УДК 616.441-089:004

Dagmar Schweinfurth[1], Jochen Schuld[2], Peter Jacob[2], Sven Richter[1]

INTERNAL QUALITY MANAGEMENT THROUGH SYSTEMATIC IMPLEMENTATION OF IT-BASED CLINICAL PATHWAYS: THE EXAMPLE OF THYROID SURGERY

[1] *Department of General, Visceral and Vascular Surgery, Fürst Stirum Klinik, D-76646 Bruchsal, Germany*
[2] *Department of General, Visceral, Vascular and Pediatric Surgery, University of Saarland, D-66421 Homburg/Saar, Germany*

Background. As economic pressure continues to increase throughout European healthcare systems, process oriented management represented for example by clinical pathways (CPs) has become a necessity. CPs serve as controlling instruments by ensuring the best possible path of a specific type of patient at each diagnostic and therapeutic intersection, within a given time sequence. For the first time worldwide, CPs have been implemented by means of an IT-based framework supported by SAP/i.s.h.med at the Department of General, Visceral, Vascular and Pediatric Surgery, University of Saarland, Homburg/Saar, Germany.

The present study aims at analysing whether IT-based CPs serve to improve internal quality management.

Methods. New IT-supported evidence-based CPs were used as a base for data acquisition. Control reports for internal quality management for patients with thyroid surgery were implemented; their efficacy was then evaluated.

Results. The newly established process of quality management in thyroid surgery enables efficient follow-up even after discharge from hospital, which includes not only postoperative vocal chord controls, but also swift transmission of unexpected histological findings, thus contributing considerably to the improvement of patients' safety.

Conclusion: It emerges that IT support is indispensable for the implementation of CPs. Its advantages include straightforward identification of areas where objectives are not yet fulfilled, and generation of control reports, which are essential for internal quality management, thus enabling swift analysis of adverse events (modification or violation of standardised pathways). Thus, adjustments can be made in order to improve our standards of care.

Key words: *internal quality management, clinical pathways, thyroid surgery.*

ВНУТРЕННИЙ МЕНЕДЖМЕНТ КАЧЕСТВА КАК СИСТЕМНЫЙ ПОДХОД К ОБЕСПЕЧЕНИЮ ВЫПОЛНЕНИЯ КЛИНИЧЕСКИХ РУКОВОДСТВ, БАЗИРУЮЩИХСЯ НА IT-ТЕХНОЛОГИЯХ: НА ПРИМЕРЕ ХИРУРГИИ ЩИТОВИДНОЙ ЖЕЛЕЗЫ

Д. Швайнфург[1], Й. Шульд[2], П. Якоб[2], С. Рихтер[1]

[1] *Отделение общей, абдоминальной и сосудистой хирургии, Фюрст Штирум Клиник, г. Брухзаль, Германия*
[2] *Отделение общей, абдоминальной, сосудистой и детской хирургии, Университетская клиника Федеральной Земли Саар, г. Гомбург, Германия*

Обоснование. Поскольку во всех европейских системах здравоохранения продолжает нарастать давление экономических факторов, возник процесс-ориентированный менеджмент, представленный, в частности, необходимостью использования клинических руководств (КР). КР служат инструментом контроля, обеспечивая оптимальную для конкретного пациента последовательность действий на каждом этапе диагностики и лечения в рамках отведенного на них времени. Впервые в мире метод КР осуществлен с использованием базирующихся на информационных технологиях в отделении общей, абдоминальной, сосудистой и детской хирургии Университета Федеральной Земли Саар, Гомбург/Саар, Германия.

Цель настоящего исследования: проанализировать, служит ли метод КР, поддержанный информационными технологиями, улучшению внутреннего менеджмента качества.

Методы. Новые КР, поддерживаемые информационными технологиями и основанные на доказательствах, применяли в качестве базы для пополнения данных. Для внутреннего менеджмента качества использовали контрольные сообщения о хирургическом лечении пациентов с заболеваниями щитовидной железы; затем производилась оценка их эффективности.

Результаты. Новая организация процесса менеджмента качества в хирургии щитовидной железы позволяет эффективно осуществлять динамическое наблюдение даже после выписки из больницы, которое включает не только послеоперационный контроль состояния голосовых связок, но также и быструю пересылку данных гистологических исследований, значительно способствуя безопасности пациентов.

Заключение. Очевидно, что информационная поддержка необходима для осуществления КР. Ее преимущества связаны с непосредственным обнаружением тех сфер, где поставленные цели еще не достигнуты; воспроизводством контрольных сообщений, которые играют существенную роль во внутреннем менеджменте качества, давая при этом возможность произвести быстрый анализ побочных явлений (изменение или нарушение последовательности стандартизированных действий). Таким образом можно произвести поправки по улучшению наших стандартов лечения.

Ключевые слова: *внутренний менеджмент качества, клинические руководства, хирургия щитовидной железы.*

Introduction

Increasing demands on health care facilities in a context of limited budget allowances have necessitated extensive remodelling and rationalisation of clinical medicine, modelled on procedures better known from a non-medical economic background [1].

So-called 'clinical pathways' (CPs) for orthopaedic [2–4] and interventional procedures [5, 6], as well as for conservative therapies [7, 8] have already been implemented, with the common goal of improving the respective processes in analogy to process management in industrial production.

CPs serve as controlling instruments by describing the best possible path of a specific type of patient at each decisive diagnostic and therapeutic intersection, within a given time sequence [1]. They may be defined for any single procedure or diagnosis, and also for more complex clinical patterns and symptoms. When CPs are created, evidence-based standards must be taken into consideration [9], but they require customizing for the respective hospital or clinical section. Thus, CPs are generally not universally valid; they have to be adapted to the existing infrastructure and resources. Likewise, it is impossible to create CPs which remain permanently valid. Rather, as standards and guidelines evolve, they require continuous revision and adjustment [1].

CPs can thus be defined as a specialised form of medical process management, the principles of which resemble in many ways those of industrial process management. However, the transfer of this concept is anything but straightforward. The area of hospital management or medical process management is distinguished from other types of process management by characteristic features. Process oriented key data must be generated with a view to quality goals, patient requirements, costs and time frame [10]. Primary business processes (or core processes) in hospitals are exceedingly complex, which makes it difficult for non-medical professionals to implement control measures equivalent to industrial process management. While controlling tasks (e.g. definition of processes on the basis of evidence-based guidelines) should remain the responsibility of medical professionals, the required skills are not part of basic medical training. Furthermore, cooperation between several professional groups within a hospital is an especially important and challenging issue in process management [11, 12]. CPs offer a unique chance to respond to these challenges.

In order to generate data suitable for successful initiation of controlling processes, IT-support is indispensable when creating and applying CPs [13, 14]. This approach enables all those working on CP-related tasks to participate in implementing CPs.

Once a CP area is defined, the following questions should be asked, which are essential from an economical point of view:

Which are the costs for this procedure in our institution?

Can we cover our costs when offering this procedure?

Is it possible to improve each single process?

Further advantages of IT-based CPs are the following:

- standardised best care;
- improved confidence through evidence-based guidelines;
- swift analysis of adverse events (path modifications);
- reduction of documentation responsibilities;
- improvement of documentation quality;
- transparency of costs, improved allocation of resources;
- improved satisfaction of employees and patients.

Hypothesis

The aim of this study was to analyse to which extent quality management could be improved by means of IT-supported CPs. It was thought that immediate documentation, implementation of certain control measures, and interface improvement should have a considerable beneficial effect.

To this end, a quality analysis of postoperative adverse events was conducted at the Department of General, Visceral, Vascular and Pediatric Surgery, University of Saarland, Homburg/Saar, Germany, where for the first time worldwide, CPs have been implemented by means of an IT-based framework supported by SAP/i.s.h.med.

Patient pathways in thyroid surgery were analysed with reference to the question whether efficient quality management of postoperative vocal chord paresis was possible, i. e. whether postoperative management was straightforward, timely, and accurate (by comparison with patient histories). Moreover, swift transmission of histological findings was desirable in order to guarantee best possible safety for patients.

Methods

All data generated for this study were taken from CPs and patient histories stored in the hospital's EDP system (SAP/i.s.h.med) within the module, i.s.h.med pathways' specifically allocated to each patient. All patients were included who received thyroid surgery for benign or malignant thyroid disease between 18.02.2008 and 10.05.2009. Thus, by comparison with earlier studies, a far more thorough analysis of the postoperative period was possible. Control reports were used to integrate postoperative ENT findings, date of examination and frequency of pathological as opposed to normal results. Moreover, the timing of retrieval and documentation of histological reports, which mostly arrive after the patient has been discharged from hospital, were evaluated. Unexpected histological findings which necessitated resurgery were analysed in comparison with normal results. Unfortunately, it was impossible to compare these data with those of a control group prior to the establishment of IT-supported CPs, as no comparable documentation was available. Nevertheless, swift drafting and mailing of final doctors' reports (which, as opposed to preliminary reports, include histological results and recommendations for further treatment) were compared between groups before and after the implementation of IT-supported CPs.

For all data, standard errors of the mean (SEM) were recorded. Once primary data acquisition from the

hospital's EDP system was completed and data transferred into Excel (Microsoft), statistical analysis was carried out by means of SigmaStat and SPSS (Chicago, USA). Kruskal-Wallis one-way analyses of variance by ranks and t-tests for unconnected samples were calculated with the level of significance fixed at $p < 0,05$.

Results

Throughout a period of 15 months, a total of 96 thyroid procedures were carried out at the Department of General, Visceral, Vascular and Pediatric Surgery, University of Saarland, Homburg/Saar, Germany. 83 patients were registered for the CP 'benign thyroid disease', whereas 13 patients were classified in the CP 'thyroid cancer'. Mean time between first presentation and surgery was 22 ± 2 days, during which time any necessary diagnostics were completed. In 90 patients, surgery was performed on the day after admission to hospital. In four patients, surgery had to be postponed for a day due to emergencies, two patients had asked for admission on the morning of the surgery. Mean duration of surgery was 112 ± 3 min, mean blood loss 42,2 ± 6,0 ml. 92% of the patients with 'benign thyroid disease' (76 of 83) or 'thyroid cancer' (12 of 13) completed the respective CP without any irregularities and were discharged from hospital after four days, as consistent with the regular pathway. The remaining patients suffered from wound infections, vocal chord paresis, persistent hypocalcaemia, or comorbidity, which made it necessary to violate the CPs.

Prior to discharge from hospital, patients underwent ENT examination. In 87%, function of vocal chords was normal. In 13%, pathological findings were reported, although one patient had been known to suffer from vocal chord pathologies even before surgery. The mean period between surgery and ENT examination was 2.8 ± 0.1 days, mean time between examination and documentation in SAP/i.s.h.med 0.5 ± 0.1 days. All patients who did not present normal vocal chord function could thus be further monitored and referred to an ENT specialist, in order to differentiate between transient and permanent vocal chord dysfunction.

In 49 patients (51%), the final histological report was available when the patient was discharged from hospital. In 47 patients (43 with benign thyroid disease, 4 with thyroid cancer) the final histological report was only completed after discharge from hospital. In these cases, the report was available at mean 3.1 ± 0.7 days after discharge, and transmitted in a letter – mostly supplemented by a phone call – to the patient's family doctor as soon as possible.

The final doctor's report was sent to the patient's family doctor at mean 16.0 ± 0.7 days after surgery. By contrast, before implementation of CPs the period between surgery and mailing of the final doctor's report was mean 24.7 ± 1.7 days. This suggests highly significant improvement ($p < 0.001$).

Four of 83 patients who had initially been allocated to the group 'benign thyroid disease' revealed malignancy in histological analysis. These patients were immediately scheduled for re-surgery. Re-surgery took place mean 5.0 ± 0.6 days after primary surgery. Even for patients who did not show unforeseen histological features, timely transmission of the final doctor's report resulted in improved care, as substitution of thyroid hormones may only begin once the final histological analysis is completed. These patients were able to start with substitution medication significantly earlier than before.

Discussion

Implementation of IT-supported CPs in the course of comprehensive process management frequently leads to extensive restructuring in clinical management [13, 14]. Apart from availability of infrastructure (sufficient hardware, i. e. computer workplaces), a functional solution must be found for software requirements, ideally integrating CPs into the hospital's EDP system. Only then, standards which are already in use can be replaced by IT-supported CPs.

Reasons often quoted in favour of the implementation of CPs include improvement of processes, increasing of efficiency, cost limitation, reduction of documentation load and improvement of documentation, satisfaction among employees as well as patients, and quality management [1–8, 10, 15–17].

The present study has shown, on the example of surgery for benign and malignant disease of the thyroid, that internal quality management is significantly improved through CPs. Automated reminders to initiate or retrieve postoperative vocal chord check-ups or histological results respectively guarantee best possible follow up, even after the patient has been discharged from hospital.

The present study has shown the benefits of IT-supported CPs. After implementation of CPs, the mean period before re-surgery could be reduced by comparison with pre-CP scheduling, which leads to a significantly lower risk of vocal chord dysfunction after re-surgery. Furthermore, the final doctor's report is sent to the patient and his family doctor significantly earlier, so that in the case of benign histology, hormone substitution may begin.

Even after implementation of CPs, continuous improvement is necessary. IT-supported analysis of patients' treatment allows for differentiation of 'good' areas with little room for improvement, and 'bad' areas requiring extensive revision. Problems appearing in the analysis should be corrected during regular revisions of CPs. This is a prerequisite for process improvement from an economic point of view. It is one of the advantages of IT-supported CPs that they can be adjusted to new guidelines with relative ease [9]. Finally, this leads to improved satisfaction of employees and patients [15, 16]. IT-supported CPs are an indispensable feature of modern hospital management.

Literature

1. *Hindl D.* Clinical pathways: a serious business // Health management bulletin. – 1997. – № 1. – P. 1–34.

2. *Brunenberg D.E., van Steyn M.J., Sluimer J.C., Bekebrede L.L., Bulstra S.K., Joore M.A.* Joint recovery programme versus usual care: an economic evaluation of a clinical pathway

for joint replacement surgery // Med Care. – 2005. – № 43. – P. 1018–1026,

3. *Dowsey M.M., Kilgour M.L., Santamaria N.M., Choong P.F.* Clinical pathways in knee and hip arthroplasty: a prospective randomised controlled study // Med J Aust. – 1999. – 170. – P. 59–62.

4. *Choong P.F., Langford A.K., Dowsey M.M., Santamaria N.M.* Clinical pathway for fractured neck of femur: a prospective, controlled study // Med J Aust. – 2000. – 172. – P. 423–426.

5. *Okamura K., Ozawa H., Kinukawa T., Imamura M., Saito S., Terai A., Takei M., Hasegawa T.* A questionnaire survey for TURP hospitalisation by clinical path for transurethral resection of prostate (TURP) in multiple hospitals // Nippon Hinyokika Gakkai Zasshi. – 2004. – 95. – P. 800–808.

6. *Kiyama T., Tajiri T., Yoshiyuki T., Mitsuhashi K., Ise Y., Mizutani T., Okuda T., Fujita I., Masuda G., Kato S., Matsukura N., Tokunaga A., Hasegawa S.* Clinical significance of a standardized clinical pathway in gastrectomy patients // J Nippon Med Sch. – 2003. – 70. – P. 263–269.

7. *Cheney J., Barber S., Altamirano L., Medico Cirujano, Cheney M., Williams C., Jackson M., Yates P., O'Rourke P., Wainwright C.* A clinical pathway for bronchiolitis is effective in reducing readmission rates // J Pediatr. – 2005. – 147. – P. 622–626.

8. *Marrie T.J., Lau C.Y., Wheeler S.J., Wong C.J., Vandervoort M.K., Feagan B.G.* for the CAPITAL study investigators: A controlled trial of a clinical pathway for treating community-acquired pneumonia: the CAPITAL study // JAMA. – 2000. – 283. – P. 749–755.

9. *Sackett D.L., Rosenberg W.M., Gray J.A., Haynes R.B., Richardson W.S.* Evidence-based medicine: what it is and what it isn't // Clin Orthop Relat Res. – 2007. – 455. – P. 3–5.

10. *Greiling M., Quint U.* Clinical pathways from an economic viewpoint // Orthopäde. – 2010. – 39. P. 752–757.

11. *Deneckere S., Euwema M., Lodewijckx C., Panella M., Sermeus W., Vanhaecht K.* The European quality of care pathways (EQCP) study on the impact of care pathways on interprofessional teamwork in an acute hospital setting: study protocol: for a cluster randomised controlled trial and evaluation of implementation processes // Implement. – 2012. – Sci. 18. – P. 47.

12. *Deneckere S., Euwema M., Van Herck P., Lodewijckx C., Panella M., Sermeus W., Vanhaecht K.* Care pathways lead to better teamwork: results of a systematic review // Soc Sci Med. – 2012. – 75. – P. 264–268.

13. *Schilling M.K., Richter S., Jacob P., Lindemann W.* Clinical pathways – first results of a systematic IT-supported application at a surgical department of a university hospital // Dtsch Med Wochenschr. – 2006. – 28. – P. 962–967.

14. *Graeber S., Richter S., Folz J., Pham P.T., Jacob P., Schilling M.K.* Clinical pathways in general surgery. Development, implementation and evaluation // Methods Inf Med. – 2007. – 46. – P. 574–579.

15. *Schuld J., Richter S., Folz J., Jacob P., Gräber S., Schilling M.K.* Influence of IT-supported clinical pathways on patient satisfaction at a surgical department of a university hospital // Dtsch Med Wochenschr. – 2008. – 133. – P. 1235–1239.

16. *Schuld J., Schäfer T., Nickel S., Jacob P., Schilling M.K., Richter S.* Impact of IT-supported clinical pathways on medical staff satisfaction. A prospective longitudinal cohort study // Int J Med Inform. – 2011. – 80. – P. 151–156.

17. *Abrams M.N., Cummings S., Hage D.* Clinical care paths: a role for finance in clinical decision-making // Healthc Financ Manage. – 2012. – 66. – P. 86–91.

PD Dr. Sven Richter (corresponding author), Department of General, Visceral and Vascular Surgery, Fürst Stirum Klinik, Gutleutstrasse 1–14, 76646 Bruchsal, Germany. Tel.: +49-7251-70857400; Fax: +49-7251-70857403; e-mail: sven.richter@kliniken-lk.de