with a high risk or generally leading to severe complications, the treatment of which is generally expensive, consumes extensive resources or demands prolonged length of stay in the hospital (Fleischmann et al. 2002; Ibarra et al. 1996; Ramos and Ratliff 1997; Schriefer et al. 2000).

Due to the fact that in Bulgaria CPs are predominantly a financial instrument with the intention to cover the greatest possible number of hospitalisation causes, the Bulgarian CPs include more than 7,000 diseases and conditions, but naturally not all of these are associated with a high consumption of resources, prolonged LOS or a high risk for the patient.

Select a team

Generally, a multidisciplinary team should be charged with defining the major interventions, such as diagnosis, treatment, medication and discharge planning, as well as the right sequence and timing in order to achieve the best possible intermediate and discharge outcomes for particular types of cases using the best available research evidence and clinical guidelines (Fleischmann et al. 2002; Kaltenthaler et al. 2001; Klenner 2000; Leininger 1996; Little and Whipple 1996; Lynn 1996). Participation of representatives from different clinical specialties as well as from related disciplines in the multidisciplinary team contributes to the practicality of the pathway and ensures acceptance and support for its implementation (Fleischmann et al. 2002).

In Bulgaria, however, CPs were developed exclusively by specialists of a given area. Representatives of other clinical specialties taking part in the treatment or other medical staff were generally not included in the team. This "monodisciplinary" approach to the development of CPs is probably the cause for the absence of exact timing and

sequencing of activities and for insufficient support amongst medical professionals in the hospitals.

Evaluate current processes of care

This step is intended to facilitate the detection and analysis of the current variation in health-care processes. A thorough review of medical inpatient records is necessary to identify the outcomes and high-cost areas (Every et al. 2000). The evaluation of existing processes of care is generally performed for the purpose of optimising them wherever possible by introducing CPs, with the aim of changing medical staff behaviour, shortening the LOS and reducing costs.

In Bulgaria, this step was generally skipped during the development of CPs. As mentioned above, Bulgarian CPs were developed by specialists of a given area who work in university clinics and highly specialised hospitals. Therefore, they were familiar only with the processes in such facilities. In general, assessment and situational analysis of existing processes of care in regional or municipal hospitals were not taken into account. Recommendations were drafted mainly based on literature data while disregarding available field data from Bulgarian hospitals.

To give an example, the average length of stay was estimated according to data provided by American and Western European authors. This led to the fixed LOS being shorter than the usual LOS for these diseases in Bulgaria. Regardless, this fixed LOS is currently mandatory for the providers according to the NFC.

The Bulgarian set of CPs therefore defines an unrealistically low fixed LOS. Thus, one of the ultimate goals of the health-care reform, shortening the average LOS, was instituted as a prerequisite for meeting the new guidelines without first acquiring sufficient evidence from existing practice that shortening the LOS was medically justified in all instances. A proper analysis of re-hospitalisations and intermediate- and long-term outcomes for the same disease has not been undertaken, nor has the level of readiness of outpatient services to provide care for patients discharged prematurely been sufficiently studied.

Evaluate medical evidence

According to the guidelines for defining CPs, a comprehensive literature review should be the first step in this process. Data on best practices should be collected in order to define the best possible processes of care to be included in clinical guidelines.

Clinical guidelines are systematically developed statements aimed at assisting decision-making regarding appropriate health-care interventions in specific clinical circumstances. Guidelines can be linked in order to form CPs or algorithms of typical cases (Grundmann 2000). The philosophy underlying the application of clinical guidelines is to improve the quality of outcome by raising the quality of the individual intermediate diagnostic and therapeutic processes.

If we look more closely at the algorithm definition given by Banks (1996), the "clinical algorithm" is a set of rules or instructions leading to the solution of a defined medical problem whose implementation depends on specific conditions.

Algorithms are designed on the basis of a decision-node logic for defining the next CP step for the respective condition or disease, age, sex, co-morbidity and complication. Each algorithm is designed solely for a single specific function. Examples include pharmacological treatment algorithms, surgical treatment algorithms or complication management algorithms. An algorithm offers only one solution in specific circumstances. In other words, if a condition is met, then an exactly predefined decision-behaviour follows under the given circumstances. This is an "if – then" algorithm.

The algorithm of the "*90-min accelerated critical pathway for chest pain evaluation*", developed and applied by the University Department of San Diego, California, can be used for a more exact illustration of the aforementioned (Ng et al. 2001). This algorithm defines the steps by which the nature of chest pain and its subsequent aetiology-based treatment can be evaluated within 90 min, making use of certain clinical and biochemical indicators. The *chest pain early diagnosis CP* is followed by other clinical pathways for further treatment.

In Bulgaria, neither clinical guidelines nor clinical algorithms were successfully integrated into most of the CPs. This occurred primarily because only a few clinical guidelines had been introduced in Bulgaria when CPs were implemented. Secondly, over 80% of the Bulgarian CPs are a combination of similar diagnoses and conditions. Like the diagnosis related groups (DRGs) for patients differing in their medical and biological characteristics, they are rather broad in scope and therefore cannot contain a clinical algorithm as an option for solving a particular problem, but rather offer a range of possible diagnostic and therapeutic strategies. Incorporating multiple diagnoses, conditions and critical procedures into one CP, parallel to the DRGs, impedes the implementation of clinical guidelines and clinical algorithms.

Determine the critical pathway format

Usually the CPs represent a scheme of procedures and a sequence of actions (Asadi and Baltz 1996). There are different solutions for including the clinical pathway in the in-patient record. It could be a part of the medical record or a separate file as a documentation tool (Little and Whipple 1996).

In Bulgaria, record keeping of processes has been subject to continuous changes during the past 5 years. While the hope is to find the best solution in this regard, results are still unsatisfactory. The NHIF reviews indicate that the most common infringements were associated with documenting treatment according to CPs - 42% of all identified infringements in 2004 and 45.3% in 2005 (National Health Insurance Fond 2004, 2005).

Document and analyse variance

A key issue related to the use of CPs in hospital practice is the influence of deviation from established standards on intermediate and discharge outcomes. Some authors recommend documenting the variance from CPs (Little and Whipple 1996; Every et al. 2000). Variance is defined as the difference between the planned process for a homogeneous patient group and the differences identified in individual members of this group (Leininger 1996). If variance influences outcomes in a negative direction, the specific causes should be identified and eliminated.

In the case of deviation in a positive direction, the phenomenon should be investigated by analysing the activities that had positive impact on the patient's condition for eventual future incorporation in CPs.

Until 2005, instances of deviation were recorded and analysed in Bulgaria in rather general terms, mainly due to problems associated with the documentation format, the annual introduction of new CPs and the lack of data-processing capacity both in the hospitals and in the NHIF. They have not been documented thereafter.

In addition, the use of CPs must be safe for the patients. Therefore, piloting every CP is recommended prior to its general introduction by monitoring its intermediate and long-term outcomes (Fleischmann et al. 2002).

In Bulgaria, CP monitoring has never been undertaken regardless of the existing assumptions that treatment under certain CPs leads to long-term outcomes that do not differ significantly from previous practice. Likewise, patient satisfaction with the received treatment, which is an important feedback for ongoing quality improvement (Chou and Boldy 1999), has not been studied.

Clinical pathways as a financial tool

As mentioned above, CPs are also used as a financial tool in the Bulgarian health-care setting. Any medical activity requires certain financial and human resources. The accurate estimate of all resources necessary for treatment of a particular diagnosis or CP may provide a clear picture of costs and show which clinical activities are consuming substantial resources. Some authors (Asadi and Baltz 1996) recommend the integration of *activity-based costing* (ABC) to CPs as a financial tool. The ABC tool enables health-care decision-makers to explore the kind and quantity of resources needed for a given treatment, to determine how to allocate resources efficiently and to examine if the provided CPs are profitable.

In Bulgaria, the amount paid for treatment by the NHIF according to the CPs can hardly cover the actually incurred costs. The resources spent for specific crucial activities, the prices of the administered drugs and consumables as well as staff salaries were not taken into account when estimating the CP remuneration. For CP no. 54, the "acute coronary syndrome with persistent ST-elevation and thrombolysis", the NHIF pays 1,176 euros (National Framework Contract 2005) per hospital stay, for example. However, the price at which the hospitals buy the most commonly marketed drug Actilyse is 869.00 euros for 20 mg powd. inj. The more expensive and thus rarely used Rapilysin costs 1,023 euros for 2×10 U. This means that hospitals performing thrombolysis are not able to cover their costs. Due to such "deficient financing" of CPs, physicians face limitations in decision-making. In the example cited above, thrombolysis in acute coronary syndrome with persistent ST elevation is applied relatively rarely in Bulgaria.

CPs could be applicable in health systems with different financing principles, including defined budget or state subsidies (Cheah 2000; Ramos and Ratliff 1997). In countries with limited financial resources, they may assist in the efficient use of limited funds without compromising the quality of care (Cheah 2000). In Bulgaria, health-care funds are rather limited. For the past 7 years, the government allocated an average of 4.2% of the GDP to health care. According to the current Bulgarian legislation, CP prices are fixed annually, i.e., there is a defined inpatient care budget per CP. In 2007, the MoH realised that in 75% of the cases, the amounts allocated for CPs covered only up to 60% of the actual costs (Ministry of Health 2007). Additionally, some authors (Cheah 2000) speculate that while the costs in the hospital sector are decreasing due to optimised processes and a shorter LOS, the costs for follow-up treatment may be increasing. Since there is only insufficient information on this matter, it is impossible to determine whether the Bulgarian CPs are able to increase efficient use of health-care resources. Similarly, it is impossible to estimate the impact of CPs on the overall cost-effectiveness of the health-care system or on the society.

Conclusions

The introduction of CPs in Bulgaria aimed at improving the quality of health services and optimising health-care costs. However, the providers and the public soon identified negative aspects as well, which did not ensue from the CPs

themselves but rather from their incorrect development, introduction and implementation.

Regarding the Bulgarian set of CPs, it may be stated that they have been designed according to literature data and experience from other countries and have been imposed administratively as a tool for containing health-care costs on a national level. The essential and internationally recognised steps for the design and implementation of CPs have not been complied with. The Bulgarian CPs offer general solutions to health-care problems, which are most frequently not in line with local capacity and without defining the sequence of clinical procedures. In general terms, the requirements for "understanding the procedures involved in providing care, defining the rules of care, monitoring deviations from the rules and ultimately refining the rules and modifying practice behaviour" (Little and Whipple 1996) have not been complied with while developing the CPs in Bulgaria.

Furthermore, there is no capacity in the hospitals for collecting and analysing data on processes and outcomes of care and on their variance between providers, especially for non-surgical CPs. The evaluation of medical and financial outcomes on both the hospital and the national level is an issue of the indefinite future.

Despite the broad scope of discussion in Bulgaria and the experience and knowledge gained in the past 5 years, the utilisation of CPs for improving the quality of medical care is still unsatisfactory. Bulgarian health decision-makers only used the title of a tool with proven qualities in managed care and efficient resource utilisation without implementing it according to international standards.

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Conflict of interest The authors declare that they have no relevant associations that might pose a conflict of interest.

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